



ಕರ್ನಾಟಕ ರಾಜ್ಯಪತ್ರ

ಅಧಿಕೃತವಾಗಿ ಪ್ರಕಟಿಸಲಾದುದು

ಬಿಶೇಷ ರಾಜ್ಯ ಪತ್ರ

ಭಾಗ-IVA	ಬೆಂಗಳೂರು, ಶುಕ್ರವಾರ, ಫೆಬ್ರವರಿ ೯, ೨೦೧೮ (ಮಾಘ ೨೦, ಶಕ ವರ್ಷ ೧೯೩೯)	ನಂ.೨೫೯
Part-IVA	Bengaluru, Friday, February 9, 2018 (Magha 20, Shaka Varsha 1939)	No.259

HEALTH AND FAMILY WELFARE SECRETARIAT

NO. HFW 11 FPR 2018 BENGALURU, DATED: 09.02.2018

NOTIFICATION

The draft of the following rules further to amend the Karnataka Private Medical Establishments Rules, 2009 which the Government of Karnataka proposes to make in exercise of the powers conferred by said section of the Karnataka Private Medical Establishments Act, 2007 (Karnataka Act 21 of 2007) is hereby published as required by sub-section (1), of said section, of the said Act, for the information of all persons likely to be affected thereby and notice is hereby given that the said draft will be taken into consideration after fifteen days from the date of its publication in the Official Gazette.

Any objection or suggestion which may be received by the State Government from any person with respect to said draft before the expiry of the period specified above will be considered by the State Government. The objections and suggestions may be addressed to the Additional Chief Secretary to Government, Department of Health and Family Welfare, Vikasa Soudha, Bengaluru-560 001.

DRAFT RULES

1. Title and Commencement. - (1) These rules may be called the Karnataka Private Medical Establishments (Amendment) Rules, 2018.

(2) They shall come into force on such date as the State Government may by notification in the Official Gazette, may appoint.

Provided that different dates may be appointed for different provisions of these rules and any reference in any such provision to the commencement of these rules shall be construed as a reference to the coming into force of that provision.

2. Amendment of Chapter-2.- In Chapter-2 of the Karnataka Private Medical Establishments Rules, 2009, (hereinafter referred as the said rules), for the heading "CATEGORIES OF PRIVATE MEDICAL ESTABLISHMENTS" the following shall be substituted, namely:-

"CATEGORIES OF PRIVATE MEDICAL ESTABLISHMENTS AND REGISTRATION"

3. Amendment to rule 3. - In rule 3 of the said rules,-

(i) for sub-rule (2), the following shall be substituted, namely:-

"(2) Private medical establishments shall be further classified into the following categories, namely:-

- (i) Clinic/Polyclinic Only Consultation
- (ii) Clinic/Polyclinic with Diagnostic Support

- (iii) Clinic/Polyclinic with Dispensary
- (iv) Clinic/Polyclinic with Observation
- (v) Health Check-up Centre
- (vi) Integrated Counselling Centre
- (vii) Hospital (Level 1A)
- (viii) Hospital (Level 1B)
- (ix) Hospital (Level 2)
- (x) Hospital (Level 3)(Non-Teaching with Super Specialty Services)
- (xi) Specialty / Super-Specialty Specific Hospital
- (xii) Hospital (Level 4)(Teaching)
- (xiii) Dental Lab or Clinic
- (xiv) Allied Health Professional Centre
- (xv) Ayush Therapy Centre
- (xvi) Medical Diagnostic Laboratory
- (xvii) Diagnostic Imaging Centre

Provided that the definition and scope of above categories of establishment shall be the same as prescribed by the National Council constituted as under the Clinical establishment (Registration and Regulation) Act 2010 (Central Act 23 of 2010).”

(ii) sub-rule (3) and (4) shall be omitted.

