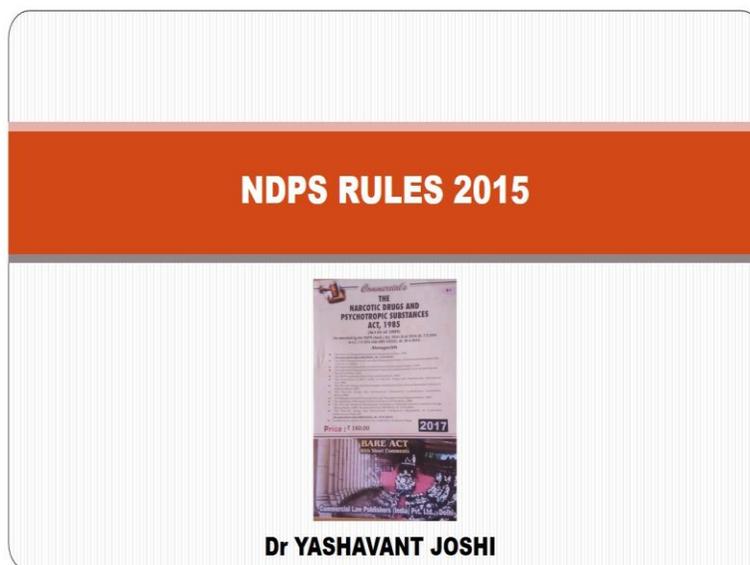


Basic Certificate in Palliative Care
Dr. Geeta Joshi
Dr. Piyush Gupta
Dr. Col. Yashavant Joshi
International Institute of Distance Learning
Indian Institute of Technology, Kanpur

Week-11
Lecture 05: NDPS Rules 2015

Good morning, I am K. Radhakrishnan Menon, Vice President, Content Development Training and Conferences, National Association of Palliative Care for AYUSH and Integrative Medicine.

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I would like to present before you a session prepared by Colonel Dr. Yashawant Joshi, my fellow Vice President of National Association of Palliative Care for AYUSH and Integrative Medicine. So let us discuss in detail what is NDPS Act. NDPS stands for Narcotic Drugs and Psychotropic Substance Act, which was passed in 1985.

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How Laws Are Formed?

Laws: A law is a general term for any legal rule or regulation enforced by the governments to regulate behaviour or activities in that society. The term can additionally mean a system of rules that are created and enforced by the government for the same purpose.

Societal Behaviour
Regulation



What are NDPS rules which were formed on the basis of the Act in 1985? How laws are formed? Societal Behavior Regulation, Bill, Act, Rules and Systems of Procedures. These are the four fundamental, you know, areas where each, you know, rule or act is concerned with. Now how laws are formed? What is law? A law is a general term for any legal rule or regulation enforced by the governments to regulate behavior or activities in that society. The term can additionally mean a system of rules that are created and enforced by the government for the same purpose.

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How Laws Are Formed?

A Bill is proposed Law, drafted by the government or by the law makers, to be debated and voted upon in the legislature, and if passed by the legislature, to be enacted into force by a certain constitutional procedure.



A bill is proposed by law, drafted by the government or by the lawmakers to be debated and voted upon in the legislature and if passed by the legislature to be enacted in the force by a certain constitutional procedure.

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How Laws Are Formed?

An Act is enacted legislation, the written law (the statute). The "Act" most usually means primary legislation i.e. the principal statute enacted according to the lawmaking procedure by the legislature. Very often the Act will have secondary or delegated legislation (usually called "Regulation" or "Rules") to fine-tune the operation of the Act.

An act is enacted legislation, the written law or the statute. The act most usually means primary legislation, that is the principal statute enacted according to the law making procedure by the legislature. Very often the act will have secondary or delegated legislation. We usually call them regulation or rules to fine tune the operation of the act.

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How Laws Are Formed?

Ordinances are temporary laws. They are circulated by the President of India on the recommendation of the Union Cabinet. They can only be delivered when the Parliament is not in Session. They enable Indian government to take immediate legislative action.

