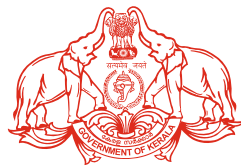


**KERALA CLINICAL ESTABLISHMENT
(REGISTRATION AND REGULATION) ACT, 2018**

A Comprehensive Overview and Analysis



**KERALA STATE COUNCIL FOR CLINICAL ESTABLISHMENTS
THYCAUD, THIRUVANANTHAPURAM**



MESSAGE

It gives me immense pleasure to present this booklet on the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, a significant step towards ensuring transparency, quality, and accountability in the healthcare sector. This Act provides a structured framework for the regulation of all clinical establishments including public and private sector, ensuring that healthcare services in Kerala meet standardized norms and uphold the highest levels of patient care.

The Kerala Clinical Establishments Bill, 2018 was passed by the Kerala Legislative Assembly on 1st February 2018, and the Act was officially notified on 22nd February 2018. As part of its phased implementation, Provisional Registration of clinical establishments commenced on 1st January 2019, enabling institutions to align their operations with the prescribed regulations. Subsequently, Permanent Registration began on 26th April 2023, ensuring that all registered establishments comply fully with the Act's provisions.

I am pleased to note that 13321 healthcare institutions have completed their Provisional Registration, while 1,256 institutions have successfully transitioned to Permanent Registration. This reflects the commitment of healthcare providers across Kerala in upholding the principles of quality healthcare and patient safety.

I appreciate the tireless efforts of all stakeholders, including healthcare professionals, regulatory bodies, and the administration, in implementing this crucial legislation. This booklet serves as a valuable resource for all clinical establishments, guiding them through the registration process and compliance requirements.

I urge all healthcare institutions to adhere to the provisions of this Act in its true spirit, contributing towards a more robust, ethical, and patient-friendly healthcare system in Kerala.


VEENA GEORGE

Foreword

The Kerala Clinical Establishments (Registration & Regulation) Act, 2018, was enacted to ensure the standardization, regulation and proper governance of all clinical establishments across the state. The Act aims to maintain uniformity in healthcare services, improve quality standards, and streamline the registration process for all medical institutions, including Modern Medicine, AYUSH, Dental, Laboratories and Diagnostic Services. The implementation of the Act has been carried out in a phased manner, with several milestones achieved over the years.

The KCEA 2018 was passed by the Kerala Legislative Assembly on February 1, 2018, and officially came into force on January 1, 2019. To ensure a smooth implementation, a State Council, an Executive Committee and District Registering Authorities (DRA) were constituted. These bodies have played a crucial role in overseeing registration, monitoring compliance and addressing grievances. Additionally, IT Subcommittees have been set up to handle administrative and technical aspects of the implementation process. Several high-level meetings have been conducted at different intervals to review progress, address challenges, and refine regulatory mechanisms. The Government constituted a technical group comprising of Additional Chief Secretary, Principal Secretary, State Mission Director, Director of Health Services, Director of Medical Education, Directors of ISM and Homoeopathy Departments and many others from relevant fields.

The registration process was introduced in a phased manner. Provisional registration for modern medicine establishments was initiated in January 2019 in 3 pilot districts of Malappuram, Thrissur and Palakkad and expanded to every district by June 2019. Similarly, AYUSH establishments were brought under the regulatory framework starting in 2019, with a pilot phase in Malappuram, Thrissur and Palakkad before expanding statewide by 2020 and later expanded to all districts. In order to ensure progress, Principal Secretary along with state level committee members conducted online meetings on a daily/ weekly basis with the selected districts. In these meetings, issues raised by the Hospitals and officers were discussed and appropriate troubleshooting was done concurrently so as to ensure progress. Subsequently in April 2023, the Permanent Registration Portal was launched, allowing clinical establishments to transition from provisional to permanent registration.

To ensure compliance, the government constituted expert groups and introduced Minimum Standard Rules (MSR) for all categories of healthcare facilities, including Modern Medicine, dental clinics, AYUSH institutions, Laboratories and Diagnostic Services. These standards define the necessary infrastructure, equipment, manpower, and operational protocols required for clinical establishments to

function legally. As the whole world faced Covid pandemic to address emerging challenges and stakeholder concerns, in the year 2021 and 2022 amendments extended the validity of provisional registrations to facilitate smoother transitions. In addition to registration and compliance, Grievance Redressal mechanisms have been established at the district and state levels. A dedicated online Grievance portal was launched, enabling the public to raise complaints related to service quality. These efforts were supported by building IT infrastructure through National Informatics Centre (NIC) to ensure management of various activities under the Act.

In order to ensure smooth operations, a Panel of Assessors has been appointed to inspect and verify compliance with the standards. These assessors shall conduct field inspections, review documentation, and provide feedback on adherence to the MSR guidelines.

Additionally, the government has focused on Information, Education, and Communication (IEC) initiatives to raise awareness among healthcare providers about the importance of registration and compliance.

One of the major strengths of the Act is its comprehensive coverage of all clinical establishments, including modern medicine, AYUSH, dental, laboratory and diagnostic centers except clinical establishments which provide consultation services only and those which are under the Armed Forces. By setting Minimum Standard Rules (MSR), the Act ensures uniform service quality across all healthcare providers.

KERALA HEALTH is well known for its quality of health service in private as well as Government sector. The Kerala Clinical Establishments (Registration & Regulation) Act, 2018, is the catalyst and facilitatory tool to ensure the standardization of infrastructure as well as the services in the state and it will set a benchmark in quality service delivery by ensuring involvement of all in public and private sector.

Dr Rajan Khobragade IAS

Addl Chief Secretary

Health and Family Welfare , AYUSH

INDEX

1.	Background and Relevance	9 - 10
2.	Overview of the Document	11 - 11
3.	Historical Context of Health Regulations	12 – 21
4.	Key Definitions and Terminology	22 - 37
5.	Overview of Registration Processes	38 - 39
6.	Inspection and Inquiry	40 - 44
7.	Penalties under the Clinical Establishments Act	45 – 47
8.	Kerala Clinical Establishment (Registration and Regulation) Amendment Act, 2021	48 - 48
9.	Kerala Clinical Establishment (Registration and Regulation) Amendment Act, 2022	49 - 49
10.	Kerala Clinical Establishment (Registration and Regulation) Amendment Act, 2024	50 - 50
11.	Conclusion	51 - 51
12.	References	52 - 52
13.	Annexures	52 - 52

Background and Relevance

Kerala, a state in southern India, presents a unique case in the study of health sector development. Despite relatively low per capita income, limited industrialization, and modest agricultural output compared to other regions, Kerala has achieved remarkable success in health care and education. The state boasts near-universal literacy and impressive healthcare indicators comparable to those found in more advanced economies.

The success in health development in Kerala is attributed to several intersectoral factors, including widespread education, political engagement, improved infrastructure, and social movements. However, the healthcare sector itself has played a critical role. Continuous investment in education and health infrastructure has been a hallmark of Kerala's policy, regardless of the political party in power.

