

Forms and Official Documents Relevant to Stocking and Dispensing Essential Narcotic Drugs as per the Amended NDPS Regulations - 2014

Appendices

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APPENDIX 1 -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

APPENDIX 2 - 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)	:	
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Full Name / Designation (if any)	Signature of the Consignor with date
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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.

APPENDIX 3 - 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 authorized officers whenever called upon during the course of their inspection/investigation.

APPENDIX 4 - 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 : _____

AADHAR No. of Patient may be added

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.

APPENDIX 5 -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	:	
	Category of RMI (Palliative care / direct administration / Opioid substitution therapy)		
5.	Name (s) of the qualified medical practitioner (s) who would be in charge of essential narcotic drugs (give details of their training for the category mentioned above)	:	
6.	If there is more than one qualified medical practitioner who is trained in medical use of 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 :

Name:

Seal:

Position

APPENDIX 6 - 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 fromto.....
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.

APPENDIX 7 - 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	:	

Signature of the overall in charge

Full Name / Designation (if any)

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.

APPENDIX 8 - 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

APPENDIX 9 - 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 Secretary to the Government of India.

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.

Appendix 10 – Government Order to Chief secretaries of States and UT on Stocking ENDS in RMIs

वी. एन. शर्मा
P. N. SHARMA, IAS
अपर सचिव एवं मु. स. अ.
ADDITIONAL SECRETARY & C. V. O



D.O. No. N.11011/1/2014-NC-II
भारत सरकार
वित्त मंत्रालय
राजस्व विभाग
नॉर्थ ब्लॉक, नई दिल्ली-११०००९
GOVERNMENT OF INDIA
MINISTRY OF FINANCE
DEPARTMENT OF REVENUE
NORTH BLOCK, NEW DELHI-110001

22nd July, 2016

Dear Sir,

As you are aware, 'opioids' like Morphine, is considered the best analgesic and is recommended by the World Health Organization (WHO) in cases of excruciating pain such as one suffered by terminally ill cancer patients. At least two-third of estimated 2.5 million cancer patient in the country would require opioids for pain relief.

2. However, the issue of adequate access to opioids for medical use has been a subject matter of concern in India. After reaching a peak of 573 kilograms in 1985, morphine use began to decrease. Between 1985 and 1997, morphine consumption decreased by 97%, reaching a low of 18 kilograms in 1997. In 1997, India's per capita consumption of morphine ranked among the lowest in the world (113th of 131 countries). During the same period, global consumption of morphine increased by 437%. Needless to say that in the present scenario aggressive action was required to address the issue.

3. The Central Government, vide notifications dated 05.05.2015, has notified six narcotic drugs as 'Essential Narcotic Drugs' - (i) Codeine, (ii) Dihydrocodeinone (commonly known as Hydrocodone), (iii) Dihydroxy Codeinone (commonly known as 'Oxy-codone and Dihydroxycodone), (iv) Fentanyl, (v) Methadone, and (vi) Morphine - and amended the Narcotic Drugs and Psychotropic Substances Rules, 1985 (NDPS Rules) wherein regulatory provisions relating to sale, purchase, possession, consumption, use, etc. of essential narcotic drugs have been simplified. For your ready reference, a summary of the major provisions is annexed herewith.

4. These new simplified provisions maintain a fine balance between the easy availability of the essential narcotic drugs for medical use and the required control to prevent their diversion for abuse. The concept of 'Recognized Medical Institution' has been introduced for stocking and dispensing essential narcotic drugs. Such Recognized Medical Institutions will not require any additional approval or licence to stock essential narcotic drugs hitherto required under the rules made by the State Government. All hospitals, dispensaries, etc. run by Government, Municipal Corporation, Municipal Council, Zila Parishad shall be deemed Recognized Medical Institutions without seeking any additional approval. Further, medical institutions in private sector can get themselves recognized by the State Government recognized medical institutions.

5. In the light of the above, I would request you to take following action urgently:-

- aforesaid regulatory provisions may be brought to the knowledge of all enforcement agencies for being followed up scrupulously through appropriate directives, including amendment of State NDPS Rules, if required;
- hospitals and dispensaries in the Government sector may be advised to keep adequate stock of essential narcotic drugs for their medical use;
- hospitals and dispensaries in the private sector may be encouraged to get themselves recognized for stocking and dispensing essential narcotic drugs for medical use.

Contd...2/-

Appendix 11 - Essential Narcotic Drugs Notified by the department of Revenue

1. 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 milligrams 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
2. 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
3. Dihydroxy Codeinone (commonly known as Oxycodone and Dihydroxycodone), its salts (such as Eucodal Boncodal Dinarcon Hydrolaudine, Nucodan, Percodan, Scopodal, Tebodal and the like) and, its esters and the salts of its ester and preparation, admixture, extracts or other substances containing any of these drugs
4. 4-diphenyl-6-dimethylamino-heptanone-3 (otherwise known as 6-dimethyl amino 4:4 -diphenyl-3-heptanone and as Methadone) and its salts such as (Adanon, Algolysin, Amidon, Amdosan, Butalgin, Depridol, Diaminon, Dianone, Dolafin, Dolamid, Dolphine, Doriexol, Heptadol, Hocchst, 10820, Detalgine, Mecodin, Mepection, Mephenon, Miadone, Moheptal, Physeptone, Pysoseptone, Polamidon, Simporon, Turnanon and the like) and preparations, admixtures, extracts or other substances containing any of these drugs
5. Morphine and its salts and all preparations containing more than 0.2 percent of Morphine
6. 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

Appendix 12 - The Maximum quantity of Essential Narcotic Drug that may be possessed by a Registered Medical Practitioner *

Sl.No.	Name of the Essential Narcotic Drug	Quantity
(1)	(2)	(3)
1.	Morphine and its salts and all preparations containing more than 0.2percent. Of Morphine	500Milligrammes
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	2000Milligrammes
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	250Milligrammes
4.	Dihydro codeinone (commonly known as Hydrocodone) ,its salts (such as Dicodeide, 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	320Milligrammes
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 12.5microgram per hour and 25micro-gram 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

Appendix 13 - Proforma - Inspection Report of Recognized Medical Institutions

1. Name of institution with full postal address with Phone, and E mail.	
2. Date of inspection	
3. Name of inspecting officer	
4. Nature of institution: Hospital / Hospice / Palliative Care Society / Home Care	
5. Name of the designated medical officer in charge	
6. Storage facilities for stocking ENDS:	
7. Facility / Register for documentation of stocking dispensing of ENDS	
8. Details of any other license to hold ENDS	
9. Remarks :	

Remarks / Comments

I, after inspecting /examining the inspection report of..... (Name of institution)

.....

recommend that the institute may be approved as RMI / Not be approved for the reasons mentioned below:

.....

Date:

Signature of inspecting officer:

Place:

Name of inspecting officer:

Address:

Appendix 14 - Order of Purchase
(See Rule – 57F)

To

(Name and Address of the supplier)

1. Name and address of the recognized medical institution, which places the order.
2. Description of the quantity for which order is placed.
3. Whether the institution has been recognized by the Drug Controller.
(A photocopy of the recognition is to accompany each order of purchase.)
4. Whether this order is covered by the estimate approved by the Drug Controller.
(A photocopy of the approved estimate is to accompany each order of purchase).
5. Details of other orders of purchase made during the year.

Sl No	Quantity	To whom order was placed

Station

Signature of the person authorized to place order

Name and Designation

Date

Note:

1. A copy of this order shall be kept by the recognized medical institution which placed the order.
2. This shall be retained for the two years from the date of transaction.