MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 5th May, 2015

G.S.R. 359(E).—In exercise of the powers conferred by section 9, read with section 76 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules further to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985, namely:—

1. (1) These rules may be called the Narcotic Drugs and Psychotropic Substances (Third Amendment) Rules, 2015.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Narcotic Drugs and Psychotropic Substances Rules, 1985 (hereinafter referred to as the said rules), in rule 2,-

(i) after clause (d), the following clause shall be inserted, namely:-

'(da) "Controller of Drugs" means the officer appointed as the controlling authority by the State Government under rule 50 of the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940 (23 of 1940);' ;

(ii) after clause (e), the following clauses shall be inserted, namely:-

'(ea) "Firm" means a company, body corporate, proprietorship firm, partnership firm, limited liability partnership firm, association of persons;

(eb) "Form" means a Form appended to these rules;' ;

(iii) after clause (h), the following clauses shall be inserted, namely:-

'(ha) "Licenced chemist" means a person who has obtained a licence to possess, sell, exhibit or offer for sale or distribution by retail, essential narcotic drugs under these rules;

(hb) "Licenced dealer" means a person who has obtained a licence to possess, sell, exhibit or offer for sale or distribution by wholesale, essential narcotic drugs under these rules;

(hc) "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;

(hd) "patent or proprietary medicine" shall have the same meaning as defined in the Drug and Cosmetics Act, 1940 (23 of 1940);

(he) "prescription" means a prescription given by a registered medical practitioner for the supply of any of the essential narcotic drugs to a patient for medical use in accordance with these rules;' ;

(iv) after clause (i), the following clauses shall be inserted, namely:-

'(ia) "recognised medical institution" means a medical institution recognised as such under these rules;

(ib) "registered medical practitioner" means any person registered as a medical practitioner under the Indian Medical Council Act, 1956 (102 of 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 (16 of 1948) or under any law for the registration of dentists for the time being in force and has undergone training in pain relief and palliative care for prescription of essential narcotic drugs for pain relief and palliative care or training in opioid substitution therapy for prescription of essential narcotic drugs for treatment of opioid dependence;'.

3. In the said rules, in rule 36A, in sub-rule (1), for the words "from poppy straw", the words and number "from poppy straw produced from poppy cultivated under a licence issued under rule 8 of these rules" shall be substituted.

4. In the said rules, for rule 37, the following rule shall be substituted, namely:-

" **37. Manufacture of synthetic manufactured drugs.-** Subject to the provisions of rule 36, the manufacture of manufactured drugs notified under sub-clause (b) of clause (xi) of section 2 of the Act including the essential narcotic drugs notified under clause (viiia) of section 2 of the Act (hereafter referred to as the drug) but not including preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess is prohibited save under and in accordance with the conditions of a licence granted by the Narcotics Commissioner or such other officer as may be authorised by the Central Government in this behalf, in Form No. 3 appended to these rules.

Explanation.– For the removal of doubts it is hereby clarified that the licence to manufacture a preparation containing any manufactured drug and including the preparation notified as essential narcotic drugs under clause (viiia) of section 2 of the Act shall be regulated under the rules made by the State Government under section 10 of the Act.".

5. In the said rules, for rule 38, the following rule shall be substituted, namely:-

"**38. Application for licence.-**(1) Every application for a licence or for renewal thereof under the proviso to rule 35 or rule 36 or rule 37 shall be in such form and manner as may be specified by the Narcotics Commissioner.

(2) A fee of rupees five thousand shall be payable to the Central Government for each licence issued under rule 37 or for renewal thereof.

(3) On receipt of an application for issue or renewal of a licence under rule 37, the Narcotics Commissioner shall issue or renew the licence in Form No. 3 within thirty working days from the date of receipt of such application.

(4) In case the licence is not issued or renewed within the period specified in sub-rule (3), the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.".

6. In the said rules, for rule 39, the following rule shall be substituted, namely:-

"39.Commencement of manufacture.- (1) A person who has been issued a licence under rule 36 or rule 36A or rule 37 shall not commence manufacture without obtaining the licences required under the Drugs and Cosmetics Act, 1940 (23 of 1940) for the manufacture of the drug, and the rules framed under section 10 of the Act by State Government of the State in which he has his place of business, for the possession, sale and distribution of the drug.

(2) The licencee shall send copy of the licences specified in sub-rule (1) to the Narcotics Commissioner before commencement of manufacture of the drug.