Since the mid-1980s, there has been a notable shift in the health sector dynamics in Kerala. The growth of public health facilities has slowed substantially, while private health facilities expanded rapidly. This shift can be traced to various socio-economic factors, including increasing per capita income, higher literacy rates, and an ageing population. The growing demand for health services created by these factors has not been fully met by the government sector, leading to the private sector's rapid expansion.

Historically, Kerala's health care system was established under the influence of colonial powers and princely states. Early efforts included compulsory vaccination and measures to control infectious diseases. The state's modern health care infrastructure took shape with significant investments in both preventive and curative services.

From the formation of Kerala in 1956 until the mid-1980s, there was substantial growth in government health facilities, with a significant increase in the number of beds and institutions. However, fiscal challenges led to a slowdown in public sector growth and a shift towards increased private sector participation. The private sector has since surpassed government

facilities in terms of the number of beds and the provision of advanced medical technology.

Despite a commitment to health care expenditure, the state has faced fiscal constraints that have affected the quality and expansion of public health services. The growth of private health care facilities in Kerala reflects broader trends in increasing disposable incomes and a high demand for health services. The correlation between private sector growth and factors such as literacy and per capita income underscores the complex interplay between socio-economic development and health care provision.

In conclusion, Kerala's experience highlights the importance of government investment in health care infrastructure and training, the impact of socio-economic factors on health care demand, and the role of private sector growth in addressing unmet health needs. Moving forward, maintaining high standards in public health facilities and effective regulation of private health care will be crucial for sustaining Kerala's achievements in health development.

Overview of the Document

This document aims to provide a comprehensive overview and critical analysis of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 structured to provide detailed insights into various aspects of the Act, from its historical context to future implications. The document covers the historical context of health regulations at the international, national, and state levels, highlighting the evolution of healthcare legislation. It delves into the key definitions, registration processes, standards, compliance requirements, assessment frameworks, and penalties outlined in the Act and its corresponding Rules.

Moreover, the document explores the roles of various authorities in implementing and monitoring the Act, discussing penalties for non-compliance. It also addresses avenues for grievance redressal, appellate authority processes, and examines future challenges and opportunities in the healthcare sector within Kerala.

Additionally, amendments to the Act, including the Kerala Clinical Establishments (Registration & Regulation) Amendment Act 2021, 2022 and 2024, are analysed to understand their implications. The document concludes with a summary of key points and recommendations for future considerations.

The annexures include essential resources such as the full text of the Act and Rules, application forms, templates, and other significant documents related to the implementation of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.

Historical Context of Health Regulations

Health regulations have played a significant role in protecting public health throughout the history. From ancient civilizations to modern times, regulations have evolved to address emerging health threats and promote healthcare quality.

International Level

Health regulations at the international level have their roots in the need to control the spread of infectious diseases, especially as global trade and travel expanded. The evolution of these regulations can be explained like the following:

1. Early International Sanitary Conferences (1851-1938):

- The first International Sanitary Conference was held in Paris in 1851, in response to the cholera pandemics that swept through Europe. This pioneering conferences aimed to establish uniform procedures for quarantine and disease control, reflecting the understanding that infectious diseases could cross borders through trade and travel.
- Over the next century, a series of subsequent conferences led to agreements on standardized quarantine measures, mandatory reporting of disease outbreaks, and the standardization of health practices across countries.

2. Establishment of the World Health Organization (1948):

- The WHO was established on April 7, 1948, as a specialized agency of the United Nations responsible for international public health. The WHO's mandate includes setting global health standards, providing technical assistance to countries, and coordinating international health efforts to promote health, keep the world safe and serve the vulnerable.

- ✿ WHO's role became critical in responding to global health challenges such as disease prevention and control (in combating diseases like malaria, smallpox, HIV/AIDS, and most recently, the COVID-19 pandemic), global Health governance and Health systems strengthening

3. International Health Regulations (IHR) (1969 and 2005):

- ✿ The IHR were first adopted by the WHO in 1969 to prevent the international spread of diseases. Initially, they focused on six diseases: cholera, plague, yellow fever, smallpox, relapsing fever, and typhus.
- ✿ The IHR were significantly revised in 2005, expanding the scope to cover all public health risks and emphasizing the importance of national capacities to detect, assess, report, and respond to public health emergencies. The 2005 IHR also introduced the concept of the "Public Health Emergency of International Concern" (PHEIC), which has since been applied in situations like the H1N1 flu pandemic and the Ebola outbreak.

4. Global Health Initiatives and Frameworks (21st Century):

- ✿ The turn of the century saw the rise of global health initiatives such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria (2002) and the Global Alliance for Vaccines and Immunization (GAVI). These initiatives have mobilized significant resources to combat global health challenges and establishing standards for disease control and prevention.
- ✿ The Sustainable Development Goals (SDGs), adopted by the United Nations in 2015, include a dedicated health goal (SDG 3) that aims to ensure healthy lives and promote well-being for all, at all ages. This goal has further spurred the development of health regulations and policies globally, building on the momentum of earlier initiatives.

National Level (India)

The 71st round of the National Sample Survey Office (NSSO), conducted in January-June 2014, provided comprehensive data on health services utilization, including insights into the distribution between public and private healthcare sectors in India. This round focused on morbidity, healthcare services, and the use of both outpatient and inpatient care services across the country.

The report highlighted the significant reliance on private healthcare services in India, with most of both outpatient and inpatient care being provided by the private sector. The public sector, though significant, served a smaller portion of the population, particularly in rural areas and among economically disadvantaged groups. The high cost of private healthcare and the relatively lower utilization of public health insurance schemes pointed to ongoing challenges in ensuring equitable access to healthcare in India.

These insights are crucial for understanding the healthcare landscape and the need for regulatory frameworks like the Clinical Establishments (Registration and Regulation) Act, 2010, to ensure quality and affordability in both private and public healthcare sectors.

The *Clinical Establishments (Registration and Regulation) Act, 2010* was introduced to address critical gaps in the regulation of healthcare services across India. The rapid and largely unregulated growth of the healthcare sector, particularly the private sector, led to significant disparities in the quality of care. Before the Act, many healthcare facilities operated without adhering to essential standards for infrastructure, staff qualifications, and patient safety. This inconsistency posed serious risks to patients, leading to cases of medical negligence, unsafe practices, and poor health outcomes. The need for a standardized regulatory framework became increasingly evident to ensure that all healthcare establishments across the country provided a minimum standard of care.

One of the major drivers behind the Act was the lack of ethical oversight in the

healthcare sector. The absence of regulatory mechanisms allowed for widespread unethical practices, such as unnecessary medical procedures, overcharging, and a lack of transparency in billing. These practices often placed a heavy financial burden on patients, particularly the poor and middle-class populations, who faced exorbitant medical expenses. Moreover, disparities in access to quality care, especially in rural and underserved areas, highlighted the urgent need for national-level regulation to ensure equitable healthcare across all regions.