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NDPS Act 1985

This Act governs control and availability of groups of drugs called “narcotics” like Morphine and “psychotropic” like Amphetamine which have medical value. The scope of the Act did not address adequately the accessibility and availability issues of these drugs for medical treatment of patients in pain. Hospitals have to obtain licenses for stocking, import, export, transport etc. from different Departments.

What is NDPS Act 1985? This act governs control and availability of groups of drugs called narcotics like morphine and psychotropic like amphetamine which have medical value. The scope of the act did not address adequately the accessibility and availability

issues of these drugs for medical treatment of patients in pain. Hospitals have to obtain licenses for stocking, import, export, transport, etc. from different departments.

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Barriers in NDPS Rules 1985

- One of the chief barriers was the prohibitory regulatory procedures of the Narcotic Drugs and Psychotropic Substances Act (NDPS Act) of 1985.
- The scope of the Act did not address adequately the accessibility, availability and issues of these drugs for medical treatment of patients in pain.
- Hospitals have **to obtain licenses** for stocking, import, export, transport etc. from different Departments.
- These licences need to be valid, though often the validity period of a licence is as short as a month. BY the time the institution gets a second licence, the first would have expired its validity.
- **Most institutions solve this problem by not stocking these medicines; hence patients suffer as well as doctors don't get the experience.**

What are the barriers in narcotic drugs and psychotropic substance rules 1985? One of the chief barriers was a Prohibitory Regulatory Procedures of the Narcotic Drugs and Psychotropic Substance Act of 1985. The scope of the act did not address adequately the accessibility, availability and issue of these drugs for medical treatment of patients in pain.

Hospitals have to obtain licenses for stocking, import, export, transport, etc. from different departments. These licenses need to be valid though often the validity period of a license is as short as a month. By the time the institution gets a second license, the first would have expired its validity. Most institutions solve this problem by not stocking these medicines. Hence, patients suffer as well as doctors do not get the experience.

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NDPS Rules (Third Amendment) 05 May 2015

- Recognizing the essentiality of the Opioid as medicine, the NDPS Rules 1985 was amended in 2015. This amendment aims at broadening the scope of the Rules to include access and availability of opioids for medical and scientific use.
- Narcotic Drugs and Psychotropic Substances (Third Amendment) Rules, 2015 formed by the Central Government has introduced the concept of “Recognised Medical Institution” (RMI) for stocking and dispensing Essential Narcotic Drugs (ENDs).
- This new simplified provisions maintain a fine balance between the easy availability of the Essential Narcotic Drugs for the medical use and the required control to prevent their diversion for abuse.

We have this NDPS rules amended in May 2015. Recognizing the essentiality of the opioid as medicine, the NDPS rules 1985 was amended in 2015. This amendment aims at broadening the scope of the rules to include access and availability of opioids for medical and scientific use. Narcotic Drugs and Psychotropic Substances Third Amendment Rules 2015 formed by the central government has introduced the concept of Recognized Medical Institutions or RMI for Stoking and Dispensing Essential Narcotic Drugs, we call it ENDs.

These new simplified provisions maintain a fine balance between the easy availability or the essential narcotic drugs for the medical use and the required control to prevent their diversion for abuse.

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NDPS Rules (Third Amendment) 2015

These rules are called NDPS (Third Amendment) Rules, 2015

1. RMI Status
2. RMP Status
3. END: Six drugs have been covered under Essential Narcotic Drugs namely Codeine, Fentanyl, Hydrocodone, Methadone, Morphine, and Oxy-codone
4. Licensing process became easier and systematic
5. Transportation
6. Cancellation of RMI Status
7. Appeal Procedure

These rules are called NDPS Third Amendment Rules 2015. These specifically discuss RMI status, RMP status, END. Six drugs have been covered under essential narcotic drugs namely, Codane, Fentanyl, Hydrocodane, Methadone, Morphine and Oxycodone. Licensing process became easier and systematic. Transportation has become easier. Cancellation of RMI status. Appeal procedure. So these are the advantages of the Third Amendment of NDPS rules in 2015.