4. Substitution of rule 4.- For rule 4 of the said rules, the following shall be substituted, namely:-

"CHAPTER – III

REGISTRATION OF PRIVATE MEDICAL ESTABLISHMENTS

4. Fee for processing of registration or renewal application. - (1) The non-refundable fee payable by different categories of private medical establishments for processing of registration application shall be as specified below,-

Sl. No.	Category of Private Medical Establishments	Registration Processing Fee (in Rupees)
1	Clinic/Polyclinic Only Consultation	2500
2	Clinic/Polyclinic with Diagnostic Support	5000
3	Clinic/Polyclinic with Dispensary	5000
4	Clinic/Polyclinic with Observation	5000
5	Health Check-up Centre	5000
6	Integrated Counseling Centre	5000
7	Hospital (Level 1A)	20000
8	Hospital (Level 1B)	30000
9	Hospital (Level 2)	40000
10	Hospital (Level 3) (Non-Teaching with Super Specialty Services)	100000
11	Specialty/Super-Specialty Specific Hospital	100000
12	Hospital (Level 4) (Teaching)	200000
13	Dental Lab/Clinic	5000

14	Allied Health Professional Centre	5000
15	Ayush Therapy Centre	5000
16	Medical Diagnostic Laboratory	5000
17	Diagnostic Imaging Centre	5000
18	Blood Banks	5000

Provided that the registration processing fee for the hospitals at serial numbers 7 to 9 shall be two times of the fee mentioned in the table above, in case the hospital has more than 50 beds.

Provided further that the registration processing fee for the hospitals at serial numbers 10 and 11 shall be two times of the fee mentioned in the table above, in case the hospital has more than 150 beds.

Provided also that the registration processing fee for a charitable establishment providing free treatment to all patients shall be twenty-five percent of the fee specified above.

(2) The non-refundable fee for processing of renewal application shall be fifty percent of the fee specified under sub-rule (1).

(3) The fee for processing of registration or renewal application specified under sub-rule (1) shall stand enhanced by twenty-five percent, rounded off to nearest hundred rupees, every five years from the date of commencement of the Karnataka Private Medical Establishments (Amendment) Rules, 2018.

(4) The registration or renewal processing fee shall be paid online on the website <https://k2.karnataka.gov.in> of Khajane 2, Integrated Financial Management System of Government of Karnataka.

5. Amendment to rule 6. – In rule 6 of the said rules, in sub-rule (1),-

(a) for the words and letter “shall apply for registration in Form-A”, the words and letters “shall apply online on the IT portal of Health and Family Welfare Department for registration in Form A” shall be substituted.

(b) after sub-rule (1), so amended the following provisos shall be inserted, namely:-

“Provided that the existing establishments already holding the registration also shall provide the details in Form A within three months from the date of commencement of the Karnataka Private Medical Establishments (Amendment) Rules, 2018.

Provided further that Aadhaar, Mobile Number and Email details provided in Form A shall not be put in the public domain and shall be shared only with other departments of the State Government and Government of India.”

6. Amendment to rule 7. - In rule 7 of the said rules, in sub-rule (1) for the words and letter “shall apply for registration in Form B”, the words and letters “shall apply online on the IT portal of Department of Health and Family Welfare for registration in Form A” shall be substituted.

7. Insertion of new rules 7A, 7B and 7C.- After rule 7 of the said rules, the following shall be inserted, namely:-

“7A. Renewal of Registration. – (1) A registered private medical establishment shall apply for renewal of its registration minimum three months prior to due expiry of its five-year registration validity period.

(2) The application for the renewal shall be made online on the IT portal of Health and Family Welfare Department in Form B along with fee specified in rule 4.

7B. Composition of Registration and Grievance Redressal Authority.- (1) The non-official members of the Authority of a district shall have the qualification specified below.

- (a) The members representing Indian Medical Association and one more association shall be medical professional with postgraduate degree with experience of minimum ten years in medical profession.
- (b) The woman member shall have a graduate degree with experience of minimum twenty years in field of social work or academic profession or medical profession.

(2) The non-official members of the Authority of a district shall be nominated by the Chairman in the manner specified below.

- (a) The member representing Indian Medical Association shall be the nominee of the Chapter of the Association having the largest membership in the district.
- (b) The member representing another Association shall be the nominee of a registered Association representing private medical establishments having the largest membership in the district.
- (c) The woman member of the authority relevant for purpose of grievance redressal only shall be selected on recommendations of three-member committee consisting of Deputy Commissioner of the district, Chief Executive Officer of the Zilla Panchayat and Deputy Director of Women and Child Development Department.

