# Guidelines for Stocking and Dispensing Essential Narcotic Drugs in Medical Institutions

NCG Palliative Care Committee

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Disclaimer

*The information provided below is under review by the central government, at the time of writing this chapter. The reader is requested to check for the updates on the revised rules at the Department of Revenue website. We would also do our best to update this document as needed.*

Table of Contents

## Contributors to Poor Access and Availability of Opioids for medical use in India[1]

1. Historical origins of regulations are from the archaic legislature for British India for narcotics as a trade crop. It emphasized heavy restrictions to safeguard their commercial interests. The NDPS Act 1985, reflected the same prohibitory tone and language.
2. The state NDPS rules were non-uniform, preventing movement of legitimate opioids for medical use across the country.
3. The mandates given to government offices were prohibitory. All efforts were geared to eliminate any form of action involving narcotics and hence there was deep-rooted resistance to incorporate medical and scientific use.
4. There was no governance to ensure consistent supply from the government factory to manufacturers producing oral Morphine.
5. Medical Institutions faced stringent regulations - maintaining multiple licenses for acquiring, stocking, prescribing and using opioids.
6. Harsh punishment prescribed in the NDPS Act 1985 (e.g. possible10 years of rigorous imprisonment even for clerical errors) alienated institutions and pharmacists from stocking these medicines.
7. Attitude and knowledge of professionals towards using opioids were negative:
    a. Exposure of professionals was restricted to injectable opioids as used in acute or emergency situations. This led to exaggerated fears about addiction and respiratory depression for all formats.
    b. Lack of availability of opioid formats like oral Morphine at medical colleges and hospitals, prevented exposure and training of professionals in using them for managing chronic pain.
    c. This developed into unfounded fears opiophobia.
8. The public associated opioids with addiction or as the last resort and are reluctant to use the drug even if it meant great degree of suffering. This fear was often reinforced by professionals.

The NDPS[2] Act 1985, was amended in 2014, to achieve these goals.
http://mpsja.mphc.gov.in/Joti/pdf/LU/NDPS%20SINGH%20SIR.docx%20corrected.pdf

[1] MR Rajagopal et al, India: Opioid Availability - An Update, J Pain and Symptom Management, Nov 2006

[2] Narcotic Drugs and Psychotropic Substances

**Basis for the NDPS Amendment 2014**

- Opioids are safe, economical and effective for management of severe pain in selected groups of patients.
- There is need to facilitate and improve access to opioids for medical use while maintaining, strengthening and integrating programs to control misuse and diversion
- Uniform and simple procedures are required for procurement of opioids for medical use across the country

The NDPS Rules pertaining to the Act are now applicable uniformly across India.

A Glimpse: The Amended NDPS Act 2014

1. Expanded the scope of the Act to include Medical and Scientific Use
2. Prepared a notified list of Essential Narcotic Drug [ENDs], i.e. the opioids identified for medical use, approved by the Drug Controller General of India.
3. The notified list of ENDs currently includes - Morphine, Methadone, Codeine, Hydrocodone, Oxycodone, and Fentanyl
4. Transferred the power to regulate Essential Narcotic Drug [ENDs] to the Central Government.
5. Regulations are applicable uniformity across India.
6. It defined 'Recognized Medical Institutions' (RMIs) with criteria for stocking and dispensing opioids for medical use.
7. Conferred the powers for authorizing medical institutions as RMIs, for stocking and dispensing ENDs, to a single state agency - the State Drug Controller-SDC / Commissioner, Food & Drug Administration - FDA
8. Those Institutions fulfilling the criteria to be RMIs, may apply to the State Drug Controller-SDC / Commissioner, Food & Drug Administration - FDA, to procure and dispense ENDs.
9. The authorisation of RMIs is for periods of 3 years, and renewable from the same agency. This removes the need for renewing multiple licenses from different government agencies every few months.

Implicitly this requires strengthening the awareness, education and monitoring systems of licit narcotic usage - to prevent misuse and diversions.

*This document provides simple and immediately usable guidelines and procedures for application, procurement, storage and dispensing of medical opioids in medical institutions as RMIs.*

Important Terminology in the NDPS Regulations.

Medical Institution

A hospital, dispensary, a clinic or an institution that offers services or facilities requiring diagnosis, treatment or care of illness, disease, injury, deformity or abnormality, established, administered or maintained by the government or Municipal Corporation, Municipal Council or Zilla Parishad or any person or body of persons.

Recognized Medical Institution (RMI)

A medical institution, officially recognised by the State Drug Controller for purchasing, possessing and dispensing essential narcotic drugs for medical and scientific purposes.