Activism in Maharashtra played a significant role in bringing these issues to the forefront. The state, with its vibrant civil society, witnessed numerous cases of medical negligence, exorbitant charges, and denial of care, which triggered public outcry and demands for government intervention. Non-governmental organizations (NGOs) and civil society groups, such as the Jan Swasthya Abhiyan (JSA), were at the forefront of advocating for healthcare reforms. These organizations conducted campaigns, held public meetings, and published reports that exposed the systemic issues within the healthcare sector, emphasizing the need for a regulatory framework like the Clinical Establishments Act.

The Clinical Establishments (Registration and Regulation) Act, 2010, was enacted by the Parliament of India on 17th August 2010, with the aim of ensuring the registration and regulation of all clinical establishments across the country. This Act is designed to set and enforce minimum standards of facilities and services provided by clinical establishments, thereby contributing to the improvement of public health as mandated by Article 47 of the Indian Constitution.

Key Provisions of the Act:

1. Objective and Scope:

- The Act mandates the registration and regulation of all clinical establishments in India to ensure they meet minimum standards necessary for providing safe and effective

- ✿ healthcare. It applies to a wide range of establishments, including hospitals, maternity homes, nursing homes, dispensaries, clinics, and similar institutions offering services across all recognized systems of medicine, such as Ayurveda, Unani, Siddha, and Homeopathy.
- ✿ The Act covers establishments in both the public and private sectors, including those run by individuals, partnerships, companies, or organizations, except for those managed by the Armed Forces.

2. Implementation:

- ✿ The Act was officially notified on 28th February 2012 and enforced on 1st March 2012 in the states of Arunachal Pradesh, Himachal Pradesh, Mizoram, and Sikkim, as well as in all Union Territories except Delhi.
- ✿ Later, the states of Uttar Pradesh, Rajasthan, Bihar, Jharkhand, Uttarakhand, and Assam adopted the Act under clause (1) of Article 252 of the Constitution. As of now, the Act is applicable in 11 states and 5 Union Territories.

3. Exemptions:

- ✿ Certain clinical establishments are exempt from the Act's regulations:
 - ★ Establishments owned, controlled, or managed by the Armed Forces are not regulated under this Act.
 - ★ Clinical establishments in states or Union Territories mentioned in the schedule of the Act, unless those regions repeal their existing laws and adopt the Clinical Establishments Act.
 - ★ Establishments of categories or systems of medicine for which the state government has not yet appointed a

- ★ date for the Act's enforcement, even if the state has adopted the Act.

4. Regulatory Framework:

- ✿ The Act establishes a national-level council and state-level councils responsible for overseeing its implementation. These councils are tasked with setting standards for clinical establishments, maintaining a national register, and ensuring compliance with the prescribed standards.
- ✿ All clinical establishments covered under the Act are required to register with the designated authority and meet the minimum standards of infrastructure, equipment, and human resources as specified.

5. Implementation and Compliance:

- ✿ The Act empowers both central and state governments to take necessary actions to ensure compliance, including inspecting clinical establishments, suspending or canceling registrations, and imposing penalties for violations.
- ✿ The goal is to promote safety and quality in healthcare services, ensuring that all citizens have access to standardized and reliable healthcare.

State Level (Kerala)

Kerala, known for its progressive social policies and high health indicators, has developed a unique healthcare regulatory framework that reflects its specific needs and context.

1. Early Health Initiatives:

- ✿ Even before India's independence, Kerala (then part of the princely state of Travancore) had a well-established public health system, with a focus on primary healthcare and disease

- ✿ prevention.
- ✿ The state's public health initiatives, such as the establishment of primary health centers and the promotion of sanitation and hygiene, laid the groundwork for Kerala's later achievements in health.

2. Post-Independence Period:

- ✿ After independence, Kerala continued to prioritize healthcare, achieving remarkable progress in public health indicators such as infant mortality, life expectancy, and literacy rates. This success was largely due to the state's investments in public health infrastructure, education, and social welfare.
- ✿ The Kerala State Health Policy of 1996 and its subsequent revisions highlighted the need for regulation and quality assurance in both public and private healthcare sectors.

3. Kerala Clinical Establishments (Registration and Regulation) Act, 2018:

The Kerala Clinical Establishments (Registration and Regulation) Act, 2018, is a significant piece of legislation aimed at improving public health in Kerala by regulating clinical establishments across all recognized systems of medicine. The Government of Kerala, after considering the demand from the public and other stakeholders brought about the Kerala Clinical Establishments (Registration and Regulation) Act 2018 (KCEA 2018), passed by the Kerala Legislative Assembly on 1st of February 2018. This Act is aligned with the national Clinical Establishments (Registration and Regulation) Act, 2010, but includes provisions specific to Kerala, such as the categorization of hospitals based on their size and the nature of services provided.

The Act covers all clinical establishments in Kerala, irrespective of whether they are in the public or private sector, and encompass Modern Medicine including Dental, Ayurveda, Yoga & Naturopathy, Homoeopathy,

Siddha, and Unani systems. This includes hospitals, clinics, nursing homes, dental clinics, laboratories, diagnostics centers and other healthcare facilities except Armed Forces Establishments and clinical establishments offering Consultation Services only.

Salient Features

1. **Mandatory Registration:** All clinical establishments must register with the concerned authority.
2. **Minimum Standards:** The Act prescribes basic minimum standards for different categories of clinical establishments to ensure quality healthcare.
3. **Regulatory Authority:** A State Council, 14 District Registering Authorities, an Executive Committee, a Grievance Redressal Committee and an Appellate Authority were established to oversee the implementation of the Act.
4. **Grievance Redressal Committee:** Has a Grievance Redressal mechanism in place to hear grievances from the public.
5. **Appellate Authority:** The clinical establishments can file appeal against orders of District Registering Authority's to the Appellate Authority.
6. **Inspections:** Inspection under the Kerala Clinical Establishments Act is conducted for monitoring compliance with healthcare standards, maintaining the quality of care provided
7. **Penalties:** The Act imposes penalties for violations of its provisions.

The Context

- ★ In 2013, a new attempt was made to refine and strengthen the national regulatory framework with the introduction of the Clinical Establishments (Registration and Regulation) Bill, 2013. However, it did not pass in Parliament. In response to the limitations of the

- ★ national Act and the unsuccessful attempt to pass the 2013 bill, states like Kerala chose to develop their own legislative measures. The Government of Kerala, after considering the demand from the public and other stakeholders brought introduced the Kerala Clinical Establishments (Registration & Regulation) Act, 2018, to address specific issues within its healthcare sector, such as improving quality standards, ensuring patient safety, and enhancing transparency.
- ★ The Kerala Clinical Establishments (Registration & Regulation) Act, 2018, was part of the LDF government's election manifesto 2016, which highlighted the need for targeted healthcare reform. The Act established a regulatory framework tailored to the state's needs, including detailed standards for clinical establishments, mechanisms for patient grievance redressal and appeal and provisions for regular inspections and compliance enforcement.
- ★ In an incident, that highlighted serious issues of healthcare access and medical negligence, a 46-year-old worker named Murugan from Nagercoil, Tamil Nadu, tragically died after being denied treatment at multiple major hospitals in Kollam and Thiruvananthapuram, Kerala. The refusal of treatment by these facilities, which cited various petty reasons, drew significant attention and criticism. This case underscored critical gaps in the healthcare system, including inadequate emergency response protocols and ethical lapses in the treatment of patients.
- ★ In Kerala, the healthcare landscape is characterized by a significant presence of both private and public sector services, each playing a crucial role in the state's healthcare system. The private sector in Kerala provides approximately 70-80% of outpatient care and around 60% of inpatient care (National Sample Survey Office [NSSO], 2014). This sector includes a wide range of facilities, from small clinics and nursing homes to large multi-specialty hospitals. The public sector is