(3) The term of each non-official member shall be two years and the incumbent shall not be nominated again.

7C. Composition of Inspection Committee. –The inspection committee shall consist of two medical professionals with minimum experience of ten years with one of them being in the Government service and another being one of the two members representing the associations in the Authority.”

8. Insertion of new Chapter-IV. – After rule 9 of the said rules, the following shall be inserted, namely:-

"CHAPTER-IV

STANDARDS OF INFRASTRUCTURE, STAFFING PATTERN AND QUALIFICATION OF STAFF

9A. Minimum Standards in Interim Period. – Till such time the minimum standards are prescribed by the State Government in accordance with the minimum standards as prescribed under the Clinical establishment (Registration and Regulation) Act 2010 (Central Act 23 of 2010) shall apply *mutatis mutandis* to the private medical establishments registered under the Act:

Provided that the existing establishments shall have a grace period of one year to comply with the minimum standards as per this rule.

Provided further that the minimum standards in respect of infrastructure as per this rule shall be optional for the existing establishments. The minimum standards in respect of other aspects shall be mandatory with the grace period mentioned in the first proviso."

9. Insertion of new Chapters.- After the rule 11 of the said rules, the following shall be inserted, namely:-

"CHAPTER - V

EXPERT COMMITTEES

12. Expert Committee for classification, standards of infrastructure, staffing pattern and staff qualification.- (1) The State Government shall constitute the Expert Committee for the purpose of section 9 and 9A of the Act, standards of infrastructure, staffing pattern and staff qualification shall have the consisting of the following members, namely:-

- | | |
|---|----------------------------------|
| (i) The Commissioner, Health and Family Welfare | - Ex-officio chairman |
| (ii) The Director, Health and Family Welfare: | - Ex-officio member
Secretary |
| (iii) The Director, Ayush Department | - Ex-officio member |
| (iv) The Director, Medical Education | - Ex-officio member |
| (v) One Representative of a tertiary care public health institution | - Ex-officio member |
| (vi) One Representative of the State Government from Public Health Foundation of India | - Non-official Member |
| (vii) One Representative of the State Government from National Accreditation Board for Hospitals and Healthcare Service Providers | - Non-official Member |

- (viii) One Representative of the Private Medical Establishment from Indian Medical Association - Non-official Member
- (ix) One Representative of the Private Medical Establishment from a tertiary care private medical establishments - Non-official Member
- (x) One Representative of the Private Medical Establishments from Private Hospital and Nursing Homes Association - Non-official Member

(2) As far as possible, the committee shall use as reference the classification and minimum standards as prescribed by the Government of India as under the Clinical establishment (Registration and Regulation) Act 2010 (Central Act 23 of 2010).

13. Expert Committee for standard protocols for treatments, procedures and prescription audit.- (1) The Expert Committee constituted by the State Government for recommending standard protocols for treatments, procedures and prescription audit shall have the following composition, namely:-

- (i) The Director of a Government super-specialty hospital or medical college - Ex-officio Chairman
- (ii) One Medical specialist in allopathic system of medicine in Government service. - Ex-officio Member-Secretary
- (iii) One Medical specialist in Indian system of medicine in Government service - Ex-officio member
- (iv) One Representative of a tertiary care public health institution - Ex-officio member
- (v) One Representative of the Rajiv Gandhi University of Health Sciences - Ex-officio member
- (vi) One Representative of National Health Systems Resource Center - Non-official member
- (vii) One Representative of the State Government from Indian Medical Association - Non-official member
- (viii) One Representative of the State Government from National Accreditation Board for Hospitals and Healthcare Service Providers - Non-official member
- (ix) One Representative of the State Government from a tertiary care private medical establishment - Non-official member
- (x) One Representative of the State Government from a secondary care private medical establishment - Non-official member

Provided that the committee may co-opt one relevant medical specialist each from public health institution and private medical establishment while formulating recommendations for any specialized types of treatment.

(2) As far as possible, the committee shall use as reference the standard treatment guidelines prescribed by the Government of India as under the Clinical establishment (Registration and Regulation) Act 2010 (Central Act 23 of 2010).