(3) In the event of revocation of licence issued under the Drugs and Cosmetics Act, 1940 (23 of 1940) for the manufacture of the drug or the rules framed under section 10 of the Act by State Government of the State in which he has his place of business, for the possession, sale and distribution of the drug, the licence issued under rule 36 or rule 36A or rule 37, as the case may be, shall be deemed to be revoked.".

7. In the said rules, rule 40 shall be re-numbered as sub-rule (1) thereof and after sub-rule (1) as so re-numbered, the following sub-rule shall be inserted, namely:-

"(2) The licencee shall not manufacture the drug without allotment of quota for that drug under sub-rule (2) of rule 67E.".

8. In the said rules, for rule 43 and 44, the following rule shall be substituted, namely:-

"**43. Advance notice for cessation and recommencement of manufacture**.- (1) The licencee shall give at least one month's notice in writing to the issuing authority before he ceases to manufacture the drug for any reasons whatsoever.

(2) The licencee shall give at least fifteen days notice in writing to the issuing authority prior to the date of recommencement of manufacture of the drug after cessation of manufacture of the drug as mentioned at sub-rule (1).".

9. In the said rules, after rule 45, the following rule shall be inserted, namely:-

"45A. Destruction of drugs.-(1) A licencee seeking to destroy the drug shall apply to the Narcotics Commissioner in such form and manner as may be specified by the Narcotics Commissioner.

(2) The Narcotics Commissioner shall, within a period of thirty days from the date of receipt of an application under sub-rule (1), appoint a committee comprising a Gazetted Officer in the office of the Narcotics Commissioner, or Narcotics Control Bureau constituted vide notification number S.O. 96(E) dated the 17th March, 1986, Superintendent of Central Excise of the concerned range and an authorised representative of the applicant for supervising the destruction of the drug and such destruction shall be carried out within a period of thirty days from the appointment of the committee.

(3) The destruction of the drug shall be carried out in accordance with the provision of the relevant laws for the time being in force.".

10. In the said rules, after Chapter V, the following Chapters shall be inserted, namely:-

"CHAPTER VA

POSSESSION, TRANSPORT, IMPORT INTER-STATE, EXPORT INTER-STATE, SALE, PURCHASE, CONSUMPTION AND USE OF ESSENTIAL NARCOTIC DRUGS

52A. **Possession of essential narcotic drug**. - (1) No person shall possess any essential narcotic drug otherwise than in accordance with the provisions of these rules.

(2) Any person may possess an essential narcotic drug in such quantity as has been at one time sold or dispensed for his use in accordance with the provisions of these rules.

(3) A registered medical practitioner may possess essential narcotic drug, for use in his practice but not for sale or distribution, not more than the quantity mentioned in the Table below, namely:-

TABLE

Sl. No.	Name of the essential narcotic drug	Quantity
(1)	(2)	(3)
1.	Morphine and its salts and all preparations containing more than 0.2 per cent. of Morphine	500 Milligrammes
2.	Methyl morphine (commonly known as 'Codeine') and Ethyl morphine and their salts (including Dionine), all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5 % in undivided preparations and which have been established in therapeutic practice	2000 Milligrammes
3.	Dihydroxy Codeinone (commonly known as Oxy-codone and Dihydroxycodeinone), its salts (such as Eucodal Boncodal Dinarcon Hydrolaudin, Nucodan, Percodan, Scophedal, Tebodol and the like), its esters and the salts of its ester and preparation, admixture, extracts or other substances containing any of these drugs	250 Milligrammes
4.	Dihydrocodeinone (commonly known as Hydrocodone), its salts (such as Dicodide, Codinovo, Diconone, Hycodan, Multacodin, Nyodide, Ydroced and the like) and its esters and salts of its ester, and preparation, admixture, extracts or other substances containing any of these drugs	320 Milligrammes
5.	1-phenethyl-4-N - propionylanilino-piperidine (the international-non-proprietary name of which is Fentanyl) and its salts and preparations, admixture, extracts or other substances containing any of these drugs	Two transdermal patches one each of 12.5 microgram per hour and 25 microgram per hour:

Provided that the Controller of Drugs or any other officer authorised in this behalf by him may by special order authorise, in Form 3B, any such practitioner to possess the aforesaid drugs in quantity larger than as specified in the above Table:

Provided further that such authorisation may be granted or renewed, for a period not exceeding three years at a time.

