

**Office of the Controller Food and Drugs Administration  
Madhya Pradesh**

No.  
To,

V/Misc/July/2016

4141

Bhopal, Dated 29/7/2016

✓ All Drugs Inspector,  
Madhya Pradesh

**Sub.:-** Recognition of Medical Institution under the Narcotics Drugs & Psychotropic substances Rules 1985.

As it is already known, Government of India, Ministry of Finance (Department of Revenue) vide notification No. G.S.R. 359(E) has amended the Narcotics Drugs & Psychotropic substances, Rules, 1985. The new Rules which are now called the Narcotics Drugs & Psychotropic substances (Third Amendment) Rules 2015 now have come into force w.e.f. 05-05-2015.

- 1) As per Rule 52N of the Narcotics Drugs & Psychotropic substances (Third Amendment) Rules 2015 – "Government, etc. hospital, dispensary to be deemed recognized medical institution :- Government of Municipal Corporation or Municipal Council or Zila 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 or training in opioid substitution therapy for prescription of essential narcotic drug for treatment of opioid dependence, who shall prescribe and dispense essential narcotics drugs, shall be deemed to be recognized medical institution under these rules for possessing, dispensing or selling of essential narcotic drugs for medical purpose".

It has been clarified in the explanation is this Rule that "Medical Institution" means a hospital, dispensary clinic or an institution by whatever name called that offer services or facilities requiring diagnosis treatment or care of illness, disease injury, deformity or abnormality, established and administered, maintained by the Government or Municipal corporation or Municipal Council or zila parishad or any person or body of persons.

- 2) In order to streamline the process of recognition of Medical Institutes under these Rules following general instructions are hereby issued.
  - i. Application by a Medical Institute seeking recognition under these Rules for possessing, dispensing or selling essential narcotics drugs for medical purposes shall be made in Form No. 3F to the Controller of Drugs. [Photocopy of Form No. 3F is enclosed herewith].
  - ii. Following documents shall be submitted along with the applications:-
    - a) Application Form No. 3F.
    - b) Estimate of Annual requirement Form No. 3J.
    - c) List of qualified staff (Doctors, Nurses & Technician).
    - d) Storage plan & facilities for the essential narcotics drugs.
    - e) Details of Authorised person who would prescribe/receive/dispense these drugs viz Name, Designation, Education Qualification etc..
    - f) Copy of recognition of the Medical institutions (if already recognised).
    - g) Photocopy of stock register of all the drugs. (If the medical institution is already using such drugs.)

Continued 2.....



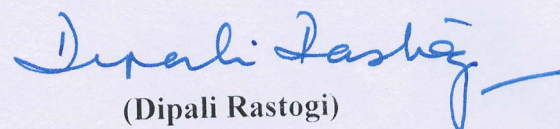
- h) Photocopy of registration of the medical institution.
  - i) Declaration from the Designated Medical Practitioner as overall in-charge specifying while the quantity as applied in Form 3J is required. (format enclosed)
- 3) On receipt of the application, the controller of Drugs (Controlling Authority) shall instruct the concerned Drugs Inspector to inspect the medical institute, verify the necessary documents and submit the report to the office of the Controller.
- 4) The report of Drugs Inspectors should be precise. It must clearly state the following:-
- a) Whether the medical institute is registered by the District CMHO or not ?
  - b) Bed Capacity of the hospital.
  - c) Types of treatments/surgeries/facilities provided by the hospital.
  - d) Details of overall in-charge of hospital viz Name, Educational Qualification & specialisation.
  - e) Details of the doctors who would prescribe the essential narcotics drugs viz Name, Educational Qualification & specialisation.
  - f) Details of the staff who would receive such drugs viz Name, Educational Qualification.
  - g) Storage plan of these drugs along with facilities.
  - h) Details of the recognition under NDPS Act and Rules (if any) held by the medical institute viz recognition No., date of issue and validity.
  - i) Stock details of available essential narcotics drugs with the closing stock on the inspection date duly verified by the Drugs Inspector.
  - j) Estimate of annual requirement which is recommended for approval.
- 5) Rule 52T of these Rules specifies that every recognized medical intuitions shall submit the estimate of its annual requirement of essential narcotics drugs in Form No. 3J by the 30<sup>th</sup> November of the preceding calendar year and if the requirement exceeds the annual estimate submitted to the Controller of Drugs, the medical institute shall submit a revised estimate by the 31<sup>st</sup> August of the calendar year to which the said annual estimate pertains. These dates should be strictly adhered to.
- 6) If a medical institute applies for the approval of formulation containing these drugs, it should be ensured the in-charge Registered Medical Practitioners possess the minimum qualification of a degree in medicine or dentistry and has undergone training in pain relief and palliative care for prescription of essential narcotics drugs for pain relief and palliative care or training in opioid substitution therapy for prescription of essential narcotics drugs for treatment of opioid dependence.
- 7) During Verification of the physical stock of the essential narcotics drugs it should be mandatorily ensured that the physical stock of these drugs exactly match the closing stock as mentioned in the stock register. There should be no blank entries in the stock register and cutting/overwriting (if any) shall by countersigned by the doctor in-charge. Also it is to be ensured that daily accounts of essential narcotics drugs in Form 3D, Form No. 3H, and details of the patients to whom essential narcotics drugs are dispensed - Form No. 3E, are duly maintained by the recognized medical institute. (Formats of these forms enclosed).



