



## GOVERNMENT OF KERALA

### Abstract

Health and Family Welfare Department- Judgment of the Hon'ble High Court in WA Nos. 1621/2025 and 1806/2025- Instructions for strict compliance- Orders Issued.

### **HEALTH & FAMILY WELFARE (FW)DEPARTMENT**

**G.O.(Rt)No.378/2026/H&FWD Dated,Thiruvananthapuram, 31-01-2026**

Read: Judgment dated 26.11.2025 of the Hon'ble High Court in WA Nos. 1621/2025 filed by Kerala Private Hospitals Association and another and 1806/2025 filed by Indian Medical Association and another.

### ORDER

The Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and its Rules are intended to provide for the registration and regulation of clinical establishments rendering services in recognized systems of medicine in the State, and for matters connected therewith and incidental thereto, with a view to prescribing standards of facilities and services that may be provided by them for the improvement of public health, thereby safeguarding public health and ensure patient safety and quality of care. In exercise of the powers under section 13 (1) r/w section 52 of the Act, the Government have issued Kerala Clinical Establishments (Minimum Standards for Modern Medicines, diagnostic Centres, Medical Laboratories, Dental) Rules, 2023, prescribing the minimum standards to be maintained by the clinical establishments in the State.

2. The Hon'ble High Court of Kerala in its judgment dated 26.11.2025 of the Hon'ble High Court in WA Nos. 1621/2025 filed by Kerala Private Hospitals Association and another and WA 1806/2025 filed by Indian Medical Association and another held that the validity of the Sections 16,39, and 47 of the Kerala Clinical Establishments (Registration and Regulation) Act,2018,along with the allied Rules and Schedules, is *intra vires* to the Constitution and requires no interference since the provisions are neither vague nor disproportionate and are in conformity with the global standards.

3. The Hon'ble High Court also considered it appropriate to issue certain guidelines to ensure the effective implementation of the Act, consistent with its objectives and the spirit of its preamble.The Hon'ble High Court has

issued directions to the Chief Secretary, Government of Kerala, and State Police Chief to issue appropriate notifications/orders and ensure strict compliance with the procedures and directions contained in the judgment, as well as with the provisions of the Act. The State Government is further directed to publicise the effective contents/directions issued in the judgment through visual media and print media, for a period of one month, in Malayalam and English daily, having wide circulation, so as to ensure broad public and to enable citizens to understand their rights regarding medical treatment. It has been further directed to file a detailed compliance report shall be filed before the Court within thirty (30) days from the date of receipt of a certified copy of the judgment.

4. The Guidelines issued by the Hon'ble High Court in paragraph no. 38 of the judgment is as follows:-

**i. Capacity-Graded Emergency Care**

Every clinical establishment shall, at a minimum:

- (a) screen and stabilize emergency patients within its capacity; and
- (b) ensure safe transfer, with proper documentation and communication, to a higher centre when indicated. No establishment shall deny initial life-saving aid on the ground of non-payment of advance or lack of documents.
- (c) At the time of discharge of a patient from the hospital, the hospital authorities shall ensure that, along with the discharge summary, all investigation reports pertaining to the treatment, such as ECG, X-ray, CT scan, and other test reports, are also handed over to enable the patient to maintain proper records.

**ii. Transparency and Public Display (Reception/Admission Areas and Website)**

Each clinical establishment shall prominently display, in Malayalam and English, at the Reception/Admission desk and on its official website:

- (a) the list of services offered.
- (b) baseline and package rates for commonly performed procedures, with a note that unforeseen complications or additional procedures shall be itemised.
- (c) key facility information, including bed categories, availability of ICU/OT, imaging and laboratory facilities, and ambulance/contact details.
- (d) a summary of Patients' Rights, including emergency care, informed consent, confidentiality, non-discrimination, access to medical records within 72 hours, itemised bills, and grievance redressal pathway; and
- (e) the name, phone number, and email ID of the Grievance Officer, along with contact details of the District Registering Authority/DMO helpline and other escalation contacts.

**iii. Patient Information Brochure**

At the time of admission, and as a downloadable document from the establishment's website, every hospital shall provide a brochure or leaflet in Malayalam and English containing information on:

- services offered- baseline and package rates with inclusions. - deposit and refund policy- insurance/TPA empanelment and claim procedures- estimate and billing policy- discharge procedures- ambulance and transport charges- 24×7 emergency care protocol; and - grievance redressal and escalation mechanism.