- ★ responsible for about 20-30% of outpatient care and 40% of inpatient care in Kerala (NSSO, 2014). This sector comprises primary health centers (PHCs), community health centers (CHCs), and government hospitals, which are crucial for providing essential and preventive healthcare services.
- ★ The IT Mission of Kerala facilitated the infrastructure necessary for the Act's execution by providing servers for hosting the relevant systems. Additionally, the software developed by the National Informatics Centre (NIC) was instrumental in managing the registration and regulation processes. These coordinated efforts between healthcare schemes, technological support, and software development have collectively strengthened the implementation and efficacy of the act.
- ★ The successful implementation of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, was further supported through extensive Training of Trainers (ToTs) conducted at multiple levels, both online and offline. These training sessions were pivotal in equipping District Medical Officers (DMOs), Medical Officers (MOs), and data entry officers with the necessary skills and knowledge for effective execution of the Act. The State Health Systems Resource Centre - Kerala (SHSRC-K) played a central role in organizing these ToTs.

Key Definitions and Terminology

This chapter aims to provide a clear understanding of the key terms and definitions used throughout the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, and its subsequent rules. A comprehensive grasp of these terms is essential for effective interpretation and implementation of the Act.

Definitions

- ✿ **Appellate Authority:** The Appellate Authority constituted under subsection (1) of section 34 of the Act. It is the designated authority responsible for hearing and deciding appeals against the decisions or orders of the Registration Authority.
- ✿ **Authority:** A District Registering Authority constituted under subsection (1) of section 14 of the Act. It is the primary authority responsible for registering clinical establishments within its jurisdiction and overseeing their compliance with the Act's provisions.
- ✿ **Clinical Establishment:** As per Section 2(c) of the Act, a clinical establishment refers to a hospital, maternity home, nursing home, clinic, sanatorium, or any institution that offers services, facilities with or without beds, for treatment, diagnosis, or care for illness, injury, deformity, abnormality, dental care, pregnancy, or infertility in any recognized system of medicine. It includes establishments providing diagnostic or investigative services with the aid of laboratory or medical equipment. Clinical establishments owned, controlled, or managed by the Government, trusts, individuals, partnerships, corporations, or local self-government institutions are covered under this definition, except those providing only consultation services and those owned by the Armed Forces.
- ✿ **Council:** The State Council for Clinical Establishments established in 2018, under Section 3 of the Act. It is a regulatory body responsible for

- ✿ advising the government on matters related to clinical establishments, formulating policies, and ensuring the implementation of the Act's provisions.
- ✿ **Emergency Medical Condition:** As defined in Section 2(e) of the Act, an emergency medical condition refers to a medical condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate medical attention could reasonably be expected to result in serious jeopardy to life, serious impairment to bodily functions, or serious dysfunction of any organ or part of the body.
- ✿ **Government:** The Government of Kerala.
- ✿ **Local Self Government Institution:** A Panchayat or Municipality constituted under the relevant Acts.
- ✿ **Notification:** A notification published in the Official Gazette.
- ✿ **Prescribed:** Prescribed by rules made under the Act.
- ✿ **Recognized System of Medicine:** Modern Medicine (including dentistry), Naturopathy, Ayurveda, Homoeopathy, Siddha, and Unani systems of medicine or any other system of medicine recognized by the Government.
- ✿ **Register:** The State register maintained and published by the Authority under sub-section (1) of section 12 of the Act containing details of the registered clinical establishments.
- ✿ **Registration:** The registration of a clinical establishment under Section 16 of the Act.
- ✿ **Standards:** The standards prescribed by the Government under Section 13 for the registration of clinical establishments.
- ✿ **Stabilize:** To provide such medical treatment of an emergency medical 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.

Major Milestone in the Development and Execution of the Kerala Clinical Establishments (Registration and Regulation) Act and Rules

Following the enactment of the Clinical Establishments (Registration and Regulation) Act, 2010, states in India were given the option to either adopt the national legislation or develop their own regulatory frameworks for healthcare establishments. This flexibility was provided to accommodate the diverse needs and challenges faced by different states.

The act was initially piloted in specific districts (Palakkad, Malappuram, and Thrissur) before being expanded statewide. The initial implementation primarily targeted healthcare facilities practicing modern medicine including dental and laboratory diagnostic centres.

○ ***The State Council***

On December 31, 2018, the Kerala Government established the State Council for Clinical Establishments by notification, in accordance with Section 3 of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018. The State Council under the Kerala Clinical Establishments Act is chaired by the Secretary of the Health and Family Welfare Department, with the Secretary of the Ayush Department as the Vice Chairperson. It includes ex-officio members such as the Directors of Health Services, Medical Education, Indian Systems of Medicine, Homeopathy, and Public Health Laboratory. Additionally, representatives from the Councils of Modern Medicine, Indigenous Medicine, Homeopathy, Dental, and Nursing, along with nominees from government departments, medical associations, and patient welfare organizations, are part of the Council. The Secretary of the Council, an officer not below the rank of Deputy Director of Health Services, is appointed by the

Government.

The Council is responsible for classifying clinical establishments and setting minimum standards. It compiles and updates the State Register of Clinical Establishments, appoints assessors for inspections, and periodically reviews establishments to ensure compliance. It recommends modifications to regulations in accordance with the changes in technology or social conditions, mandates public disclosure of essential data, and submits periodic updates to the National Register. The Council has the authority to direct the cancellation of registrations where public health and safety are at risk. Additionally, it establishes a grievance redressal mechanism for complaints. Meetings are held quarterly for the first two years and biannually thereafter. The Council maintains a live online register, publishing updated details monthly for public access.

○ ***Executive Committee***

The Executive Committee is chaired by the Secretary of the Health and Family Welfare Department, with the Secretary of the Ayush Department as the Vice-Chairperson. Other members include the Directors of Health Services, Medical Education, Indian Systems of Medicine, Homeopathy, and the Public Health Laboratory. Additionally, a representative from a patient welfare organization, nominated by the Government, is included. The Secretary of the Council, an officer not below the rank of Deputy Director of Health Services, serves as the Convenor.