Essential Narcotic Drugs [END]

This refers to the list of 'notified' medicines which have been identified by the office of Drug Controller General of India, for medical use in an RMI.

The Officer in charge of the RMI

Any person registered as medical practitioner under the Indian Medical Council Act 1956, or registered as dentist under the Dentist Act 1948, or under any law that is time-being in force; and who has undergone training in the medical use[3] of ENDs

Prerequisites for RMI

The concept of RMI [defined above] came into existence within the Rules, to ensure safe medical usage of the ENDs. It links training and competency in safely using ENDs, with the authorization for stocking/dispensing them.

Any Institution as defined above, can purchase, store and dispense oral morphine once it conforms to the NDPS Rules 2015. They are as follows:

1. The institution must have an Officer in-charge of Essential Narcotic Drugs within the RMI responsible for managing Essential Narcotic Drugs at the RMI
2. The Office in-charge must be a qualified doctor and registered with the Medical Council of India or the Dental Council of India and be trained in the medical use of opioids.
3. The institution must have the facility for safe storage for ENDs; a double locking system e.g. a cupboard with two locks.
4. The facility should have basic infrastructure facilities and staff for evaluating and managing the treatment of the patients who would need ENDs.
5. The facility should provide proof of space and personnel for the mandated record keeping

[3] The training details are yet being finalised, but for RMI status in providing Palliative Care services, it may be said to include – best practices in using opioids in managing pain and for other symptoms, evaluation and practices for safe usage, prevention of misuse and diversion.

6. The facility should have capacity to maintain a register of consumption for each opioid as given in Forms provided with the Rules.

Responsibilities of RMIs

1. RMI shall ensure and maintain the Minimum Mandatory Requirements as listed above.
2. Government hospitals are deemed RMIs provided they follow all mandated requirements mentioned above and must submit the annual consumption report.
3. The drugs shall be prescribed only by Registered Medical Practitioners
4. Every RMI shall designate one or more RMP who shall be using essential narcotic drugs. When there are more than one registered medical practitioners, one of them shall be designated as Overall officer-In-Charge.
5. The RMI shall ensure that the RMP, designated as the Medical Officer in Charge has completed the certified training in medical use of ENDs as per the Rules. This officer shall be responsible for the safe use of ENDs at the institution.
6. The drugs shall be purchased only from authorized chemists/ dealers. The list for the same should be available with the authorising State agency. The list of licensed manufacturers would be available with the Narcotic Commissioner at the centre.
7. ENDs shall be prescribed as per the rules and dispensed only to selected patients, registered with the RMI.
8. END stock with the RMI shall not be transferred, loaned or sold to other institutions except with the written permission of the Drugs Controller of the state.
9. All records and registers shall be maintained as indicated in the Rules, for a period of two years from the last entry. They should be made available for inspection for the Commissioner of Food & Drugs Control Administration or any other officer authorised by him in this regard
10. The expired stock of ENDs shall be destroyed in the presence of an official designated by the State Drug Controller / Commissioner of Food & Drugs Control Administration.
11. The unused ENDs returned by the patients, shall be considered as receipts, provided the drugs are not damaged or otherwise unacceptable for use.
12. RMI shall submit the annual return [Form 3 I] before 31st of March every year even if they have not used any ENDs in the preceding year.
13. If there is a change in the 'Officer in charge', the details with date of change shall be intimated to the State Drug Controller / Commissioner of Food & Drugs Control Administration, within seven days for re-issue of the RMI certificate with endorsement of the newly employed doctor in charge of the RMI.