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Medical Institution

“Medical Institution” means a hospital, dispensary, clinic or an institution by whatever name called that offers services or facilities requiring diagnosis; treatment or care of illness, disease, injury, deformity or abnormality, established and administered or maintained *by the Government or Municipal Corporation or Municipal Council or Zila Parishad or any person or body of persons.*

What is Medical Institution? Medical institution means a hospital, dispensary, clinic or institution by whatever name called that offers services or facilities requiring diagnosis, treatment or care of illness, disease, injury, deformity or abnormality established and administered or maintained by the government or municipal corporation or municipal council or zilla parishad or any person or body of persons.

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Recognised Medical Institution

“Recognised Medical Institution (RMI)” means a medical institution recognised as such under the Central Government gazette notification dated 05 May, 2015 regarding the Narcotic Drugs and Psychotropic Substances (Third Amendment) Rules, 2015.

What is Recognized Medical Institution? Recognized Medical Institution or RMI means a medical institution recognized as such under the central government gasset notification dated 5 May 2015 regarding the narcotic drugs and psychotropic substance Third Amendment Rules 2015.

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Registered Medical Practitioner

- **Registered Medical Practitioner (RMP)** means any person registered as a medical practitioner under the Indian Medical Council Act, 1956 or under any law for the registration of medical practitioner for the time being in force, or registered as a dentist under the Dentists Act, 1948 or under any law for the registration of dentists for the time being in force and has undergone training in either one of the following courses:
 - Training in Pain Relief and Palliative Care for prescription of essential narcotic drugs (ENDs).
 - Opioid Substitution Therapy for prescription of essential narcotic drugs (ENDs) for treatment of opioid dependence

Who is a registered medical practitioner? A registered medical practitioner or RMP means any person registered as a medical practitioner under the Indian Medical Council Act 1956 or under any law for the registration of medical practitioner for the time being in force or registered as a dentist under the Dentist Act 1948 or under any law for the registration of dentist for the time being in force and has undergone training in either one of the following courses. Training in pain relief and palliative care for prescription of essential narcotic drugs or ENDs. Opioid substitution therapy for prescription of essential narcotic drugs for treatment of opioid dependence.

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Designated Medical Practitioner

Designated Medical Practitioner: If RMI has only one RMP, he will be responsible for stocking and dispensing of ENDS and their relevant documentation. He will be known as Designated Medical Practitioner. In a RMI, where more than one RMPs are available, one of them shall be designated as Overall-In-Charge to carry out the duties of Designated Medical Practitioner.

What is meant by designated medical practitioner or DMP? Designated medical practitioner if RMI has only one RMP he will be responsible for stocking and dispensing of ENDS and their relevant documentation.

He will be known as designated medical practitioner. In a RMI where more than one RMPs are available one of them shall be designated as overall in charge to carry out the duties of designated medical practitioner.

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Essential Narcotic Drugs (ENDs)

Essential Narcotic Drugs (ENDs): Only those Narcotic Drugs which shall be prescribed and dispensed by RMI to patients under the Narcotic Drugs and Psychotropic Substances (Third Amendment) Rules, 2015 and subsequent amendments.

Essential narcotic drugs or ENDS. Essential narcotic drugs only those narcotic drugs which shall be prescribed and dispensed by RMI to patients under the Narcotic Drugs and Psychotropic Substance Third Amendment Rules 2015 and subsequent amendments.