Explanation. - The expression "for use in his practice" covers only the actual direct administration of the drugs to a patient under the care of the registered medical practitioner in accordance with established medical standards and practices.

(4) For renewal of the authorisation referred to in the second proviso to sub-rule (3), application shall be made to the Controller of Drugs atleast thirty days before the expiry of the previous authorisation.

(5) (a) The Controller of Drugs may, by order, prohibit any registered medical practitioner from possessing for use in his practice under sub-rule (3) any essential narcotic drug, where such practitioner –

(i) has violated any provision of these rules; or

(ii) has been convicted of any offence under the Act; or

(iii) has, in the opinion of the Controller of Drugs, abused such possession or otherwise been rendered unfit to possess such drug.

(b) When any order is passed under clause (a) of this sub-rule, the registered medical practitioner concerned shall forthwith deliver to the Controller of Drugs the essential narcotic drug then in his possession and the Controller of Drugs shall issue orders for the disposal of such drugs.

(6) The Controller of Drugs may, by a general or special order, authorise any person to possess essential narcotic drug as may be specified in that order.

(7) A recognised medical institution may possess essential narcotic drug in such quantity and in such manner as specified in these rules.

(8) A manufacturer may possess essential narcotic drug in such quantity as may be specified in the licence issued under rule 37 of these rules.

(9) A licenced dealer or a licenced chemist may possess essential narcotic drug in such quantity and in such manner as may be specified in the licence issued under these rules.

52B. **Provisions regarding licenced dealer and licenced chemist**.- (1) A licenced dealer or a licenced chemist shall apply for a licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, essential narcotic drug, to the authority competent to issue licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, manufactured drugs under the rules framed under section 10 of the Act by State Government of the State in which he has his place of business.

(2) Every application for issue of licence referred to in sub-rule (1) shall be in such form and manner as may be specified by the authority referred to in the said sub-rule.

(3) The licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, essential narcotic drugs shall have the same conditions as are applicable to a licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, manufactured drugs under the rules framed under section 10 of the Act by the State Government.

(4) The licence under this rule shall be obtained within a period of one hundred and eighty days from the date of commencement of these rules.

52C. **Import Inter-State and Export-Inter-State of essential narcotic drugs**. – Any person who is permitted to possess essential narcotic drug under rule 52A may import inter-State or export inter-State such drug upto the quantity he is permitted to possess.

52D. **Transport of essential narcotic drugs.-** (1) Subject to the provisions of rule 52C, no consignment of essential narcotic drugs shall be transported, imported inter-State or exported inter-State unless such consignment is accompanied by a consignment note in Form No. 3C and in the manner as provided in sub-rules (2) and (3).

(2) The consignment note referred to in sub-rule (1) shall be prepared in triplicate, and the original and duplicate copies of the said note shall be sent along with the consignment of essential narcotic drugs to the consignee who shall return the duplicate copy of the note to the consignor for his use after endorsing on the original and duplicate copies, the particulars of the receipt of the quantity consigned.

(3) The consignor and consignee shall preserve such consignment note referred to in sub-rule (1) for a period of two years:

Provided that the said consignment note shall not apply in cases where the sale of the essential narcotic drug 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:-

(a) name, address and licence number of the consignor and the consignee;

(b) description, batch number and quantity;

(c) mode and particulars of transport:

Provided further that such documents shall be preserved by the consignor and consignee for a period of two years.

Explanation.- Where the consignee is a person to whom the essential narcotic drug has been sold or dispensed for his personal use, research institution, registered medical practitioner, recognised medical institution, or hospital, the requirement of incorporating licence number of the consignee shall not be applicable.

52E. **Transmission of essential narcotic drugs by post, courier, rail or road.**– The transmission of essential narcotic drugs by inland post or courier or by rail or by road by a manufacturer, licensed dealer or licensed chemist is permitted, subject to the following conditions, namely : -

(i) the parcel of the essential narcotic drugs when sent by post shall be sent by registered post;

(ii) the parcel of essential narcotic drugs shall be accompanied by a declaration showing the names of consignor and consignee, the contents of the parcel in detail, the number of licence or authorisation or recognition held by the consignee;

(iii) the consignee shall show distinctly in his account books, if he is a licencee, the name of the consignee and the consignor respectively, and the quantity of the essential narcotic drug imported inter-State, exported inter-State or transported by and to him, as the case may be, from time to time, by post or by courier or by road or by rail.