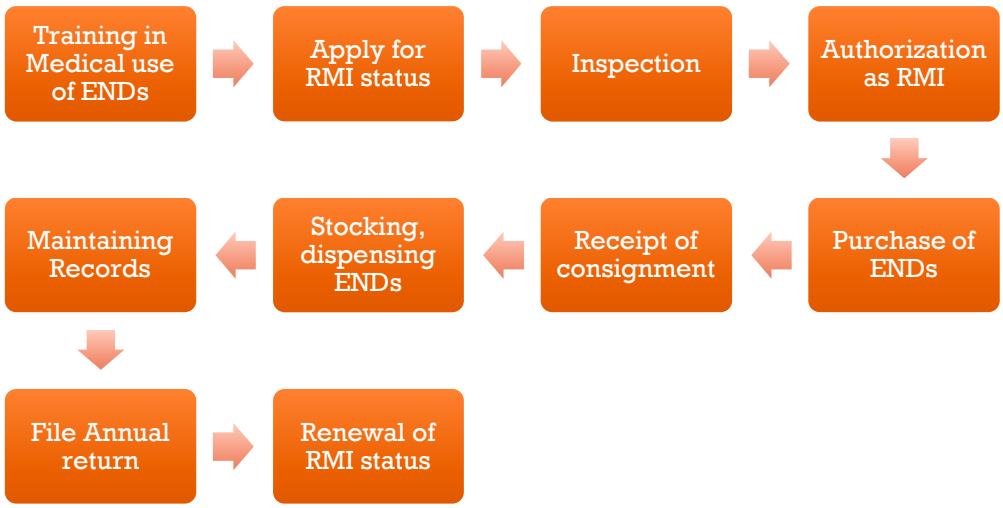
14. The RMI shall inform the State Drug Controller / Commissioner of Food & Drugs Control Administration, in writing, in the event of any change in the constitution of the RMI operating under this approval.
15. Where any change in the constitution of the RMI takes place, the current approval shall be deemed to be valid for a maximum period of 90 days from the date on which the change takes place, unless, in the meantime a fresh approval has been taken from the State Drug Controller / Commissioner of Food & Drugs Control Administration, in the name of the Institution with the changed constitution.
16. The designated medical officer in charge, shall inform the Commissioner of Food & Drugs Control Administration in writing within thirty days from the date of such change, for issue of fresh Certificate of Recognition.
17. If an RMI ceases to exist, the matter shall be informed with details of balance stock of ENDs, if any, and the authorisation certificate surrendered to the State Drug Controller / Commissioner of Food & Drugs Control Administration within 30 days, who will then issue orders for the disposal of the balance ENDs.

Responsibilities of Medical Officer in-charge of RMI

1. Ensure that ENDs shall be dispensed to the selected patients who are registered with the RMI.
2. Ensure that RMI uses ENDs in the licit manner specified in the Rules.
3. Ensure that prescriptions from the RMI are made rationally on valid clinical grounds
4. Ensure that the stock of ENDs in the RMI are uninterrupted and adequately available for medical needs of its patients, by sending estimates, and other details to the office of FDA / SDC in time.
5. Ensure that ENDs are kept under safe custody to prevent possible misuse and diversion.
6. Maintain record in Form No. 3E for each patient, which shall be preserved for a minimum period of two years from the date of last entry.
7. Maintain record of all receipts and disbursements of essential narcotic drugs in Form No. 3H which shall be preserved for a minimum period of two years from the date of last entry.
8. Shall authorize the deputed qualified personnel to carry such quantity of ENDs as may be required for treatment of home care patients registered with the RMI.
9. Maintain the record of issue and receipt of ENDs used for such home care patients
10. File return for a calendar year on or before the 31st of March of the subsequent year in Form No. 3-I to the Controller of Drugs.

11. Ensure that all records are available to inspectors from the DC office, for a period of two years from the date of last transaction.
12. Ensure that the expired stock of ENDs is destroyed in the presence of a representative of the State Drug Controller / Commissioner of Food & Drugs Control Administration.
13. In the event of any change in the constitution of the RMI, the designated Officer in charge, shall inform the State Drug Controller / Commissioner of Food & Drugs Control Administration in writing within thirty days from the date of such change for issue of fresh Certificate of Recognition.

Fig 1 The Process of Recognizing Medical Institution to stock and dispense ENDs



## Step 1 – Training

The Medical Institution ensures that a Registered Medical Practitioner is trained in the medical use of opioids.

## Step 2 - Applying to the state drugs controller for RMI status:

The application is sent in the format of Form no 3F to the State Drugs Controller/ FDA by the authority in-charge of the institution with details of the facility and with the name of the trained doctor who will be in-charge of the stocking and dispensing. The following documents are also required.

1. Covering letter stating the purpose
2. Filled application - Form 3-F.
3. Completed Form 3-J which specifies the Annual Requirement of the ENDs and source(s) for purchase
4. Name of the employed doctor who would be the Officer in-charge and copy of her/his;
    a. Medical graduation certificate
    b. Certificate of registration
    c. Certificate of training in medical use of opioids
5. Self -addressed stamped envelope [Stamp worth ₹ 27/-]

## Step 3 – Inspection and authorisation for RMI purpose

- The drugs controller / designated person will inspect the institution
- If all the prerequisites are appropriately met, the Drug Controller will authorize it as a RMI through a letter of recognition; in the format given in Form 3G, within 60 days from the date of receipt of application.
- If the RMI status is denied – the reasons are to be provided within 60 days from the date of receipt of application.