The Executive Committee is responsible for the general administration of the State Council, ensuring the effective implementation of its decisions. It assists in setting standards for clinical establishments, supervises financial and administrative matters, and oversees the functioning of the Council's office. The committee provides guidance to the Authority, Appellate Authority,

and Grievance Redressal Committee, manages financial matters, and submits half-yearly financial reports. It examines issues requiring the Council's attention, reviews representations, and recommends follow-up actions. Additionally, it approves remuneration and service conditions for deputed employees and technical advisors with government approval. The committee can order emergency inspections, conduct investigations, manage the Council's website, and perform other assigned functions. It may delegate specific powers to the Convenor, who is responsible for their execution. All decisions and actions taken by the Executive Committee are reviewed by the Council in its next meeting.

○ ***The District Registering Authority***

The District Registering Authority is chaired by the District Collector, with the District Medical Officer (Health) as the Vice-Chairperson. Other members include an Assistant Director of the Health and Family Welfare Department (nominated as the Convenor), a Medical Officer from the Indian Systems of Medicine, a Medical Officer from the Homoeopathic System of Medicine, and a representative from a professional health sector association, nominated by the District Collector for a three-year tenure.

The Authority is responsible for granting, renewing, suspending, or cancelling the registration of clinical establishments and ensuring compliance with the Act and its rules. It has the power to cancel registrations where there is an imminent risk to public health and patient or staff safety. Additionally, it prepares periodic reports as directed by the Council and submits quarterly reports on actions taken against non-registered clinical establishments.

The Authority meets at least once every two months. The Vice-Chairperson is responsible for accepting and verifying applications, issuing provisional registration certificates within 45 days if found

satisfactory. To maintain an updated State Register, all District Registration Authorities submit quarterly reports detailing newly registered clinical establishments, those that lost registration and the total number of currently registered establishments.

○ ***Grievance Redressal Mechanism***

The Grievance Redressal committee comprises a retired Government Additional Secretary, a retired medical officer, and a representative from an NGO. The committee receives grievances from the public through an online portal, where complainants can also track the status and actions taken. It examines and resolves complaints within three months, informing the complainant of the decision. The Grievance Redressal Committee, after conducting an appropriate inquiry into the petitions it considers, shall issue directions to the concerned Authority to take necessary remedial measures based on its findings.

○ ***Appellate Authority***

As per Section 34 of the Act, the Government has constituted a three-member Appellate Authority comprising the Principal Secretary of Health, the Additional Secretary of the Law Department, and the Director of Medical Education. This authority is responsible for receiving and adjudicating appeals against the decisions of the District Registering Authorities (DRA).

Any clinical establishment aggrieved by an order of the Authority or the Council may file an appeal with the Appellate Authority within 45 days of receiving the order, along with the required fee. Upon submission, appeals will be electronically acknowledged with a tracking number for online status updates. The Appellate Authority reviews the legality and propriety of the DRA's decision and disposes of the appeal within 60 days. Any further appeal against the Appellate Authority's decision must be filed with the High Court

within 60 days.

○ ***The Registration***

The provisional registration process for clinical establishments under Modern Medicine, including Dental, commenced on January 1, 2019, in three pilot districts: Malappuram, Thrissur, and Palakkad. This initiative gradually expanded to other districts in a phased manner. On April 15, 2019, the registration process was extended to Kollam, Idukki, Kottayam, Kasargod, and Wayanad. By June 15, 2019, districts such as Kannur, Kozhikode, Thiruvananthapuram, Ernakulam, and Pathanamthitta also began registering establishments.

The Act governing Indian Systems of Medicine, including Ayurveda, Siddha, Unani, Homeopathy, Yoga and Naturopathy came into force on June 16, 2019. To support this transition, a Training of Trainers (ToT) program was conducted for AYUSH officials on October 26, 2019. Following this, the provisional registration portal for AYUSH establishments was launched in the pilot districts of Malappuram, Thrissur, and Palakkad on October 28, 2019, and subsequently scaled to all districts on January 1, 2020.

In the 2023-24 period, Minimum Standards Rules for clinical establishments under Modern Medicine, Dental, Laboratory, Diagnostics services, and Ayurveda, Siddha, Unani, Homeopathy, Yoga and Naturopathy were officially notified. Simultaneously, the permanent registration portal for these categories was launched. Additionally, the Council appointed and notified a panel of independent assessors to evaluate clinical establishments prior to granting permanent registration. These assessors received formal training and were provided with an assessor's guide to ensure consistency and thoroughness in the evaluation process.

The Permanent Registration Portal for Modern Medicine, Dental,

Laboratory, and Diagnostic Services was launched on April 26, 2023, immediately following the notification of the Minimum Standards for these categories. This portal enables clinical establishments to apply for permanent registration, ensuring compliance with the notified standards for quality and service.

The Permanent Registration Portal for AYUSH establishments was officially opened on March 7, 2024. This portal allows establishments under Ayurveda, Unani, Homeopathy, Siddha, and Yoga & Naturopathy to apply for permanent registration in accordance with the notified minimum standards for these systems of medicine.

- ***The Minimum Standards***

The notification of Minimum Standards for clinical establishments is a mandatory prerequisite to initiate the Permanent Registration process. Subcommittees were formed to establish these standards across various sectors, including Modern Medicine, Dental Services, Indian Systems of Medicine, Homeopathy, Laboratories, Diagnostic Centers, and the collection of statistics and information from clinical establishments. The notification of these subcommittees was officially released on May 21, 2019 and published in the official website of the Kerala State Council for Clinical Establishments.

The Minimum Standards Rules for Modern Medicine, Dental Services, Laboratories, and Diagnostic Centres were subsequently notified under SRO No. 503/2023, dated March 11, 2023. This notification marks a key step in ensuring compliance and uniformity in the healthcare sector, laying the foundation for the Permanent Registration process.

The Minimum Standards Rules for clinical establishments under the categories of Ayurveda, Unani, Homeopathy, Siddha, and Yoga & Naturopathy have been officially notified through various

government orders. Each of these are available in the https://clinicalestablishments.kerala.gov.in/index.php/content/index/notification_

The Committee formed to recommend the formats for collecting statistics and information from clinical establishments has submitted its proposed data collection format. These formats were discussed during the 5th State Council meeting held on January 28, 2023, and subsequently published on the Council's website for 20 days to gather feedback. As no feedback was received, the formats were submitted to the Government. Following the Council was instructed to notify the formats. Consequently, the formats for data collection were officially notified and published on the Council's official website.

The minimum standards under KCEA 2018 cover various aspects of a clinical establishment, including infrastructure, staffing, equipment, and operational protocols. Below are the key areas where standards are applied:

1. Infrastructure and Physical Requirements

- *Location and Premises:*
 - ↳ The establishment must be situated in a hygienic environment with easy access for patients.
 - ↳ Adequate space must be available to accommodate all the activities and services provided, ensuring patient comfort and safety.
- *Building Design:*
 - ↳ The facility must have a proper layout with designated areas for reception, consultation, treatment, procedures, inpatient care (if applicable), and emergency services.
 - ↳ The building must comply with safety norms, including fire

↪ safety measures, emergency exits, and accessibility for people with disabilities.