52F. **Sale**. – (1) A manufacturer or licenced dealer shall sell essential narcotic drugs otherwise than on prescription to–

(a) a licenced dealer;

(b) a licenced chemist;

(c) a registered medical practitioner;

(d) a person who has been authorised by the Controller of Drugs under these rules; or

(e) a recognized medical institution.

(2) A licenced chemist shall sell essential narcotic drug only on prescription and subject to the provisions of the Drug and Cosmetics Rules, 1945.

(3) A recognised medical institution shall dispense or sell essential narcotic drugs in such manner as specified in these rules.

52G. **Registered medical practitioner and conditions relating to their prescriptions.** – No prescription for the supply of essential narcotic drugs shall be given by a registered medical practitioner otherwise than in accordance with the following conditions, namely:-

(i) the prescription shall be in writing, dated and signed by the practitioner with his full name, address and registration number and shall specify the name and address of the person to whom the prescription is given and the total quantity of the essential narcotic drug to be supplied alongwith daily dose and period of consumption:

Provided that where such drug to be supplied on the prescription is a patent or proprietary medicine, it shall be sufficient to state the quantity and strength of the medicine to be supplied;

(ii) the prescription shall not be given for the use of the prescriber himself.

52H. **Authorisation and accounts**. - (1) The Controller of Drugs may by a general or special order authorise:

(a) any person in-charge of an educational institution or engaged in scientific research to possess and use, for educational or scientific purposes only, essential narcotic drug, in such quantity and in such manner as may be specified in the said order;

(b) a pilot of an aircraft or captain of a ship to possess and use, on the aircraft or ship, as the case may be, in any emergency, essential narcotic drug, in such quantity and in such manner as may be specified in the said order;

(c) a person in-charge of an ambulance or a first-aid station or a first-aid box to possess and use, in an emergency, essential narcotic drug, in such quantity and in such manner as may be specified in the said order.

(2) Every registered medical practitioner, and a person authorised by general or special order under this rule shall maintain day to day accounts in respect of all transactions of essential narcotic drug in Form No. 3D and the records of the daily accounts shall be preserved for a minimum period of two years from the date of last entry**.**

(3) Every registered medical practitioner shall also maintain a separate record in Form No. 3E for each patient and such record shall be preserved for a minimum period of two years from the date of last entry.

52-I. **Suspension and cancellation of authorisation**.- (1) Without prejudice to any action that may be taken under the provisions of the Act, the Controller of Drugs may, for the reasons to be recorded in writing, cancel or suspend the authorisation under rules 52A or 52H, -

(a) if the purpose for which the authorisation was granted ceases to exist; or

(b) in the event of any breach, by the holder of such authorisation or by his servant or by any one acting with his express or implied permission on his behalf, of any of the terms and conditions of such authorisation or of any authorisation previously held by him.

(2) No order shall be passed under sub-rule (1) unless the authorised person has been given a reasonable opportunity of showing cause against the said order or is heard in person, if he so desires.

52J. **Appeal.**– (1) Appeal against a decision or order made or passed under rule 52-I may be filed by the person against whom such decision or order has been made or passed, to the Secretary to the State Government responsible for implementation of the Drugs and Cosmetic Rules, 1945 in the State within a period of sixty days from the date of communication of such decision or order to him.

(2) Every memorandum of appeal shall be accompanied by a copy of the decision or order appealed against.

52K. **Procedure for appeal.-** (1) The Appellate Authority referred to in sub-rule (1) of rule 52J shall give an opportunity to the appellant to be heard in person, if he so desires.

(2) The said 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 was not willful or unreasonable.

(3) The aforesaid 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.

(4) The order of the Appellate Authority disposing of the appeal under this rule shall be in writing and shall state the points of determination, the decision thereon and the reasons for the decision.

52L. **Surrender of authorisation, etc.-** An authorised person, if he so desires, surrender his authorisation by giving not less than fifteen days notice in writing to the issuing authority.

52M. **Disposal of stocks of essential narcotic drugs on expiry, surrender, cancellation of authorisation, etc.-** (1) Such stocks of essential narcotic drugs as may be in the possession of an authorised person, on the expiry or cancellation or surrender of his authorisation, shall be disposed of in such manner as may be specified by the Controller of Drugs in this behalf.

(2) The expired stock of essential narcotic drugs as may be in the possession of an authorised person or a registered medical practitioner shall be destroyed in such manner as may be specified by the Controller of Drugs.