## Step 4 – Order of Purchase of ENDs

- The order for purchase of each opioid and each formulation that is required, is then filled by the RMI and submitted to the licensed pharmaceutical agency along with a copy of RMI certificate.
- If the annual estimate is utilised before time, the RMI can repeat the order of purchase of that amount, during the year as per the need, in case of unexpected increase in the number of patients needing ENDs.
- The repeat order of purchase is best done with at least 3 months remaining for the existing stock of the drug to run out. This can prevent interruption in the availability of pain medication for the patients registered with the RMI.

## Step 5 – Receipt of the consignment

- The applicant will get the original consignment of ENDs along with a copy in the format of Form No 3C Which contains the details of the consignment and the time of receipt.
- Retain the original.
- One copy is returned to the supplier and one copy is sent to the State Drug Controller.

## Step 6 – Maintaining stock and records

1. The consignment of ENDs is kept in a cupboard or locker safely under the supervision of the doctor in charge of the RMI.
2. Record of the consignment notes is maintained for two years
3. The quantity of each formulation of individual drug should be entered in a specified section of the END register which is prepared as per Form no 3H.
   For e.g. if the RMI procures 10 mgs and 20 mgs tablets of oral Morphine, the stock of each should go into separate sections. Separate registers may also be maintained for each formulation.
4. The name and address of each patient for whom END was prescribed is entered in the register along with the quantity disbursed. Record of every patient to whom END was dispensed is maintained in the format of Form 3E
5. At the end of the day the total quantity of END disbursed that day, should be subtracted from the initial quantity with which the register was started. This amount naturally forms the initial quantity for the next day.
6. Record of day to day accounts of every transactions in END is maintained in the format of Form 3D
7. Once verified, the doctor in charge signs below the last entry of the day in the register.
8. All records are kept for period of two years from the date of last entry.
9. Although support staff may manage the day to day entries, the medical officer in charge has primary responsibility of the stock and dispensing ENDs.
10. The total quantity possessed by the RMI at any one time, should not exceed the submitted estimate (or revised estimate, if any). This quantity may be ordered repeatedly during the year, if the need for ENDs scales up during the year.
11. If the requirement for ENDs has increased during the course of the year, the officer in charge of the RMI can submit the revised estimate for the same year by the 31$^{st}$ August. A brief justification for the same is provided while filing the annual return in Form-3 I.
12. File annual return to the Controller of drugs, for the calendar year on or before 31st of March of the subsequent year in the format of Form 3 I.

Maintaining vigilance of left over stock by the Officer in charge, and early action for replenishing stocks, would avoid the most distressful state for patients, resulting from interrupted stocks. This would avoid suffering of patients due to non-availability of essential medicines in the RMI.

### Renewal of RMI

The Recognition of RMI is valid for three years. The application for renewal [form no 3F] is sent from the RMI, at least 60 days prior to the date of expiry of recognition - to the State Drug Controller stating the following.

1. Balance of each END from the year's stock
2. The total quantity purchased during the year
3. The total quantity disbursed in the current year and the balance quantity
4. The quantity needed for next year
5. If the RMI requires to revise the annual estimate, application for the same should be submitted to the Controller of Drugs by 31st of August of the calendar year. The Medical Officer in charge shall record the justification for the same while filing the annual return in Form 3-I.

It is recommended that the RMI should keep enough END stock, to cover requirements for at least 3 months to ensure uninterrupted supply. The order of purchase for the next consignment is readied and sent accordingly to the supplier to ensure at-least 3 month's buffer stock.

### Guidelines for individual Registered Medical Practitioners

Any individual Registered Medical Practitioner [RMP] may hold a small stock of ENDs as indicated below, for emergency purposes in her/his own practice, without any special authorisation.

1. Morphine formulations – total quantity not > 500 mg
2. Codeine formulations – not > 2000mg
3. Hydrocodone - total quantity not > 320 mg
4. Fentanyl – 2 TD patches one each of 12.5 ug / hour and 25 ug / hour
5. Oxycodone - total quantity not > 250 mg
6. Methadone – the upper limit of quantity is not yet mentioned in the Rules.

If the RMP requires to stock more than the quantity mentioned, she/he can apply using Form 3B to the state drug controller/ FDA officer to request for the same and receive special permission for period of three years.

## Prescribing ENDs

1. Prescriptions must be in capital writing, dated and signed by the RMP with full name, address and her/his registration number
2. Prescriptions must specify name, and the address of the person to whom prescription is given,
3. Prescriptions must mention the total quantity of the END, daily dose and the duration of the prescription.

## References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