14. Expert Committee for uniform package rates for healthcare assurance schemes in participating establishments.- (1) The Expert Committee constituted by the State Government for recommending uniform package rates for healthcare assurance schemes of the State Government for participating private medical establishments shall consist of following members, namely:-

- (i) The Additional Chief Secretary, Principal Secretary / Secretary to Government, Department of Medical Education - Ex-officio Chairman
- (ii) The Executive Director, SAST - Ex-officiomember Secretary

- | | | | |
|--------|---|---|---------------------|
| (iii) | The Commissioner, Department of Health and family Welfare Services | - | Ex-officio member |
| (iv) | The Director, Medical Education | - | Ex-officio member |
| (v) | Additional Chief Secretary / Principal Secretary / Secretary to Government, Finance Department or his representative not below the rank of Deputy Secretary | - | Ex-officio member |
| (vi) | One Representative of a tertiary care public health institution | - | Ex-official member |
| (vii) | One Representative of the State Government from Public Health Foundation of India | - | Non-official member |
| (viii) | One Representative of the State Government from IIMB | - | Non-official member |
| (ix) | One Representative of the Private Medical Establishment from Indian Medical Association | - | Non-official member |
| (x) | One Representative of the Private Medical Establishment from a tertiary care private medical establishment | - | Non-official member |
| (xi) | One Representative of the Private Medical Establishment from a secondary care private medical establishments. | - | Non-official member |

Provided that the committee may co-opt one relevant medical specialist each from public health institution and private medical establishment and one cost accountant while formulating recommendations for package rates for specific types of treatment.

(2) As far as possible, the committee shall use as reference the standard costing template formulated by the National Council constituted as under the Clinical establishment (Registration and Regulation) Act 2010 (Central Act 23 of 2010).

Provided that the recommended rates shall have reference to median rates notified by the private medical establishments as per section 10 of the Act.

Provided further that the recommended rate for a treatment as per the standard treatment guidelines shall cover the estimated cost of drugs, consumables, implants, tests, professional fee, OT charges, bed charges in general ward, and rental expenses of the hospital, but not the cost of land and building and debt-servicing.

15. Allowance for Members. – All non-official members shall be entitled for a sitting fee of rupees ten thousand for each meeting of the committee in addition to travelling allowance and daily allowance as applicable to Group-A officers of the State Government.”

"CHAPTER-VI

INFORMATION DISCLOSURE

16. Notification of Establishment Details. – (1) Every private medical establishment shall display its details in Form C on the IT portal of the Health and Family Welfare Department and on its own website in case the establishment has one:

Provided that the operational guidelines for the display and secured access to the IT portal shall be provided by the department.

(2) Notwithstanding anything contained in second proviso to sub-rule (1) of rule 6, Mobile Number and E-mail details of the establishment administrator or manager shall be available in the public domain.

(3) Every private medical establishment shall update the details displayed as per sub-rule (1) on monthly basis before fifth day of each month.

(4) Every private medical establishment shall display prominently at its reception area the system of medicine which the establishment is authorized to practice.”

17. Notification of Schedule of Charges. - (1) Every private medical establishment shall display its schedule of charges in Form D to these rules on the IT portal of Health and Family Welfare Department and on its own website in case the establishment has one:

Provided that the operational guidelines for the display and secured access to the IT portal shall be provided by the Department.

(2) Every private medical establishment shall update the schedule of charges displayed as per sub-rule (1) at least one week before the date on which the revision is planned to be effective.”

"CHAPTER-VII

PATIENT CHARTER AND PRIVATE ESTABLISHMENT CHARTER

18. Manner of making complaint. – (1) A complaint in respect of violation of any of the provisions of the Patient Charter, Private Medical Establishment Charter, or these rules shall be made online on the IT portal of the Department:

Provided that the application can be made by the patient or his near relative only.

(2) The complaint may also be made in physical form the office of the Chairman or Member-Secretary of the Registration and Grievance Redressal Authority. It shall be obligatory for the office to record the complaint in the IT portal in presence of the complainant, and provide a portal generated acknowledgment at the same time.