CHAPTER VB

SPECIAL PROVISIONS RELATING TO RECOGNISED MEDICAL INSTITUTION

52N. **Government, etc. hospital, dispensary to be deemed recognised medical institution**.- Government or Municipal Corporation or Municipal Council or Zilla Parishad hospital, dispensary or medical institution, with at least one registered medical practitioner possessing a minimum qualification of a degree in medicine or dentistry and who has undergone training in pain relief and palliative care for prescription of essential narcotic drugs for pain relief and palliative care or training in opioid substitution therapy for prescription of essential narcotic drugs for treatment of opioid dependence, who shall prescribe and dispense essential narcotic drugs, shall be deemed to be a recognised medical institution under these rules for possessing, dispensing or selling of essential narcotic drugs for medical purpose.

Explanation.- For the removal of doubts it is hereby clarified that Government or Municipal Corporation or Municipal Council or Zilla Parishad hospital, dispensary and medical institution, shall be exempt only from making application to the Controller of Drugs for recognition as recognised medical institution, but all other provisions of this Chapter shall be equally applicable to such deemed recognised medical institution as are applicable to other recognised medical institution.

52-O. **Recognition of medical institutions**. – (1) A medical institution seeking, to be a recognised medical institution or renewal of such recognition, under these rules for possessing, dispensing or selling essential narcotic drugs for medical purposes shall apply in Form No. 3F to the Controller of Drugs.

(2) The Controller of Drugs, on receipt of application referred to in sub-rule (1) may, subject to any inquiry which may be necessary, issue a Certificate of Recognition in Form No. 3G and such certificate shall be issued within sixty days from the date of receipt of such application.

(3) In case the Certificate of Recognition is not issued within the period mentioned in sub-rule (2), the Controller of Drugs or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.

(4) The Certificate of Recognition shall be issued for a period not exceeding three years at a time.

(5) For renewal of the recognition referred to in sub-rule (1), application shall be made to the Controller of Drugs at least sixty days before the expiry of previous recognition.

(6) The Certificate of Recognition shall be obtained within a period of one hundred and eighty days from the date of commencement of these rules.

(7) In the event of a change in the constitution of a recognised medical institution, 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.

52P. **Suspension and Cancellation of recognition**.- (1) Without prejudice to any action that may be taken under the provisions of the Act, for the reasons to be recorded in writing, the Controller of Drugs may suspend or cancel the recognition referred to in rule 52-O,–

(i) if the essential narcotic drugs obtained by a recognised medical institution were supplied for non-medical use; or

(ii) in the event of any breach of the conditions of the recognition; or

(iii) in the event of violation of any of the provisions of the Act or rules and orders made there under.

(2) No order shall be passed under sub-rule (1) unless the recognised medical institution has been given a reasonable opportunity of showing cause against the said orders or is heard in person, if he so desires.

52-Q. **Designated medical practitioner**.– (1) Every recognised medical institution shall designate one or more registered medical practitioner who has undergone training in pain relief and palliative care for prescription of essential narcotic drugs for pain relief and palliative care or training in opioid substitution

therapy for prescription of essential narcotic drugs for treatment of opioid dependence, who shall prescribe and dispense essential narcotic drugs.

(2) When more than one registered medical practitioner is designated, one of them shall be designated as over-all in charge.

(3) The name of the designated medical practitioner or the over-all in charge, as the case may be, shall be endorsed on the Certificate of Recognition issued under rule 52-O by the Controller of Drugs.

(4) Whenever there is a change in the designated medical practitioner or the over-all in charge, as the case may be, the recognised medical institution shall inform the Controller of Drugs within seven days from date of such change for appropriate endorsement on the Certificate of Recognition.

52R. **Duties of designated medical practitioner.-** (1) The designated medical practitioner or the over-all in charge, as the case may be, shall, –

(a) register the patients to whom essential narcotic drugs shall be dispensed or sold for medical use only;

(b) 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;

(c) 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; and

(d) 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.

(2) In the event of any change in the constitution of the recognised medical institution, the designated medical practitioner or the over-all in charge, as the case may be, shall inform the Controller of Drugs in writing within thirty days from the date of such change for issue of fresh Certificate of Recognition.

52S. **Surrender of recognition.-** (1) A recognised medical institution may surrender its recognition by giving not less than thirty days' notice in writing to the Controller of Drugs.

(2) On surrender of the recognition, the essential narcotic drugs as may be in the possession of the recognised medical institution shall be disposed of in such manner, including transfer to another recognised medical institution, as may be specified by the Controller of Drugs.