#### **iv. Grievance Redress Mechanism**

(a) Every clinical establishment shall maintain a Grievance Desk/Helpline and register every complaint with a unique reference number, issuing an acknowledgement immediately through SMS,WhatsApp, or in physical form.

(b) The establishment shall endeavour to resolve all complaints within seven (7) working days. Unresolved or serious matters shall be escalated to the District Registering Authority/DMO without delay.

(c) Each establishment shall maintain a Complaint Register, in physical or electronic form, available for inspection. A summary of grievances and actions taken shall form part of the monthly compliance reports submitted to the competent authority.

#### **v. Updates and Accuracy**

All displayed rate lists, brochures, and website information shall be kept current. Any change in services, rates, or grievance contact details shall be promptly updated, with the date of revision clearly indicated.

#### **vi. Compliance with the Kerala Clinical Establishments (Registration and Regulation) Act, 2018**

(a) Every clinical establishment shall file an undertaking of compliance with Sections 39 and 47 of the Act and the above directions within thirty (30) days from the date of this judgment before the District Registering Authority.

(b) The said Authority shall conduct verification audits within sixty (60) days from the date of this judgment and thereafter periodically, taking appropriate action for any deficiencies detected, in accordance with the Act and Rules.

#### **vii. Patient Remedies (Without Prejudice to Other Rights)**

Patients shall remain at liberty to:

(a) pursue remedies for deficiency of service before the competent Consumer Disputes Redressal Commission.

(b) lodge complaints with the local police where appropriate, including cases involving alleged fraud or cheating.

(c) escalate grave or systemic grievances to the Chief Secretary and the State Police Chief; and

(d) seek assistance from the District or State Legal Services Authorities for

advice and facilitation.

All establishments shall cooperate fully and issue receipts for all payments and complaints received.

### **viii. Language and Accessibility**

All mandatory displays, notices, and brochures shall be provided in Malayalam and English, and shall be clear, legible, and prominently accessible at the Reception/Admission areas and other conspicuous locations within each establishment, as well as on the homepage of its official website.

### **ix. Non-Compliance**

Non-compliance with these guidelines shall attract regulatory action under the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, including suspension or cancellation of registration and imposition of penalties, in addition to any civil, criminal, or constitutional remedies available to patients..

5. In compliance with the judgment read above, Government hereby order that all the Clinical Establishments in Government and Private sector, Heads of the Departments viz Director of Health Services, Director of Medical Education, Director of ISM, Director of Homeopathy, District Registering Authorities, District Medical Officers (Health), District Medical Officers of AYUSH, and all other officers concerned shall ensure strict compliance with the directions contained in the Judgment and as per the provisions of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.

(By order of the Governor)  
DR A JAYATHILAK I A S  
CHIEF SECRETARY

To:

The Advocate General, EKM (with covering letter)

The Secretary, Kerala Council for Clinical Establishments.

The Director of Health Services, Thiruvananthapuram

The Director of Indian Systems of Medicine, Thiruvananthapuram

The Director of Homeopathy, Thiruvananthapuram

State Mission Director, National Health Mission, Tvpm

All DMOs (Health/ Ayush)

All DRAs (through Secy, Kerala Council for Clinical Establishments)

The State Mass Media Officer, o/o DHS, Tvpm

Information & Public Relations Dept (For wide publicity)

Stock File / Office Copy

Forwarded /By order

Signed by

Vipin Kumar. S

Section Officer

Copy to : The Private Secretary to Minister of Health & WCD

Date: 31/01/2020 19:24:35

The Officer of Spl Duty to the Chief Secretary.

PS to Addl. Chief Secretary Health &FW Dept

**Annexure**

**The detailed directions under each category have already been identified and appended for ready reference.**

ALL CLINICAL ESTABLISHMENTS			
Sl No	Direction	Description	DRA/STATE COUNCIL TO GIVE DIRECTION
1	Capacity-Graded Emergency Care	<p>Screen and stabilize emergency patients within its capacity</p> <p>Ensure safe transfer, with proper documentation and communication, to a higher centre when indicated. No establishment shall deny initial life-saving aid on the ground of non-payment of advance or lack of documents.</p> <p>At the time of discharge of a patient from the hospital, the hospital authorities shall ensure that, along with the discharge summary, all investigation reports pertaining to the treatment, such as ECG, X-ray, CT scan, and other test reports, are also handed over to enable the patient to maintain proper records.</p>	<p>A notification has been issued by the Council under Section 47(2) of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, vide No.217/Accts/KSCCE/2023 dated 02.05.2023.</p> <p>A notification has been issued by the Council under Section 47(2) of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, vide No.217/Accts/KSCCE/2023 dated 02.05.2023.</p> <p>The stipulation that on the ground of non-payment of advance or lack of documents does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018. The matter is being examined in Government</p> <p>As per SECTION 40 KCEA 2018, Every clinical establishment shall maintain medical records of patients, in accordance with the laws for the time being in force, regarding the diagnosis, result of investigations, treatment given, condition at the time of discharge and advice given to the patients and a copy thereof shall be made available to the patient or to relatives free of cost.</p>

