

**DRUGS CONTROL DEPARTMENT
KERALA STATE**

Narcotic Drugs & Psychotropic Substance (Third Amendment) Rules, 2015 has come into force vide Gazette notification GSR 359(E) dated 5th May 2015.

As a part of implementation of the said Rules, it is decided to set out instructions which are to be followed by Recognized Medical Institutions (RMIs) based on the amendment. Certificate of Recognition will be issued in newly introduced form from 01/01/2017 onwards.

All RMIs are requested to follow the instructions in true letter and spirit.

Instructions to be followed by the Recognised Medical Institutions (RMIs)

1. RMIs shall submit the **original application** for grant/renewal of Certificate of Recognition as Recognised Medical Institution in **Form 3F** dully filled along with requisite documents to the **Drugs Controller, Kerala State**. Copy of the same shall be forwarded to the **Advisory Panel Member**.
2. The application shall be accompanied by
 - a. Covering letter addressed to the Drugs Controller signed by the Medical Officer in charge of the RMI.
 - b. Application for issue /renewal of Certificate of Recognition as Recognised Medical Institution in **Form 3F**.
 - c. Annual return of procurement /disbursement of Essential Narcotic Drugs in **Form 3-I** (in case of Renewal of RMI)
 - d. Estimate of annual requirement of Essential Narcotic Drugs in **Form 3J**.
 - e. Self attested copies of Registration and Qualification Certificates of the Medical Officer in charge of RMI (in case of Fresh RMI application / change in Medical Officer).
 - f. Copy of the certificate in proof of training as notified in NDPS Rules (in case of Fresh RMI application / change in Medical Officer)..
 - g. Original of RMI certificate in **Form 3G** (in case of renewal of RMI).
 - h. Details of suppliers from whom the Essential Narcotic Drugs are procured.
 - i. Self addressed and stamped envelope worth Rs. 30/-
3. Certificate of Recognition (RMI) shall be **valid for 3years**.
4. Application for the **renewal** of RMI shall be made to the Drugs Controller at least **60days** before the expiry (**before 31st October**) of previous recognition.
5. Every Recognised Medical Institution shall be liable to periodic inspections by the **Officer** (Drugs Inspector/Senior Drugs Inspector/ Regional Drugs Inspector/ Member of Advisory Panel) authorized by the Drugs Controller.
6. In the event of change in constitution of Recognised Medical Institution, the current Recognition shall be deemed to be **cancelled** if the same is not intimated to the Drugs Controller within **90days** of such change.
7. Change in Medical Officer/ change in name of the RMI shall be intimated to the Drugs Controller immediately.
8. Copy of every consignment note of Essential Narcotic Drugs in **Form 3C** dully filled and signed by both the consigner and consignee, shall be forwarded to the Drugs Controller. Original of the same shall be retained by the RMIs for a period of **2years** from the date of transaction and such records shall be produced before the authorized officer on demand during inspection.
9. Every RMI shall also maintain a separate record as per **Form 3E** for each patient and such records shall be retained for period of **2years** from the date of last entry. This record shall be produced before the authorized officer on demand during inspection.
10. Every RMI shall maintain daily accounts of all receipts and dispensed quantities for **each** Essential Narcotic Drug as per **Form 3H**, which shall be retained for a period of **2years** from the date of last entry. This record shall be produced before the authorized officer on demand during inspection.
11. Every RMI shall submit an estimate of its annual requirement of essential narcotic drugs in **Form 3-J** by **30th November** of the proceeding calendar year to the Drugs Controller.
12. If the disbursement of the Essential Narcotic Drugs exceeds the estimate of annual requirement in **Form 3J**, a revised estimate shall be submitted in **Form 3J** in due course.

13. *Details of suppliers of Essential Narcotic Drugs other than regular suppliers shall be intimated in due course.*
14. *RMIs shall file **annual return** of procurement/disbursement of essential narcotic drugs for a calendar year on or before **31st of March** of the subsequent year in **Form 3 I** to the Drugs Controller.*
15. *The Medical Officer in charge of the Recognised Medical Institution shall record a brief justification where the annual disbursement is more than **10%** of the estimate or revised estimate along with **Form 3 I**.*
16. *All the Forms detailed above are available in the Departmental web site dc.kerala.gov.in.
(<http://dc.kerala.gov.in/index.php/statutory-forms.html>)*

**Drugs Controller
Kerala State**