52T. **Estimates of requirement.-** (1) Every recognised medical institution shall submit an estimate of its annual requirement of essential narcotic drugs in Form No. 3J by the 30th November of the preceding calendar year to the Controller of Drugs.

(2) If the requirement of a recognised medical institution exceeds the annual estimate submitted to the Controller of Drugs, it shall submit a revised estimate by the 31st August of the calendar year to which the said annual estimate pertains, to the Controller of Drugs.

Explanation.- For the removal of doubts it is hereby clarified that a recognised medical institution may sell and disburse essential narcotic drugs over and above the quantity indicated in the estimate submitted to the Controller of Drugs as specified in this rule, but the designated medical practitioner or the over-all in charge, as the case may be, shall record a brief justification for such increase while filing return in Form No. 3-I.

52U. **Possession of essential narcotic drug by recognised medical institution**. – A recognised medical institution 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 under rule 52T.

52V. **Miscellaneous**.- (1) The expired stock of essential narcotic drugs shall be destroyed by the recognised medical institution in the presence of an officer nominated by the Controller of Drugs.

(2) The unused essential narcotic drugs returned by the patients shall be considered as receipts by the recognised medical institution.

(3) Essential narcotic drugs shall not be transferred, loaned or sold by the recognised medical institution to other institutions without the prior approval of the Controller of Drugs.

52W. **Home care treatment**.- (1) Notwithstanding anything contained in these rules, where home care treatment is provided to a patient registered with a recognised medical institution by deputing qualified personnel of such recognised medical institution 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 essential narcotic drugs as may be required for treatment of such patient:

Provided that home care treatment shall not be provided for treatment of opioid dependence.

(2) The designated medical practitioner or the over-all in charge shall maintain proper record of such issue and also of the unused essential narcotic drugs received from such personnel after completion of visit to the patient.

52X. **Maintenance of records**.- All records generated under this Chapter shall be kept for a period of two years from the date of last entry.

52Y. **Inspection of stocks.**– The stocks of essential narcotic drugs under the custody of a recognised medical institution shall be open for inspection by the Controller of Drugs or any other officer authorised by him in this regard.

52Z. **Appeal** .– (1) A recognised medical institution aggrieved by any decision or order passed by the Controller of Drugs under this Chapter 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.

(2) Every memorandum of appeal shall be accompanied by a copy of the decision or order appealed against.

52ZA. **Procedure for appeal.-** (1) The Appellate Authority referred to in sub-rule (1) of rule 52Z shall give an opportunity to the appellant to be heard in person, if he so desires.

(2) The Appellate Authority referred to in sub-rule (1) of rule 52Z 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.

(3) The Appellate Authority referred to in sub-rule (1) of rule 52Z 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.

(4) 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.".

11. **Insertion of new Forms.-** In the said rules, after Form No. 3A, the following Forms shall be inserted, namely:-

"FORM NO. 3B

[See rule 52A(3)]

SPECIAL AUTHORISATION FOR POSSESSION OF

ESSENTIAL NARCOTIC DRUGS BY REGISTERED MEDICAL PRACTITIONER

Authorisation No_____ Date of issue_____

……is hereby authorised to possess the following essential narcotic drugs on the premises situated at……for use in his practice.

Name of essential narcotic drug Quantity

(1)

(2)

2. The authorisation shall be in force from ……..to……..

3. The authorisation is subject to the conditions stated below and to such other conditions as may be specified under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules made thereunder.

Signature……

Designation……..

Conditions of authorisation

1. This authorisation is not transferable.
2. This authorisation and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for the purpose by the issuing authority.

FORM NO. 3C

(See rule 52D)

CONSIGNMENT NOTE

Date and time of dispatch of the consignment:_____

1.	Name and complete postal address of the consignor	:	
2.	Whether Manufacturer or Licenced Dealer (Quote Licence Number and the Issuing Authority)	:	
3.	Name and complete postal address of the consignee	:	
4.	Description and quantity of the consignment	:	

Particulars of the essential narcotic drugs showing Trade Marks, Proprietary Names, Batch number, etc.	Number of packages	Quantity	
		Gross	Net

5.	Mode of transport (particulars of the transporter, Registration number of the vehicle or Railway Receipt. / Lorry Receipt, if the transport is by railways or good transports)	:	

Full Name / Designation (if any)	Signature of the Consignor with date

To be filled by the consignee

6.	Date and time of receipt by the consignee and his remarks	:	
7.	Whether the consignment received in full as per description and quantity mentioned at serial number 4 above	:	Yes / No (If 'no', details to be mentioned below.)