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Essential Narcotic Drugs

1. Methyl Morphine (Commonly known as '*Codeine*') and Ethyl Morphine and their salts (including Dionine),
2. 1-phenethyl-4-N- propionylanilino-piperidine (the international- non-proprietary name of which is *Fentanyl*)
3. Dihydrocodeinone (commonly known as *Hydrocodone*), its salts
4. 4:4-diphenyl-6-dimethylamino-heptanone-3 (otherwise known as 6-dimethyl amino 4 : 4-diphenyl-3-heptanone and as *Methadone*)
5. Morphine and its salts and all preparations containing more than 0.2 per cent. of *Morphine*;
6. DihydroxyCodeinone (commonly known as '*Oxy-codone and Dihydroxycodeinone*'),

Essential narcotic drugs methylmorphine commonly known as codeine and ethylmorphine and their salts including dionine, fentanyl, phenethyl, Propionyl-anilinopiperidine the international non-proprietary name of which is fentanyl.

Dihydrocodeinone commonly known as hydrocodone its salts. diphenyl dimethylamino-heptanone otherwise known as dimethyl amino-diphenyl-heptanone and as methadone. Morphine and its salts and all preparations containing more than 0.2 percent of morphine. Dihydroxy codeinone commonly known as oxycodone and dihydroxy codeinone.

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Process of Registration as RMI

- Government or Municipal Corporation or Municipal Council or Zilla Parishad hospital, dispensary or medical institution with mandatory requirements fulfilled *shall be deemed to be a recognised medical institution (RMI)* for possessing, dispensing or selling of essential narcotic drugs for medical purpose and shall be exempt from making application to the Commissioner, Food and Drugs Control Administration (FDCA) for recognition as recognised medical institution.
- For registration by *private medical institutions* to get RMI status, an application along with forwarding letter will be made as per **Form No.3F** and to be submitted to the Commissioner, Food and Drugs Control Administration

Process of registration as registered medical institution, recognized medical institution. Government or municipal corporation or municipal council or zilla parishad hospital, dispensary or medical institution with mandatory requirements fulfilled shall be deemed to be recognized medical institution or RMI for processing dispensing or selling of essential narcotic drugs for medical purpose and shall be exempt from making application to the commissioner food and drugs control administration or FTCA for recognition as recognized medical institution. For registration by private medical institutions to get RMI status an application along with forwarding letter will be made as per form number 3F and to be submitted to the commissioner food and drugs control administration.

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Approval of a RMI

- The Commissioner, FDCA, on receipt of application, subject to any inquiry which may be necessary, issue a Certificate of Recognition in **Form No. 3G**. This certificate shall be issued within sixty days from the date of receipt of such application.
- In case the Certificate of Recognition is not issued **within sixty days of period**, the Commissioner, FDCA or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.
- The name of the **designated medical practitioner** or the **Overall-In-Charge**, as the case may be, shall be endorsed on the Certificate of Recognition issued by the Controller of Drugs.
- The Certificate of Recognition shall be issued for a period **not exceeding three years** at a time.
- In the event of a **change in the constitution of a RMI**, the current recognition shall be **deemed to be valid for a maximum period of ninety days** from the date on which the change takes place.
- In the event of **any change in the constitution of the RMI**, the designated medical practitioner or the Overall-In-Charge, as the case may be, **shall inform the Commissioner, FDCA in writing within thirty days from the date of such change** for issue of fresh Certificate of Recognition.

Approval of an RMI. The commissioner FDCA on receipt of application subject to any inquiry which may be necessary issue a certificate of recognition in form number 3G.

This certificate shall be issued within 60 days from the date of receipt of such application. In case a certificate of recognition is not issued within 60 days of period the commissioner FDCA or any other officer authorized by him in this regard shall inform the applicant the reasons thereof. The name of the designated medical practitioner or the overall in charge as the case may be shall be endorsed on the certificate of recognition issued by the controller of drugs. The certificate of recognition shall be issued for a period not exceeding three years at a time. In the event of a change in the constitution of an RMI the current recognition shall be deemed to be valid for a maximum period of 90 days from the date on which the change takes place.

In the event of any change in the constitution of the RMI the designated medical practitioner or the overall in charge as the case may be shall inform the commissioner FDCA in writing within 30 days from the date of such change for issue of fresh certificate of recognition.