- *Hygiene and Sanitation:*

↪ Adequate provisions for sanitation, including clean water supply, waste disposal systems, and cleanliness of the premises, must be maintained.

↪ Separate toilets for staff and patients, including gender-specific and accessible options, must be available.

2. Staffing and Human Resources

- *Qualified Personnel:*

↪ The establishment must employ adequately qualified and trained healthcare professionals, including doctors, nurses, and paramedical staff, as per the nature and size of the facility.

↪ All healthcare professionals must be registered with the appropriate medical or para medical councils.

- *Staffing Levels:*

↪ The establishment must maintain a sufficient number of staff to ensure continuity of care and to provide round-the-clock care, including emergency services

↪ Staff to patient ratio: Ensure optimal staff to patient ratio to deliver high quality care and patient safety.

3. Equipment and Medical Devices

- *Availability of Equipment:*

↪ The establishment must have all the necessary medical equipment and devices required for the services it offers, such as diagnostic tools, surgical instruments, and life-support systems.

↪ Equipment must be regularly maintained and calibrated to ensure accuracy and safety.

- *Safety Standards:*

↪ Medical equipment must comply with the safety standards prescribed by relevant authorities, including guidelines for radiation safety where applicable, ensuring protection for patients and staff

4. Patient Care and Treatment Protocols

- *Standard Treatment Guidelines:*

↪ The establishment must follow standard treatment guidelines and protocols for the management of various medical conditions, ensuring evidence-based care.

- *Patient Records:*

↪ Accurate and comprehensive patient records must be maintained, including details of diagnosis, treatment, medications, and follow-up care.

↪ There must be a secure system for storing and retrieving patient records, with measures in place to protect patient confidentiality.

- *Emergency Services:*

↪ The establishment must be equipped to handle medical emergencies, with protocols in place for triage, stabilization, and referral to higher care centers if needed.

↪ Emergency response plan to be developed and regularly updated for managing any emergencies or disasters

↪ Emergency response equipment, such as defibrillators and oxygen supply, must be readily available.

5. Quality Assurance and Continuous Improvement

- *Quality Control Systems:*
 - ↳ The establishment must implement quality control systems to monitor and improve the quality of care provided, including regular audits, patient feedback mechanisms, and corrective action plans.
- *Accreditation:*
 - ↳ Although not mandatory, the establishment is encouraged to seek accreditation from recognized bodies to ensure compliance with higher standards of care.
- *Infection Control:*
 - ↳ Stringent infection control protocols must be in place to prevent hospital-acquired infections, including sterilization of equipment, use of personal protective equipment (PPE), and proper waste management.

6. Legal and Ethical Compliance

- *Compliance with Laws:*
 - ↳ The establishment must comply with all applicable laws and regulations, including those related to medical ethics, patient rights, and confidentiality.
 - ↳ There must be protocols for handling medico-legal cases, consent forms, and documentation of patient interactions.
- *Ethical Practices:*
 - ↳ The establishment must ensure that all services are provided ethically, without discrimination, and with respect for patient autonomy and dignity.

7. Licensing and Documentation

- *Valid Licenses:*
 - ↳ All necessary licenses and permits, including those for operating as a healthcare facility, must be in place.
 - ↳ The establishment must display its registration certificate prominently, along with the licenses of its medical professionals.
- *Regular Updates:*
 - ↳ The establishment must regularly update its registration details, including any changes in services offered, staff employed, or infrastructure.

* *Measures for Effective Implementation*

- The Assessors' Guide and checklists, essential for the evaluation of clinical establishments prior to granting permanent registration, has been prepared by the Council. This guide received approval from the 6th Executive Meeting held on May 4, 2023 and was subsequently endorsed during the 6th State Council Meeting on September 14, 2023. The guide ensures a standardized approach to assessments, facilitating consistent and thorough evaluations of clinical establishments.
- The Kerala State Council for Clinical Establishments organized different training sessions for the implementation of the Kerala Clinical Establishment (Registration & Regulation) Act and Rules, 2018.
- The panel of independent assessors, tasked with assessing and evaluating whether registered clinical establishments comply with the prescribed standards, was officially notified by the Council. This notification, issued with the Government's approval, was published on the Council's official website under Notification No. 951/Admin/KSCCE/2023, dated May 10, 2023. These assessors play a

- crucial role in ensuring that clinical establishments meet the required standards before receiving or maintaining registration.
- Orientation training for the panel of assessors in the categories of Modern Medicine, Dental, Laboratory, and Diagnostics was conducted on June 19, 2023, via Google Meet. Additionally, the orientation training for assessors in AYUSH categories took place on May 18, 2024, also through Google Meet. In total, 157 participants attended these training sessions, equipping them with the necessary knowledge and skills for effective assessment of clinical establishments.
- On June 14, 2023, a team from the State Health Systems Resource Centre (SHSRC), Maharashtra, visited the Kerala State Council for Clinical Establishments. During the visit, the team engaged in discussions about the Kerala Clinical Establishments (Registration & Regulation) Act and Rules, 2018, with the Secretary of the KSCCE. The Secretary delivered a comprehensive PowerPoint presentation on the Act and its regulations, addressing the team's queries and providing clarity on various aspects of the Kerala Clinical Establishments Act (KCEA) 2018.
- The Principal Secretary, the Secretary of the KSCCE, attended a state-level orientation program on June 22, 2023, focused on the Clinical Establishment Act and the significance of its registration. This program was conducted by the Indian Dental Association, during which they addressed and clarified various queries raised by the members regarding the Act and its implications for clinical establishments.
- As per section 47 of Kerala Clinical Establishment (Registration and Regulation) Act 2018, the clinical establishment shall provide, such medical examination and treatment as may be required and can be provided with the staff and facilities available in the establishment, to

- save the life of the patient and ensure safe transportation of the patient to any other hospital and the Council has to notify the lifesaving services to be provided by each category of clinical establishments. As per the direction of the 4th State Council, a meeting with Special Officer held on 16.06.2022 has decided to constitute a sub-committee for submitting report in this matter. The committee had coopted other experts from various Specialties. 5 meetings of the subcommittee held and the final report had been approved by the 5th State council held on 28/01/2023. The notification has been published in the official website of the Council.
- During the 4th State Council meeting held on May 9, 2022, the importance of developing an Information, Education, and Communication (IEC) strategy for the Kerala Clinical Establishments (Registration & Regulation) Act, 2018, was discussed. Following the council's directive, a meeting with the Special Officer took place on June 16, 2022, where it was decided to form a subcommittee to propose an IEC strategy. The decisions made by the subcommittee were approved by the 5th State Council, and a proposal for the IEC strategy was submitted to the Government. Additionally, an IEC subcommittee with representatives from various associations, constituted to strengthen provisional registration, convened on August 30, 2022.
- The Security Audit of the online portal (portal.clinicalestablishments.kerala.gov.in) for the registration of clinical establishments under the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 is completed confirming that the portal met the necessary security standards for continued operation.
- The 6th Executive Committee of the Kerala State Council for Clinical Establishments decided to organize a registration drive to ensure that

- clinical establishments that had not yet obtained registration under Section 17 of the Kerala Clinical Establishments Act (KCEA), 2018, were brought into compliance. During the Senior Medical Officers Conference held on November 14, 2023, it was agreed to conduct a state-wide registration drive on November 27 to identify unregistered clinical establishments. The registration drive was subsequently carried out across all districts, and the district registering authorities submitted their reports. As a result of the registration drive, which took place from November 27, 2023, to January 11, 2024, a total of 1,856 clinical institutions successfully obtained new user registrations.
- As the permanent registration portal of Modern Medicine, Dental and Laboratory and Diagnostics Services has been opened on 26.04.2023, the 6th State Council Meeting held on 14.09.2023 decided to close the provisional registration portal for the said categories. as per GO (Rt) No. 68/2024/H&FWD dated 11.01.2024 the date of closure of provisional registration portal for Modern Medicine, Dental and Laboratory and Diagnostics Services was 31.01.2024. The provisional registration process for AYUSH clinical establishments is ongoing.