Full Name / Designation (if any) Signature of the Consignee with date

Note:

(1) This consignment note shall be serially numbered on annual basis.

(2) The consignor shall record a certificate on the cover page of each book containing consignment note indicating the number of pages contained in the consignment note-book.

(3) The consignor shall maintain a Register showing the details of the books of consignment note brought in use during a particular year.

(4) This consignment note shall be retained for a period of two years from the date of transaction.

(5) The records referred to in this note shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.

FORM NO. 3D

[See rule 52H(2)]

DAILY ACCOUNTS OF ESSENTIAL NARCOTIC DRUGS TO BE MAINTAINED BY REGISTERED MEDICAL PRACTITIONER AND AUTHORISED PERSONS

Name of the Essential Narcotic Drug		:	_____	Authorised limit	:	_____
Date		:	_____			
1.	Opening stock				:	
2.	Quantity received				:	
2(i)	Received from (give details)				:	
2(ii)	Consignment Note / Bill / Invoice / Cash Memo, Number etc.				:	
3.	Quantity dispensed				:	
4.	Name and address of the person to whom dispensed (include patient registration number maintained in Form No. 3E, where applicable)				:	
5.	Closing stock				:	

Full Name / Designation (if any) Signature

Note:

(1) This record shall be maintained on day to day basis and entries shall be made for each day.

(2) Entries shall be completed for each day before the close of the day.

(3) The pages of the register shall be serially numbered.

(4) Separate record shall be maintained for each essential narcotic drug.

(5) This record shall be retained for two years from the date of last entry.

(6) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.

FORM NO. 3E

[See rule 52H(3)]

DETAILS OF THE PATIENT

TO WHOM ESSENTIAL NARCOTIC DRUGS DISPENSED

(TO BE MAINTAINED BY REGISTERED MEDICAL PRACTITIONER / RECOGNISED MEDICAL INSTITUTION)

Registration Number : _____ Date : _____

1.	Name	:	
2.	Complete postal address (with contact number, if any)	:	
3.	Brief description of the illness	:	
4.	Whether registered with any other registered medical practitioner / recognized medical institution (If yes, details to be recoded)	:	
5.	Details of the essential narcotic drugs dispensed	:	

Date	Name of the essential narcotic drugs	Quantity	Signature / Thumb impression of the patient	Remarks, if any

Note:

(1) This record shall be retained for two years from the date of last entry.

(2)This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.

FORM NO. 3F

[See rule 52-O(1)]

APPLICATION FOR ISSUE / RENEWAL OF CERTIFICATE OF RECOGNITION AS RECOGNISED MEDICAL INSTITUTION

1.	Name and complete postal address of the institution with telephone number, facsimile number and e-mail ID (relevant supporting documents to be submitted)	:	
2.	Name of the Head / In-charge of the Institution	:	
3.	Number of persons employed (i) Doctors (ii) Nursing staff (iii) Others	:	
4.	Number of patients treated during the previous calendar year (i) in patients	:	

	(ii) out patients (iii) home care		
5.	Name (s) of the qualified medical practitioner (s) who would prescribe essential narcotic drugs (give details of their training in pain relief and palliative care or opioid dependence treatment)	:	
6.	If there is more than one qualified medical practitioner who would prescribe essential narcotic drugs, indicate the name of the medical practitioner who shall be overall in charge	:	
7.	Number and date of the certificate of recognition issued earlier (attach copy)		
8.	Whether the recognition of the institution was withdrawn earlier (if the recognition was withdrawn earlier, the details are to be given)		

Date: Signature:

Place: Full name:

Seal: Position:

FORM NO. 3G

[See rule 52-O(2)]

CERTIFICATE OF RECOGNITION

No_____ Date of issue_____

This is to certify that ……(Name of the institution)…… situated at…… is a Recognised Medical Institution to possess, dispense and sell essential narcotic drugs.

2. The institution is a Recognised Medical Institution since ….(mention date of the certificate issued for the first time)….

3. This certificate shall be in force from ……..to……..

4. The certificate is subject to the conditions stated below and to such other conditions as may be specified under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules made thereunder.

Signature……

Designation……

Seal…….

Conditions of recognition

1. This certificate is non-transferable.
2. This certificate and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer authorised for the purpose by the issuing authority.