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Renewal & Surrender of RMI Status

1. Renewal of Registration as RMI: Recognised Medical Institutions (RMIs); both, Government and Private, for renewal, will apply to the Commissioner, FDCA as per Form No.3F, at least sixty days before the expiry of previous recognition.

2. Surrender of Recognition as RMI

- A RMI may surrender its recognition by giving not less than thirty days' notice in writing to the Commissioner, FDCA.
- On surrender of the recognition, the ENDS as may be in the possession of the RMI shall be disposed of in such manner, including transfer to another RMI, as may be specified by the Commissioner, FDCA.

Renewal and surrender of RMI status. Recognized medical institutions both government and private for renewal will apply to the commissioner FDCA as per form number 3F at least 60 days before the expiry of previous recognition. Surrender of recognition as RMI. An RMI may surrender its recognition by giving not less than 30 days notice in writing to the commissioner FDCA.

On surrender of the recognition the ends may be in the possession of the RMI shall be disposed of in such manner including transfer to another RMI as may be specified by the commissioner FDCA.

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Designated Medical Practitioner

- Every RMI shall designate one or more RMP who shall prescribe and dispense ENDS. When more than one RMPs is designated, one of them shall be designated as Overall-In-Charge. The name of the designated medical practitioner or the Overall-In-Charge, as the case may be, shall be endorsed on the Certificate of Recognition issued by the Controller of Drugs.
- Whenever there is a change in the designated medical practitioner or the Overall-In-Charge, as the case may be, the RMI shall inform the Commissioner, FDCA within seven days from date of such change for appropriate endorsement on the Certificate of Recognition.

Designated medical practitioner. Every RMI shall designate one or more RMP who shall prescribe and dispense ends. When more than one RMP is designated one of them shall be designated as overall in charge. The name of the designated medical practitioner or the overall in charge as the case may be shall be endorsed on the certificate of recognition issued by the controller of drugs.

Whenever there is a change in the designated medical practitioner or the overall in charge as the case may be the RMI shall inform the commissioner FDCA within 7 days from the date of such change for appropriate endorsement on certificate of recognition.

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Duties of Designated Medical Practitioner

- Register the patients to whom essential narcotic drugs shall be dispensed or sold for medical use only.
- Maintain separate 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.
- Maintain record of all receipts and disbursements of ENDs in **Form No.3H** which shall be preserved for a minimum period of two years from the date of last entry.
- File return for a calendar year on or before the 31st of March of the subsequent year in **Form No. 3I** to the Controller of Drugs.
- Purchase ENDs from authorised Manufacturers or Licenced Dealers or Licensed Chemists.
- Facilitate for safe stocking of ENDs.

Duties of designated medical practitioner. Consider the patients to whom essential narcotic drugs shall be dispensed or sold for medical use only. Maintain separate record in form number 3E for each patient which shall be preserved for a minimum period of 2 years from the date of last entry. Maintain record of all receipts and disbursements of pens in form number 3H which shall be preserved for a minimum period of 2 years from the date of last entry.

File return for a calendar year on or before the 31st of March or the subsequent year in form number 31 to the controller of drugs. File return for a calendar year on or before the 31st of March of the subsequent year in form number 3I to the controller of drugs. Purchase ends from authorized manufacturers or licensed dealers or licensed chemists. Facilitate for safe stocking of ends.

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Requirement of END

1. Estimates of Requirement of END: Every RMI shall submit an estimate of its annual requirement of ENDS in **Form No. 3J** by the 30th November of the preceding calendar year to the Commissioner, FDCA. The Commissioner of Food & Drugs Control Administration shall consider it and either approves, modify or reject the estimate and inform the applicant by 31st December. In the event of rejection, the reason for the same will be intimated in writing to the applicant.