2	Transparency and Public Display (Reception/ Admission Areas and Website)	<p>Each clinical establishment shall prominently display, in Malayalam and English, at the Reception/ Admission desk and on its official websites:</p> <ul style="list-style-type: none"> <li>a) The list of services offered.</li> <li>b) Baseline and package rates for commonly performed procedures, with a note that unforeseen complications or additional procedures shall be itemised.</li> <li>c) Key facility information, including bed categories, availability of ICU/OT, imaging and laboratory facilities, and ambulance/ contact details.</li> </ul>	<p>Circular has already been issued by the Council to all DRA's under Section 39, and Rule 19 of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, vide No.288/ADMN/KSCCE/2025 dated 15.10.2025 for ensuring the display of fees and package rate during every stage of assessments.</p> <p>The stipulation that 'unforeseen complications or additional procedures shall be itemised,' does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018. The matter is being examined in Government.</p>
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		<p>d) A summary of Patient's Rights, including emergency care, informed consent, confidentiality, non-discrimination, access to medical records within 72 hours, itemised bills, and grievance redressal pathway; and</p>	<p>The stipulation that 'The name, phone number, and email ID of the Grievance Officer, along with contact details of the District Registering Authority/ DMO helpline and other escalation contacts' does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018. The matter is being examined in Government.</p>
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		e) The name, phone number, and email ID of the Grievance Officer, along with contact details of the District Registering Authority/ DMO helpline and other escalation contacts.	
3	Patient Information Brochure	At the time of admission, and as a downloadable document from the establishment's website, every hospital shall provide a brochure or leaflet in Malayalam and English containing information on : <ul style="list-style-type: none"><li>- services offered</li><li>- baseline and package rates with inclusions.</li><li>- Deposit and refund policy.</li><li>- Insurance/TPA empanelment and claim procedures.</li><li>- Estimate and billing policy</li><li>- Discharge procedures</li><li>- Ambulance and transport charges.</li><li>- 24x7 emergency care protocol; and</li><li>- Grievance redressal and escalation mechanism.</li></ul>	It is does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.
4	Grievance Redress Mechanism	The establishment shall endeavor to resolve all complaints within seven(7) working days. Unresolved or serious matters shall be escalated to the District Registering	It is does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.

		<p>Authority/DMO without delay.</p> <p>Each establishment shall maintain a Complaint Register, in physical or electronic form, available for inspection. A summary of grievances and actions taken shall form part of the monthly compliance reports submitted to the competent authority.</p>	
5	Updates and Accuracy	<p>All displayed rate lists, brochures, and website information shall be kept current. Any change in services, rates, or grievance contact details shall be promptly updated, with the date of revision clearly indicated.</p>	<p>It is does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.</p>
6	Compliance with the Kerala Clinical Establishments	<p>a) Every clinical establishment shall file an undertaking of compliance with Sections 39 and 47 of the Act and the above directions within thirty (30) days from the date of this judgment before the</p>	<p>The applicant is required to submit forms 2 &amp; 2A for provisional registration and 5 &amp; 5A for permanent registration as mandated under the KCEA 2018 (refer Annexure) under the CEA 2018 (refer Annexure). Hence in compliance with judgment dated 26.11.2025 whether all clinical establishments required to submit undertaking at compliance on section 39 and 47 again. The matter is being examined in Government.</p>