FORM NO. 3H

[See rule 52R (1)(c)]

DAILY ACCOUNTS OF ESSENTIAL NARCOTIC DRUGS TO BE MAINTAINED BY RECOGNISED MEDICAL INSTITUTION

Name of the Essential Narcotic Drug : _____ Date : _____

1.	Opening stock	:	
2.	Quantity received	:	
2(i)	Received from (give details)	:	
2(ii)	Consignment Note / Bill / Invoice / Cash Memo, Number etc.	:	
3.	Quantity dispensed	:	
4.	Specify registration number of the patient(s) maintained in Form No. 3E and quantity dispensed to each)	:	
5.	Closing stock	:	

Full Name / Designation (if any) Signature of the overall in charge

Note:

(1) This record shall be maintained on day to day basis and entries shall be made for each day.

(2) Entries shall be completed for each day before the close of the day.

(3) The pages of the register shall be serially numbered.

(4) Separate record shall be maintained for each essential narcotic drug.

(5) This record shall be retained for two years from the date of last entry.

(6) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.

FORM NO. 3-I

[See rule 52R (1)(d)]

ANNUAL RETURN OF PROCUREMENT / DISBURSEMENT

OF ESSENTIAL NARCOTIC DRUGS

(TO BE FILEED BY RECOGNISED MEDICAL INSTITUTION)

Return for the year	:	_____	Date of submitting return	:	_____

1.	Number and date of the current certificate of recognition	:	
2.	Name of the Recognised Medical Institution	:	

Sl. No.	Name of essential narcotic drug	Quantity in original annual estimate	Quantity in revised annual estimate (if any)	Opening stock	Quantity procured during the year	Quantity disbursed to patients during the year *	Closing stock
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

* The designated medical practitioner or the over-all in charge, as the case may be, shall record a brief justification where the actual disbursement is more than ten per cent of the estimate or revised estimate, as the case may be.

Full Name / Designation (if any) Signature of the overall in charge

FORM NO. 3J

[See rule 52T(1)]

ESTIMATE OF ANNUAL REQUIREMENT OF ESSENTIAL NARCOTIC DRUGS

Estimate for the year	:	_____	Date of submitting estimate	:	_____

1.	Number and date of the current certificate of recognition	:	
2.	Name of the Recognised Medical Institution	:	
3.	Details of the estimated annual requirement of essential narcotic drugs	:	

Sl. No.	Name of the essential narcotic drug	Quantity disbursed during previous year	Estimated annual requirement	Revised estimated annual requirement*	Reason for revision
(1)	(2)	(3)	(4)	(5)	(6)

* Please attach copy of the original estimate

Full Name / Designation (if any) Signature of the overall in charge.".

[F. No. N/11011/1/2014-NC-II (1)]

SATYA NARAYANA DASH, Under Secy.

Note.- The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 837(E), dated the 14th November, 1985 and subsequently amended vide notifications numbers S.O. 786(E), dated the 26th October, 1992, S.O. 599 (E), dated the 10th August, 1993, G.S.R. 748 (E), dated the 14th December, 1993, G.S.R. 543, dated the 24th October, 1994, G.S.R. 82, dated the 14th February, 1995, G.S.R. 556 (E), dated the 14th July, 1995, G.S.R. 25 (E), dated the 12th January, 1996, G.S.R. 509 (E), dated the 4th November, 1996, G.S.R. 350 (E), dated the 25th June, 1997, G.S.R. 214 (E), dated the 19th March, 2002, G.S.R. 763 (E), dated 14th November, 2002, G.S.R. 115 (E), dated the 21st February, 2003, G.S.R. 129 (E), dated the 26th February, 2003, G.S.R. 217 (E), dated the 17th March, 2003, G.S.R. 95 (E), dated the 4th February, 2004, G.S.R. 104 (E), dated the 25th February, 2005, G.S.R. 736 (E), dated the 22nd December, 2005, G.S.R. 639 (E), dated the 13th October, 2006, G.S.R. 2 (E), dated the 1st January, 2008, S.O. 1661 (E), dated the 13th July, 2010, S.O. 739 (E), dated the 11th April, 2011, G.S.R. 470(E), dated 21st June, 2011, G.S.R. 905(E), dated 28th December, 2011, G.S.R. 426(E), dated 1st July, 2014, G.S.R. 74(E), dated 5th February, 2015 and G.S.R. 224 (E), dated 25th March, 2015.

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