2. Revised Estimate of ENDS

- If the requirement of a RMI exceeds the annual estimate submitted to the Commissioner, FDCA, it shall submit a revised estimate as per Form No. 3 J, by the 31st August of the calendar year to which the said annual estimate pertains, to the Controller of Drugs.
- The Commissioner of Food & Drugs Control Administration shall consider it and either approves, modify or reject the estimate and inform the applicant within one month. In the event of rejection, the reason for the same will be intimated in writing to the applicant.
- It is clarified that a RMI may sell and disburse essential narcotic drugs over and above the quantity indicated in the estimate submitted to the Commissioner, FDCA, but the designated medical practitioner or the Overall-In-Charge, as the case may be, shall record a brief justification for such increase while filing return in Form No. 3-I

Requirements of END. Estimates of requirement of ENDS. Every RMI shall submit an estimate of its annual requirement of ends in form number 3J by the 30th November or the preceding calendar year to the commissioner FDCA. The commissioner of Food and Drugs Control Administration shall consider it and either approve, modify or reject the estimate and inform the applicant by 31st December. In the event of rejection, the reason for the same will be intimated in writing to the applicant.

Revised estimate of ENDS. If the requirement of a RMI exceeds the annual estimate submitted to the commissioner FDCA it shall submit a revised estimate as per form number 3J by the 31st August of the calendar year to which the said annual estimate pertains to the controller of drugs. The commissioner of Food and Drugs Control Administration shall consider it and either approve, modify or reject the estimate and inform the applicant within one month. In the event of rejection, the reason for the same will be intimated in writing to the applicant. It is clarified that an RMI may sell and disperse essential narcotic drugs over and above the quantity indicated in the estimates submitted to the commissioner FDCA but the designated medical practitioner or the overall in charge as the case may be shall record a brief justification for such increase while filing return in form number 3I.

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Purchase of ENDS

1. The RMI shall place **Orders for Purchase** of ENDS and will be attached with the following:
 - Copy of Estimate of Annual Requirement of ENDS i.e. Form No. 3J approved by the Commissioner of Food & Drugs Control Administration.
 - Copy of Certificate of Recognition i.e. Form No. 3G in case of first purchase.
2. The Purchase Order should have the following information:
 - Name and address of the recognized medical institution.
 - Description of the quantity for which order is placed.
 - A photocopy of the approved estimate is to accompany each order of purchase.
 - Details of other orders of purchase made during the year.

Purchase of ENDS. The RMI shall place orders for purchase of ends and will be attached with the following. Copy of estimate of annual requirement of ends that is form number 3J approved by the commissioner of Food and Drugs Control Administration. Copy of certificate of recognition in form number 3G in case of first purchase. The purchase order shall have the following information. Name and address of the recognized medical institution. Description of the quantity for which order is placed. A photocopy of the approved estimate is to accompany each order of the purchase. Details of other orders of purchase made during the year.

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Possession of ENDS by RMI

A RMI shall possess essential narcotic drugs in quantities not exceeding the quantities mentioned in the estimate or revised estimate, as the case may be, of the annual requirement of such drug submitted to the Controller of Drugs.

The following will be followed:

- The unused ENDS returned by the patients shall be considered as receipts by the RMI.
- Essential narcotic drugs shall not be transferred, loaned or sold by the RMI to other institutions without the prior approval of the Controller of Drugs.

Possession of ENDS by RMI. RMI shall possess essential narcotic drugs in quantities not exceeding the quantities mentioned in the estimate or revised estimate as the case may be of the annual requirement of such drugs submitted to the controller of drugs the following will be followed.

The unused ENDS returned by the patient shall be considered as receipts by the RMI. Essential narcotic drugs shall not be transferred, loaned or sold by the RMI to other institutions without the prior approval of the controller of drugs.

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Receipt of ENDS by RMI...

1. Manufacturers or Licenced Dealers or Licenced Chemists (consignors) shall sell the ENDS to the RMI (consignees) as per purchase order.
2. Consignors shall prepare the consignment note in **triplicate** as per the format given in Form 3 C.
3. Consignors shall send the **original and the duplicate copies** of the consignment note with the consignment of ENDS to the RMI.
4. On receipt of the consignment, the RMI shall enter the quantity received with date on both the consignment notes; **send the duplicate copy of the note to the consignor for his use.**
5. The consignor and consignee shall preserve such consignment notes for a period of **two years.**

Receipt of ENDS by RMI. Manufacturers or licensed dealers or licensed chemists, consignors shall sell the ENDS to the RMI consignees as per purchase order. Consignors shall prepare the consignment order note in triplicate as per the format given in form 3C.