- 8) It should also be ensured that the recognized medical institution files returns for the calendar year on or before the 31<sup>st</sup> March of the subsequent year in Form No. 3-I, to the controller of Drugs. (Format enclosed).
- 9) It should also be ensured that essential narcotic drugs should not be transferred/loaned or sold by the recognized medical institution to other institutions without the prior approval of the controller of drugs.
- 10) It should also be ensured that the expired stock of essential narcotics drugs is destroyed only in the presence of an officer nominated by the Controller of Drugs and thus the recognized medical institute shall inform in writing to the controller of Drugs and obtain relevant permission/consent. Also the quantity to be destroyed should be duly verified from the stock register before destruction.
- 11) It is also to be noted that the unused essential narcotics drugs returned by the patients should be considered as receipts by the recognized medical institutions and thus should be accordingly incorporated in the stock register.
- 12) Any personnel carrying a quantity of essential narcotics drugs required for home care treatment of the patients should be authorised by the designated medical practitioner or the overall in-charge in writing. Records are also to be maintained accordingly. It is to be noted that home care treatment shall not be provided for treatment of opioid dependence.

The Drugs Inspectors should submit his/her report with clear opinion about the eligibility of the medical institute to be recognized under Narcotics Drugs & Psychotropic substances (Third Amendment) Rules 2015 Act & Rules within fifteen days.

Encl.: As above.



(Dipali Rastogi)

Controller

Food and Drugs Administration  
Madhya Pradesh

Endt. No. V/Misc/July/2016 | 4142

Bhopal Dated 29/7/2016

Copy to:-

- 1) The Excise Commissioner, Excise Department, Moti Mahal, Gwalior (M.P.)
- 2) Indian Medical Association, I.M.A. House, Indraprastha Marg, New Delhi- 110002
- 3) Deputy Drugs Controller, Food and Drugs Administration, Madhya Pradesh.
- 4) State Licensing Authority, Food and Drugs Administration, Madhya Pradesh.



Controller

Food and Drugs Administration  
Madhya Pradesh



## **DECLARATION**

I, Dr. .... of .....  
Hospital solemnly affirm that ..... hospital is registered  
as a ..... by the CMHO District..... vide no. ....  
which is valid upto ..... I have submitted an application for recognition  
as a medical institute under the Narcotics Drugs & Psychotropic  
substances Rules 1985. I also confirm that Dr. .... shall  
be responsible for prescribing such drugs. These drugs would be stored in  
.....with Lock & key under supervision of all the relevant  
records would be maintained for such drugs & I also confirm that a  
quantity of ..... has been applied since .....

**Date :**

**Overall In-charge  
Hospital**



(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

**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	:	



**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 FILED 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 14<sup>th</sup> November, 1985 and subsequently amended vide notifications numbers S.O. 786(E), dated the 26<sup>th</sup> October, 1992, S.O. 599 (E), dated the 10<sup>th</sup> August, 1993, G.S.R. 748 (E), dated the 14<sup>th</sup> December, 1993, G.S.R. 543, dated the 24<sup>th</sup> October, 1994, G.S.R. 82, dated the 14<sup>th</sup> February, 1995, G.S.R. 556 (E), dated the 14<sup>th</sup> July, 1995, G.S.R. 25 (E), dated the 12<sup>th</sup> January, 1996, G.S.R. 509 (E), dated the 4<sup>th</sup> November, 1996, G.S.R. 350 (E), dated the 25<sup>th</sup> June, 1997, G.S.R. 214 (E), dated the 19<sup>th</sup> March, 2002, G.S.R. 763 (E), dated 14<sup>th</sup> November, 2002, G.S.R. 115 (E), dated the 21<sup>st</sup> February, 2003, G.S.R. 129 (E), dated the 26<sup>th</sup> February, 2003, G.S.R. 217 (E), dated the 17<sup>th</sup> March, 2003, G.S.R. 95 (E), dated the 4<sup>th</sup> February, 2004, G.S.R. 104 (E), dated the 25<sup>th</sup> February, 2005, G.S.R. 736 (E), dated the 22<sup>nd</sup> December, 2005, G.S.R. 639 (E), dated the 13<sup>th</sup> October, 2006, G.S.R. 2 (E), dated the 1<sup>st</sup> January, 2008, S.O. 1661 (E), dated the 13<sup>th</sup> July, 2010, S.O. 739 (E), dated the 11<sup>th</sup> April, 2011, G.S.R. 470(E), dated 21<sup>st</sup> June, 2011, G.S.R. 905(E), dated 28<sup>th</sup> December, 2011, G.S.R. 426(E), dated 1<sup>st</sup> July, 2014, G.S.R. 74(E), dated 5<sup>th</sup> February, 2015 and G.S.R. 224 (E), dated 25<sup>th</sup> March, 2015.