(Registration & Regulation) Act, 2018	District Registering Authority	Clarification requested whether clinical establishments having provisional registration also to comply with judgment. The matter is being examined in Government.
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7	Patient Remedies (Without Prejudice Other Rights)	<p>Patients shall remain at liberty to:</p> <ul style="list-style-type: none"> <li>a) Pursue remedies for deficiency of service before the competent Consumer Disputes Redressal Commission.</li> <li>b) Lodge complaints with the local police where appropriate, including cases involving alleged fraud or cheating.</li> <li>c) Escalate grave or systematic grievances to the Chief Secretary and the State Police Chief; and</li> <li>d) Seek assistance from the District or State Legal Services Authorities for advice and facilitation.</li> </ul> <p>All establishments shall cooperate fully and issue receipt for all payments and complaints received.</p>	<p>It is does not come within the purview of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.</p>
	Language and Accessibility	<p>All mandatory displays, notices, and brochures shall be provided in Malayalam and English, and shall be clear, legible, and prominently accessible at the Reception/Admission areas and other conspicuous locations within each establishment, as well as on the homepage of its official</p>	<p>As per SECTION 39 of KCEA 2018 (l) Every clinical establishment shall display, in a conspicuous place in the clinical establishment its certificate of registration, provisional or permanent.</p> <p>(2) Every clinical establishment shall display, in a conspicuous place in the clinical establishment in Malayalam as well as in English the fee rate and package rate charged for each type of service provided and facilities available, for the information of the patients.</p> <p>(3) All clinical establishments in the State shall display package rates for specific procedures.</p> <p>(4) No clinical establishment shall charge fees</p>

		<p>website.</p> <p>or package rates more than what is displayed.</p> <p>As per Rule 19 KCEA 2018; Each clinical establishment shall display the fee rate charged for each type of service provided and facilities available from that establishment, in a conspicuous place in the clinical establishment in Malayalam and in English, in printed or digital form, for the information of the patients and the relative of the patients. Depending on the magnitude of the information to be displayed, it shall be published in detail in such a manner as to be made available to the patients and relatives, in the official website of the establishment or in any other appropriate manner and the address and methodology to access such website shall also be displayed in writing in Malayalam and in English in the same place where it is to be so displayed, so as to enable layman to understand. If data is displayed in digital form, the clinical establishments shall provide adequate facilities, within their premises, for patients and relatives of the patients to verify the digital data. The package rates for treatment procedure shall be made available at the reception in printed or digital form and copy be provided on demand to the patient or relative of patient for reference. Copies may be made available on demand by realising the actual cost incurred.</p> <p>(2) The clinical establishments shall provide detailed bill specifying the treatment, investigation, consultation charges and other charges to the patient.</p>
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<b>DRA</b>			
Sl No	Direction	Description	DIRECTION
1	Grievance Redress Mechanism	The establishment shall endeavor to resolve all complaints within seven(7) working days. Unresolved or serious matters shall be escalated to the District Registering Authority/DMO without delay.	Clinical establishments level Grievance Redressal mechanism, DRA Level Grievance Redressal mechanism are not under the purview of Kerala Clinical Establishments (Registration and Regulation) Act, 2018. A state level Grievance Redressal committee has been constituted vide G.O. (Rt) No.2425/2025/H&FWD dated 19.08.2025 as per the act to receive complaints from the public regarding clinical establishments. A dedicated email online portal also available for submitting complaints from the public. The matter is being examined in Government.
2	Compliance with the Kerala Clinical Establishments (Registration & Regulation) Act, 2018	The District Registering Authority shall conduct verification audits within sixty (60) days from the date of this judgment and thereafter periodically, taking appropriate action for any deficiencies detected, in accordance with the Act and Rules.	The applicant is required to submit forms 2 & 2A for provisional registration and 5 & 5A for permanent registration as mandated under the KCEA 2018 (refer Annexure) under the CEA 2018 (refer Annexure). Hence in compliance with judgment dated 26.11.2025 whether all clinical establishments required to submit undertaking at compliance on section 39 and 47 again. The matter is being examined in Government.
3	Non-Compliance	Non-Compliance with these guidelines shall attract regulatory action under the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, including suspension or cancellation of registration and imposition of penalties, in addition to any civil, criminal, or constitutional remedies available to patients.	The DRA shall take necessary action as mandated under Section 26 & 27 of the KCEA Act.2018.