Overview of Registration Processes

Mandatory Registration

All clinical establishments in Kerala must be registered with the designated authority. Unregistered operation is prohibited. Existing establishments will be granted provisional registration initially, with a mandate to meet permanent registration standards within a specified timeframe. New establishments must apply for permanent registration within a prescribed period. Establishments offering multiple medical services require separate registration for each category, except for in-house laboratories and diagnostic centres.

Provisional Registration

Existing clinical establishments must apply for provisional registration within a specified format and fee. The authority may issue a provisional registration certificate within 45 days, or it is deemed granted. Failure to comply with the law in granting provisional registration may lead to disciplinary action. Provisional registration is valid for four and a half years.

Permanent Registration

Application for permanent registration requires a prescribed format, fees, and evidence of meeting category standards. Establishments with provisional registration must apply 60 days before its expiry. The authority must publish application details and assess the establishment before granting permanent registration. Permanent registration is granted upon meeting prescribed standards and is valid for five years, subject to renewal.

Registration Status till date

A total of 13,321 clinical establishments have registered provisionally, including 3,892 public institutions and 9,429 private institutions. Additionally, 1,256 clinical establishments have registered permanently, comprising 664 public institutions and 592 private institutions. The provisional registration portal for modern medicine, dental, laboratory, and

diagnostic services has been closed, while the provisional registration of AYUSH clinical establishments remains open. Meanwhile, the permanent registration for all categories is ongoing.

Inspection and Inquiry

Inspection of Clinical Establishments

Right to Inspection

The Kerala Clinical Establishments Act grants the Council, the Authority, or the Appellate Authority the right to inspect any clinical establishment. This includes inspections of the building, laboratories, diagnostic facilities, equipment, and operations. These inspections may also evaluate compliance with the prescribed standards and conditions of registration. Inspections are conducted by authorized personnel, with prior notice issued to the clinical establishment and an opportunity for the establishment to be represented.

Manner of Inspection

- If there is a suspicion that a clinical establishment is operating without proper registration, the Council or the Authority, or an authorized officer, may conduct an inspection after serving notice.
- The following procedures are to be observed during inspections:
 - Inspection Orders: These are to be issued in writing by the Secretary of the Council or Vice Chairperson of the Authority.
 - Evidence Collection: Photographs, videos, audio recordings, testimonials, and relevant records may be collected as evidence during the inspection.
 - Interviews: The inspection team can interact with responsible individuals at the establishment to gather necessary information.
- No individual associated with the clinical establishment may obstruct the inspection process.
- Inspecting officers may enter the premises at any reasonable time and inspect the following:

- The physical premises and equipment used at the establishment.
- Any documents, records, or instruments, with permission to collect samples if required.
- Required documents or records requested by the inspecting team must be produced by the owner, manager, or staff of the clinical establishment.
- Officers may ask relevant questions, take statements, and obtain authenticated copies of documents.

Conduct during Inspection

- Inspecting officers must ensure they do not disturb or interrupt the services provided to patients. They are also expected to maintain professionalism, accuracy, and discipline during the inspection process.
- All personnel connected to the establishment must cooperate fully, providing correct and complete information to the inspectors. Any obstruction to the inspection will result in legal action under Section 28(1) of the Act.

Consequences for Non-compliance

- If an individual fails to provide requested information, delays the submission of records, or provides misleading information, actions will be taken under Section 28(2) of the Act. Inspectors are also permitted to review confidential patient records during the inspection, ensuring confidentiality is maintained.

Submission of Inspection Report

- After the inspection, the officers must submit their findings within 48 hours using the prescribed format (Form No. 11). In cases of emergency inspections, where there is an imminent risk to public

- health or safety, an inspection may be conducted without prior notice. Such reports must be submitted within 24 hours.

Inspection Follow-Up and Actions

- Once an inspection report is submitted, the Council or Authority will notify the clinical establishment of their findings. The clinical establishment is then given the opportunity to respond and propose corrective actions. If the actions taken are deemed unsatisfactory, the Council or Authority may issue directives that must be complied with.
- Additional inspections to verify compliance may be conducted within three months, but no more than two inspections should occur within a year unless specifically directed by the Council or Appellate Authority.

Inquiry Procedures under the Kerala Clinical Establishments Act

1. Inquiry by the Council

Under Section 27 of the Kerala Clinical Establishments Act, the Council has specific powers and procedures when conducting inquiries into violations of the Act. The inquiry process is as follows:

- The Council will first issue a notice to the accused individual or clinical establishment regarding the alleged violation. This notice will detail the alleged contravention of the law and the potential penalties. The accused is required to respond with an explanation and any supporting evidence within 15 days.
- If no response is received within 15 days, the Council may proceed with further inquiry. This may involve gathering additional evidence or examining existing documentation. Based on the findings, the Council is empowered to impose a fine in accordance with the provisions of the Act.
- If the accused submits an explanation with supporting documents or evidence, the Council will notify the accused about

- the date of inquiry. The accused may present their case directly, through a representative, an advocate, or an authorized agent. The Council also holds the authority to summon relevant records, evidence, and individuals to testify as part of the inquiry.
- Before any penalties are imposed, the accused or the clinical establishment will be given a fair opportunity to present their defence. If the Council is convinced that the provisions of the Act were violated, it may impose penalties based on the gravity of the offense. In cases involving clinical establishments, factors such as the size, type, category, and location of the establishment will be taken into consideration while determining the penalty.

2. Inquiry by the Authority

Section 28 of the Act outlines the powers and procedures of the Authority in cases involving clinical establishments that are operating without registration. The key procedures include:

- If an establishment is found to be functioning without proper registration, the Authority will issue a notice to the responsible individuals. The notice will specify the alleged violation and the potential penalty, giving the accused 15 days to respond with a written explanation and supporting evidence.
- If the accused does not respond within the specified time, the Authority may conduct an inquiry, either directly or through other means. After evaluating the available evidence and documentation, the Authority can impose penalties as outlined in the Act.
- If the establishment provides a written explanation, the Authority will review the submission and, if necessary, schedule a formal inquiry. A notice specifying the date and location of the inquiry will be sent to the establishment's officials. During the inquiry, the

- accused may present their arguments and evidence through representatives, advocates, or authorized agents. The Authority also holds the power to summon individuals or documents that may be relevant to the inquiry.
- After giving the accused establishment a reasonable opportunity to defend itself, the Authority will make its decision. If the Authority is convinced that the establishment has operated without registration, it will impose the appropriate penalties. The decision will take into account factors mentioned in Section 27(4) of the Act. The order imposing the penalty will be communicated to the accused establishment within 15 days of the decision.