10. Substitution of Form A, B and C.- For Form A, Form B and Form-C of the said rules, the following shall be substituted, namely:-

"Form-A

(See sub-rule (1) of rule 6 and sub-rule (1) of rule 7)

Application for Registration of existing or new medical Establishment¹

- (1) Name of Establishment
- (2) Address of Establishment
- (3) GIS Coordinates
- (4) Category of Establishment (See rule 3)²
 - (a) System of medicine
 - (b) Number of beds
 - (c) Details of specialties or super-specialties
- (5) Current Status: Already functioning/To be started
- (6) Date of starting the Establishment/Proposed date of starting
- (7) Nature of Ownership (Proprietary/Partnership/Company/Society/Trust/LLP)³
- (8) Details of proprietor / partners/directors/executive committee members/trustees,-
 - (a) Name
 - (b) Sex and Age
 - (c) Aadhaar Number
 - (d) Contact details: Mobile / email
- (9) Details of Administrator or Manager,-
 - (a) Name
 - (b) Sex and Age
 - (c) Aadhaar Number
 - (d) Photograph
 - (e) Contact details: Mobile / email

- (10) Contact details of the Establishment,-
- (a) Email
 - (b) Phone
- (11) Details of Infrastructure,-
- (a) Land Area
 - (b) Building Area (total built-up area)
 - (c) Floor plans⁴
 - (d) Front view photograph⁵
 - (e) Occupancy certificate^{6,7}
 - (f) Fire safety certificate^{8,9}
- (12) Details of Staff,-
- (i) Details of medical staff,-
 - (a) Name
 - (b) Qualification
 - (c) Sex and Age (optional)
 - (d) Aadhaar Number
 - (e) Photograph
 - (f) Contact details: Mobile / email
 - ii. Details of para-medical staff (service head only, e.g., nursing, pharmacy, diagnostic, etc),-
 - (a) Name
 - (b) Qualification
 - (c) Sex and Age (optional)
 - (d) Aadhaar Number
 - (e) Photograph
 - (f) Contact details: Mobile / email
- (13) Internal Grievance Redressal Mechanism – Brief description and contact details of grievance redressal person
- (14) Details of fee paid – Challan Number, Date and Amount

Form-B

(See sub-rule (2) of rule 7A)

Application for Renewal of Registration of Existing Medical Establishment²³

- (1) Registration Number¹²
- (2) Name of Establishment
- (3) Address of Establishment
- (4) GIS Coordinates
- (5) Category of Establishment (See rule 3)¹³
 - (a) System of medicine
 - (b) Number of beds
 - (c) Details of specialties or super-specialties
- (6) Date of expiry of current registration

- (7) Nature of Ownership (Proprietary / Partnership / Company / Society / Trust / LLP)¹⁴
- (8) Details of proprietor / partners / directors / executive committee members / trustees,-
- (a) Name
 - (b) Sex and Age
 - (c) Aadhaar Number
 - (d) Contact details: Mobile / email
- (9) Details of Administrator or Manager,-
- (a) Name
 - (b) Sex and Age
 - (c) Aadhaar Number
 - (d) Photograph
 - (e) Contact details: Mobile / email
- (10) Contact details of the Establishment,-
- (a) Email
 - (b) Phone
- (11) Details of Infrastructure,-
- (a) Land Area
 - (b) Building Area (total built-up area)
 - (c) Floor plans¹⁵
 - (d) Front view photograph¹⁶
 - (g) Occupancy certificate^{17,18}
 - (h) Fire safety certificate^{19,20}
- (12) Details of Staff,-
- (i) Details of medical staff,-
 - (a) Name
 - (b) Qualification
 - (c) Sex and Age (optional)
 - (d) Aadhaar Number
 - (e) Photograph
 - (f) Contact details: Mobile /email
 - iii. Details of para-medical staff (service head only, e.g., nursing, pharmacy, diagnostic, etc),-
 - (a) Name
 - (b) Qualification
 - (c) Sex and Age (optional)
 - (d) Aadhaar Number
 - (e) Photograph
 - (f) Contact details: Mobile / email
- (13) Internal Grievance Redressal Mechanism – Brief description and contact details of grievance redressal person
- (14) Details of fee paid – Challan Number, Date and Amount

Form C**(See sub-rule (1) of rule 16)****Establishment Details for Display to the Public**