<b>KSCCE (State Council)</b>		
Sl No	Directions	Action to be taken
1	Maintain and publish the State Register of Clinical Establishments KSCCE must compile, update, and publish the list of all registered clinical establishments in Kerala (Act Sec. 12).	<p>Publishing the register in the official website of the council in every month</p>
2	Fix and notify minimum standards KSCCE must prescribe minimum standards for infrastructure, staffing, equipment etc	<p>Already complied.</p> <p>The notifications for Minimum Standards are notified in connection with the implementation of the Kerala Clinical Establishments (Registration And Regulation) Act, 2018 are as follows:</p> <ul style="list-style-type: none"> <li>• Minimum standards for Modern Medicine, Dental, Laboratory and Diagnostic Services have been notified vide SRO No.503/2023 dated 20.04.2023</li> </ul>
		<ul style="list-style-type: none"> <li>• Minimum standards for Ayurveda have been notified vide SRO No.213/2024 dated 29.02.2024</li> <li>• Minimum standards for Unani have been notified vide SRO No.214/2024 dated 29.02.2024</li> <li>• Minimum standards for Homeopathy have been notified vide SRO No.215/2024 dated 29.02.2024</li> <li>• Minimum standards for Siddha have been notified vide SRO No.215/2024 dated 29.02.2024 No.216/2024 has been notified.</li> <li>• Minimum Standards for Yoga and Naturopathy has been notified vide SRO No.217/2024 dated 29.02.2024.</li> </ul>
3	Conduct inspections KSCCE must ensure periodic inspections to check compliance with minimum standards (Sec. 19(12)).	<p>Circular has already been issued by the Council to all DRA's under Section 19(11) of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, vide No. 358/ADMN KSCCE/2025 dated 22.10.2025 for ensuring that all clinical institutions maintain required standards. And also submitted that, in connection with WP (PIL) No. 74/2025, the proposal for amending the Rules to enable periodic inspections, as required under Section</p>

		4(1)(e) of KCEA 2018, is being examined in Government.
4	Verify eligibility for permanent registration KSCCE must assess whether establishments meet minimum standards for granting permanent registration.	As per the Kerala Clinical Establishment (Registration and Regulation) Act, 2018, there is a provision to constitute an independent panel of assessors to conduct assessment of establishments, ensure compliance with standards and inspect establishments before granting permanent registration. Accordingly, the Council has selected a panel of assessors to visit the establishments directly and assess the standards for granting permanent registration and has issued a notification as per section 19(12) of KCEA 2018.
5	Formulate and notify lifesaving services KSCCE must categorize hospitals and specify lifesaving services required at each level (Notification 02-05-2023).	A notification has been issued by the Council under Section 47(2) of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, vide No.217/Accts/KSCCE/2023 dated 02.05.2023.
6	Ensure confidentiality & secure data handling KSCCE must maintain secure data storage of staff details and institutional records	The website and portal of the Kerala State Council for Clinical Establishments are hosted by the National Informatics Center. The details and data collected by the Council as part of registration are stored in the State Data Center and managed by the Government of Kerala. The information entered by a clinical establishment can only be accessed by the State Administrator, the District Registering Authority concerned, and the clinical establishment itself. No one else can access the data collected and entered therein. Moreover, the details and data entered by the respective clinical establishments in the official portal are secure and shall remain confidential- an affidavit to this effect was placed on record on 06.02.2024. The mode of inspection, as contemplated under Rule 26 of the Rules of 2018, must be carried out without affecting the privacy of the patients as per Rule. 26(4)(iii) and Rule 26(9) of the Rules.
7	Operate the online registration portal KSCCE must maintain the online system for applications, certificates, and data management.	A dedicated online portal is available for submitting application, issuance of certificate, Appeal submission and data management system.

8	<p>Implement District-level grievance cells</p> <p>KSCCE coordinate with the Grievance Redressal Committee</p>	<p>Clinical establishments level Grievance Redressal mechanism, DRA Level Grievance Redressal mechanism are not under the purview of Kerala Clinical Establishments (Registration and Regulation) Act, 2018. A state level Grievance Redressal committee has been constituted vide G.O.(Rt) No.2425/2025/H&amp;FWD dated 19.08.2025 as per the act to receive complaints from the public regarding clinical establishments. A dedicated email online portal also available for submitting complaints from the public.</p>
9	<p>Ensure compliance regarding display of rates</p> <p>KSCCE must ensure display of fees the Kerala Clinical Establishments and packages / rates as per Act Sec.(Registration and Regulation) Act, 2018, vide 39(2) &amp; (3) in clinical establishments.</p>	<p>Circular has already been issued by the Council to all DRA's under Section 39, and Rule 19 of 39(2) &amp; (3) in clinical establishments.</p> <p>No.288/ADMN/KSCCE/2025 dated 15.10.2025 for ensuring the display of fees and package rate during every stage of assessments.</p>