Penalties under the Clinical Establishments Act

1. *General Penalty for Contravention of the Act (Section 26)*

- **Adjudication and Inquiry:**

- ↪ The Council or Authority has the power to adjudicate, inquire, and impose penalties for contraventions of the Act.
- ↪ They must follow prescribed procedures during the inquiry.

- **Monetary Penalties:**

- ↪ First Contravention: Penalty up to `10,000.
- ↪ Second Contravention: Penalty up to `50,000.
- ↪ Subsequent Contraventions: Penalty up to `5,00,000.

- **Serious Offences:**

- ↪ For serious contraventions, the Council may, after notice and inquiry, order the closure of the establishment in addition to imposing a penalty.

2. *Penalty for Non-Registration (Section 27)*

- **Monetary Penalties:**

- ↪ First Contravention: Penalty up to `50,000.
- ↪ Second Contravention: Penalty up to `2,00,000.
- ↪ Subsequent Contraventions: Penalty up to `5,00,000.
- ↪ Continuing Contravention: An additional penalty of `10,000 per day, subject to a maximum of `5,00,000.

- **Inquiry Process:**

- ↪ The Authority conducts an inquiry after giving the accused a reasonable opportunity to be heard.
- ↪ The Authority has the power to summon witnesses and request documents.

↪ Penalty decisions consider factors such as the establishment's size, category, type, and local conditions.

- **Appeals:**

↪ Aggrieved persons may appeal to the Appellate Authority within 45 days, following prescribed procedures and fees.

3. *Penalty for Disobedience, Obstruction, and Refusal of Information (Section 28)*

- **Monetary Penalties:**

↪ Disobedience or Obstruction: Penalty up to `1,00,000.

↪ Refusal to Supply Information or Providing False Information: Penalty up to `1,00,000.

- **Inquiry Process:**

↪ The Authority conducts an inquiry and has the power to summon witnesses and request documents.

↪ Penalties must be deposited within 30 days.

- **Appeals:**

↪ Aggrieved persons may appeal to the Appellate Authority within 45 days, following prescribed procedures and fees.

- **Recovery of Fines:**

↪ Fines are recoverable as per Sections 421 to 424 of the Code of Criminal Procedure, 1973.

4. *Penalty for Minor Deficiencies (Section 29)*

- **Monetary Penalty:**

↪ For contraventions that do not pose imminent danger and are rectifiable within a reasonable time, the penalty may extend up to ₹10,000.

5. *Penalty for Contraventions by Companies (Section 30)*

- **Liability:**

- ↪ If a contravention is committed by a company, those responsible for its operations (e.g., directors, managers) are deemed guilty and liable for penalties unless they can prove lack of knowledge or due diligence.

- **Consent or Negligence:**

- ↪ If the contravention is due to the consent, connivance, or neglect of an officer, that officer is liable for penalties.

- **Definitions:**

- ↪ "Company" includes anybody corporate, firm, cooperative society, or association of individuals.

- ↪ "Director" refers to a partner in a firm.

6. *Offences by Government Departments (Section 31)*

- **Liability:**

- ↪ If a Government-controlled clinical establishment commits an offence, the responsible officer is deemed guilty and liable for penalties.

- ↪ The officer can avoid liability by proving lack of knowledge or exercising due diligence.

Kerala Clinical Establishment (Registration and Regulations) Amendment Act, 2021



This amendment extends or modifies the provisions of the original 2018 Act, particularly in Section 18, and formalizes the changes made through the 2021 Ordinance.

- ◆ Amendment to Section 18:
 - The amendment changes the word "two" to "four" in Section 18 of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018. This likely pertains to the number of years or entities referenced in that section.
- ◆ Repeal of Previous Ordinance:
 - The Kerala Clinical Establishments (Registration and Regulation) Amendment Ordinance, 2021 (Ordinance No. 114 of 2021) is repealed.
 - Actions or decisions made under the previous Ordinance are validated and considered as made under this amended Act.

Kerala Clinical Establishment (Registration and Regulations) Amendment Act, 2022



The Kerala Clinical Establishments (Registration and Regulations) Amendment Act, 2022 is a legislative update to the original Kerala Clinical Establishments Act, 2018.

Notably, the amendment made changes to Sections 18 and 51. In Section 18, the original provision that granted provisional registration certificates for "a period of four years" was extended to "four years and six months." This modification provides clinical establishments with an additional six months to meet the necessary criteria for obtaining permanent registration, thereby allowing more time for compliance. Additionally, in Section 51, the amendment substituted the word "two" with "four,"

Kerala Clinical Establishment (Registration and Regulations) Amendment Act, 2024



The Kerala Clinical Establishments (Registration and Regulation) Amendment Act, 2024 redefines "register" under Section 2 to specify that the State register of clinical establishments will be maintained and published by the Council. Section 3 updates references to the Kerala State Medical Practitioners Act, 2021, replacing the older Travancore-Cochin Medical Practitioners Act, 1953. Section 14 adds the District Medical Officers for Indian Systems of Medicine and Homoeopathy as ex-officio members and includes a government-nominated Dental Surgeon. Section 15 mandates compliance with government-issued standards for safety, infection control, and treatment methods. Section 20 extends the registration validity period from three to five years. Sections 48 and 49 expand the responsibilities of the Executive Committee alongside the Council and the Authority, granting it additional administrative powers. These amendments aim to strengthen regulatory oversight, improve compliance, and streamline the functioning of clinical establishments in Kerala.

Conclusion

The Kerala Clinical Establishments Act, 2018, is a landmark piece of legislation designed to regulate and elevate the standards of healthcare facilities across Kerala. This Act, which follows the foundation laid by the National Clinical Establishments (Registration and Regulation) Act, 2010, addresses crucial aspects of healthcare facility operations, including registration, standards, compliance, and grievance redressal.

By implementing a structured and transparent regulatory framework, the Kerala Clinical Establishments Act, 2018 plays a vital role in ensuring high-quality, accessible, and standardized healthcare services. The inclusion of a Grievance Redressal mechanism marks a significant enhancement over the CEA 2010, fostering greater public trust, ensuring higher accountability, and reinforcing patient rights by providing a structured platform for addressing concerns within the healthcare system. This progressive approach positions Kerala as a model state for healthcare governance and regulation.

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Annexure -2

- <https://clinicalestablishments.kerala.gov.in/images/RO-943-2018>
- <https://clinicalestablishments.kerala.gov.in/index.php/content/index/act-and-rules>