- (1) Name of Establishment
- (2) Address of Establishment
- (3) GIS Coordinates
- (4) Category of Establishment (See rule 3)²¹, -
 - (a) System of medicine
 - (b) Number of beds
 - (c) Details of specialties or super-specialties
- (5) Details of Administrator or Manager, -
 - (a) Name
 - (b) Sex and Age
 - (c) Photograph
 - (d) Contact details: Mobile / email
- (6) Contact details of the Establishment, -
 - (a) Email
 - (b) Phone
- (7) Infrastructure, -
 - (a) Land Area
 - (b) Building Area (total built-up area)
 - (c) Floor plans²²
 - (d) Front view photograph ²³
 - (e) Occupancy certificate ^{24,25}
 - (f) Fire safety certificate ^{26,27}
- (8) Details of Staff, -
 - (i) Details of medical staff, -
 - (a) Name
 - (b) Qualification
 - (c) Sex and Age (Optional)
 - (d) Photograph
 - (e) Contact details: Mobile / email
 - (ii) Details of para-medical staff (service head only, eg, nursing, pharmacy, diagnostic, etc), -
 - (a) Name
 - (b) Qualification
 - (c) Sex and Age (Optional)
 - (d) Photograph
 - (e) Contact details: Mobile / email

9. Internal Grievance Redressal Mechanism – Brief description and contact details of grievance redressal person

10. Number of Patients and major treatments during the Year and Month (.....),-
- Outpatients
 - Inpatients
 - Major Surgeries
 - Minor Surgeries

11. Date of last update

11. Insertion of Form D.- After Form-C so substituted, the following new Form shall be inserted at the end, namely:-

"Form D

(See sub-rule (1) of rule 17)

Schedule of Charges⁴ for Display to the Public

- Name of the Establishment
- Registration Number
- Date of effect of the Schedule of Charges

Schedule of Charges ²⁹

Sl.No.	Item ³⁰	Code	Charge (in Rupees.)
1	Consultation Fee ³¹		
2	Surgery Fee ³²		
3	Treatments ³³		
4	Diagnostic tests ³⁴		
5	Hospital Charges		

Foot Notes

- Detailed application form and guidelines shall be available on the IT portal of the department.
- Provide details of specialties or super-specialties and diagnostic facilities
- Upload supporting document
- Upload plan for each floor in A4 size
- Upload photograph of front view of the building taken as per operational guidelines
- Upload the occupancy certificate
- Occupancy certificate is optional for existing establishments
- Upload the fire safety certificate
- Nature of fire safety requirement in respect of existing establishments to be notified separately
- Detailed application form and guidelines shall be available on the IT portal of the department
- In case the establishment has already updated the information on the portal as under proviso to sub-rule (1) of rule 6, the information for items at serial numbers 2 to 14 shall be auto-populated based on the registration number entered at serial number 1. The establishment may further update the information, if required, in the auto-populated Form-B.
- Upload certificate copy

13. Provide details of specialties or super-specialties and diagnostic facilities
14. Upload supporting document
15. Upload plan for each floor in A4 size
16. Upload photograph of front view of the building taken as per operational guidelines
17. Upload the occupancy certificate
18. Occupancy certificate is optional for existing establishments
19. Upload the fire safety certificate
20. Nature of fire safety requirement in respect of existing establishments to be notified separately
21. Provide details of specialties or super-specialties and diagnostic facilities
22. Upload plan for each floor in A4 size
23. Upload photograph of front view of the building taken as per operational guidelines
24. Upload the occupancy certificate
25. Occupancy certificate is optional for existing establishments
26. Upload the fire safety certificate
27. Nature of fire safety requirement in respect of existing establishments to be notified separately
28. Charges for all medical services to be provided
29. Add rows for each item as required
30. Treatment description and code shall be as per standards formulated by the National Council constituted under the Clinical Establishment (Registration and Regulation) Act 2010 (Central Act 23 of 2010)
31. For each medical staff, if uniform fee is not followed
32. For each surgeon, if uniform fee is not followed
33. Major treatments shall be listed ahead of others
34. Major tests shall be listed ahead of others

BY ORDER AND IN THE NAME OF
THE GOVERNOR OF KARNATAKA

K. NARAYANA

ADDITIONAL SECRETARY TO GOVERNMENT
HEALTH AND FAMILY WELFARE DEPARTMENT