Consignors shall send the original and the duplicate copies of the consignment note with the consignment of ENDS to the RMI. On receipt of the consignment, the RMI shall enter the quantity received with date on both the consignment notes, send the duplicate copy of the note to the consignor for his use. The consignor and consignee shall preserve such consignment notes for a period of two years.

Receipt of ENDS by RMI

1. The consignment notes shall not apply in cases where the sale of the ENDS is accompanied by a sale bill or invoice or cash memo or any other document duly signed by the consignor or his authorised signatory, which shall include the following information about the consignment:
 - Name, address, and license number of the consignor and the consignee. Where the consignee is a person to whom the ENDS has been sold or dispensed for his personal use, research institution, RMP, and RMI, the requirement of incorporating license number of the consignee shall not be applicable.
 - Description, batch number and quantity.
 - Mode and particulars of transport.
2. These documents about Purchase and Receipt of ENDS will be preserved for a period of two years by consignor and consignee.

Receipt of ENDS by RMI. The consignment note shall not apply in cases where the sale of the ENDS is accompanied by a sale bill or invoice or cash memo or any other document duly signed by the consigner or his authorized signatory.

We shall include the following information about the consignment. Name, address and license number of the consigner and the consignee. Where the consignee is a person to whom the ENDS has been sold or dispensed for his personal use. Research institution, RMP and RMI. The requirement of incorporating license number of the consignee shall not be applicable.

Description, batch number and quantity. Mode and particulars of transport. These documents about purchase and receipt of ENDS will be preserved for a period of two years by consigner and consignee.

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Possession of ENDS by RMI

1. Possession of ENDS: A RMI shall possess essential narcotic drugs in quantities not exceeding the quantities mentioned in the estimate or revised estimate, as the case may be, of the annual requirement of such drug submitted to the FDCA. The following will be followed:

- The unused ENDS returned by the patients shall be considered as receipts by the RMI.
- Essential narcotic drugs shall not be transferred, loaned or sold by the RMI to other institutions without the prior approval of the Controller of Drugs.

2. Disposal of Expired Stock: The expired stock of ENDS shall be destroyed by the RMI in the presence of an officer nominated by the Controller of Drugs.

Possession of ENDS by RMI. Possession of ENDS. An RMI shall possess essential narcotic drugs in quantities not exceeding the quantities mentioned in the estimate or revised estimate as the case may be of the annual requirement of such drugs submitted to the FDCA.

The following will be followed. The unused ENDs returned by the patient shall be considered as receipts by the RMI. Essential narcotic drugs shall not be transferred, loaned or sold by the RMI to other institutions without the prior approval of the controller of drugs. Disposal of expired stock. The expired stock of ENDs shall be destroyed by the RMI in the presence of an officer nominated by the controller of drugs.

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Home Care Treatment

Where home care treatment is provided to a patient registered with a RMI by deputing qualified personnel of such RMI to the home or residence or place of stay, either permanent or temporary, of such patient, the designated medical practitioner or the over-all in charge, as the case may be, **shall, authorise such personnel to carry such quantity of ENDs as may be required for treatment of such patient**, provided that home care treatment shall not be provided for treatment of opioid dependence. The designated medical practitioner or the over-all in charge shall maintain proper record of such issue and also of the **unused ENDs received from such personnel after completion of visit to the patient.**

Home care treatment. Where home care treatment is provided to a patient registered with an RMI by deputing qualified personnel of such RMI to the home or residence or place of stay, either permanent or temporary of such patient, the designated medical practitioner or the overall in charge as the case may be, shall authorize such personnel to carry such quantity of ENDs as may be required for treatment of such patient provided that home care treatment shall not be provided for treatment of opioid dependence. The designated medical practitioner or the overall in charge shall maintain proper record of such issue and also of the unused ENDs received from such personnel after completion of visit to the patient.

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Maintenance & Inspection of Stocks

- 1. Maintenance of Records:** All records generated under this SOP shall be kept for a period of two years from the date of last entry.
- 2. Inspection of Stocks:** The stocks of ENDS under the custody of a RMI shall be open for inspection by the Commissioner, FDCA or any other officer authorised by him in this regard. Periodical and surprise inspections will be carried out by the Head of the RMI.

Maintenance and inspection of stocks. All records generated under this SOP shall be kept for a period of two years from the date of last entry.

Inspection of stocks. The stocks of ENDS under the custody of an RMI shall be opened for inspection by the Commissioner, FDCA or any other officer authorized by him in this regard. Periodical and surprise inspection will be carried out by the head of the RMI.

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Suspension and Cancellation of RMI Status

1. The Commissioner, FDCA may suspend or cancel the recognition as RMI for the following reasons:
 - If the ENDS obtained by a RMI were supplied for non-medical use; or
 - In the event of any breach of the conditions of the recognition; or
 - In the event of violation of any of the provisions of the NDPS Act or rules and orders made there under.
2. No order shall be passed as above unless the RMI has been given a **reasonable opportunity of showing cause against the said orders or is heard in person, if he so desires.**

Suspension and cancellation of RMI status. The Commissioner, FDCA may suspend or cancel their recognition as RMI for the following reasons. If the ENDS obtained by an RMI were supplied for non-medical use or in the event of any breach of the conditions of the recognition or in the event of violation of any of the provisions of the NDPS Act or rules and orders made there under. No order shall be passed as above unless the RMI has been given a reasonable opportunity of showing cause against the such orders or is heard in person if he so desires.

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Appeal and the Procedure for Appeal...

1. A RMI aggrieved by any decision or order passed by the Commissioner, FDCA may appeal to the Secretary to the State Government responsible for implementation of Drugs and Cosmetic Rules, 1945 **within a period of sixty days** from the date of communication to him of such decision or order.
3. Every memorandum of appeal shall be accompanied by a copy of the decision or order appealed against.

Appeal and the procedure for appeal. An RMI aggrieved by any decision or order passed by the Commissioner, FDCA may appeal to the Secretary to the State Government responsible for implementation of drugs and cosmetic rules in 1945 within a period of 60 days from the date of communication to him of such decision or order. Every memorandum of appeal shall be accompanied by a copy of the decision or order appealed against.

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Appeal and the Procedure for Appeal

3. The following procedure will be followed:

- The Appellate Authority shall give an opportunity to the appellant to be heard in person, if he so desires. The Appellate Authority may, at the hearing of an appeal allow the appellant to raise any other ground not specified in the appeal, if the Appellate Authority is satisfied that omission of that ground from the appeal was not willful or unreasonable.
- The Appellate Authority may, after making such further inquiry as may be necessary, pass such order as it thinks fit, confirming, modifying or annulling the decision or order appealed against.
- The order of the Appellate Authority disposing of the appeal under this rule shall be in writing and shall state "the points for determination, the decision thereon and the reasons for the decision."

Appeal and the procedure for appeal. The following procedure will be followed. The appellate authority shall give an opportunity to the appellant to be heard in person if he so desires. The appellate authority may at the hearing of an appeal allow the appellant to raise any other ground not specified in the appeal if the appellate authority is satisfied that omission of that ground from the appeal was not willful or unreasonable. The appellate authority may after making such further inquiry as may be necessary pass such order as it thinks fit, confirming, modifying or annulling the decision or order appealed against. The order of the appellate authority disposing of the appeal under this rule shall be in writing and shall state the points for determination, the decision thereon and the reasons for the decision. So these are some of the salient features of the Narcotic Drugs and Psychotropic Substance Act 1985 and the amendments made thereafter. Thank you.