Standard Operating Procedures (SOP) for Approval and Monitoring of

Recognized Medical Institutions (RMI)

Ref: G.O. (Ms.) No. 165/99/TD *Dated, Thiruvananthapuram, 26th Nov 1999.*

(Kerala Gazette notification dated 29 November 1999)

1. Introduction:

The Drugs Control Department of Kerala State takes all efforts to make available opioids for pain relief, while taking precautions to prevent its abuse or diversion to illicit uses. We recognize that there should not be too many controls and the procedure should be as simple as possible to encourage institutions to develop pain relief services and Medical Officers to prescribe opioids whenever necessary. This Standard Operating Procedures (SOP) intends to achieve the above object.

Any hospital, hospice or other institution providing pain relief and palliative care to patients can apply for recognition as RECOGNIZED MEDICAL INSTITUTION (RMI) for allotment of MORPHINE for stocking and dispensing. No individual shall be allowed as Recognized Medical Institution.

2. Minimum Mandatory Requirements (MMR):

A hospital, hospice or other institution applying for RMI status shall have following Minimum Mandatory Requirement (MMR)

a) A Medical Officer having a minimum qualification of MBBS with at least 10 days of "hands-on" training in pain relief and palliative care. If there are more than one Medical Officer at the institution, one of them should be designated as Over-all in Charge;

b) facilities for safe stocking of morphine; and

c) proper documentation for dispensing of morphine.

d) Conditions to be satisfied by RMIs:

i. The RMI shall ensure that the MMR and other relevant conditions are satisfied.

ii. The drugs shall be prescribed only by approved Medical Officers or under their supervision;

iii. The Over-all in Charge shall be responsible for the safe custody of morphine;

iv. The drugs shall be purchased only from authorized manufacturer/dealer.

v. The expired stock of morphine shall be destroyed in the presence of a Drug Inspector.

vi. The unused morphine returned by the patients shall be considered as receipts.

vii. Morphine shall not be transferred, loaned or sold to other institutions.

viii. Morphine is dispensed only to patients registered with the RMI.

ix. All records and registers under the law shall be maintained and kept for a period of two years from the last entry made there in and made available for inspection by the officers empowered by the Government under Section 41 and 42 of the Narcotic Drugs and Psychotropic Substances Act, 1985.

x. If there is a change in the Over all in charge, the details with date of change shall be intimated to the Drugs Controller along with the original RMI certificate and copies of the certificates (as mentioned in Section 4) immediately and the name got endorsed. Copy of such letter should be forwarded to the coordinator and the regional representative.

xi. The RMI shall inform the Drugs Controller in writing in the event of any change in the constitution of the RMI operating under this approval. Where any change in the constitution of the RMI takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place, unless, in the meantime a fresh approval has been taken from the Drugs Controller in the name of the Institution with the changed constitution.

xii. If an RMI ceases to exist, the matter shall be informed with details of balance stock of morphine, if any, and the certificate surrendered to the Drugs Controller immediately. The Drugs Controller shall issue orders for the disposal of the balance morphine.

3. **Advisory Panel:**

a) The Drugs Controller shall appoint a panel of palliative care physicians from different parts of the State to assist him for the screening of applications. The panel shall have a coordinator.

b) The tenure of the panel shall be two years from the date of its constitution and the Drugs

Controller shall publish the names of the members of the panel.

c) Services of the panel members shall be voluntary.

d)The panel member shall inspect or cause inspection of the premises of the applicant to ensure that the MMR are satisfied and give specific recommendation for grant or rejection of the application.

e)The panel shall follow up the applications, give recommendations to avoid delays and to ensure effective functioning and monitoring of the system.

f)The coordinator shall liaise with the Drugs Controller and with the panel members for effective functioning of the whole process.

f)When a panel member is unavailable for a period of time, the same shall be communicated to the Drugs Controller and alternate arrangements for uninterrupted functioning shall be made by the Drugs Controller in consultation with the coordinator.

g)When the coordinator is unavailable for a period of time, the same shall be communicated to the Drugs Controller and one of the panel member shall act as coordinator for the interim period.

h)The coordinator in consultation with the Drugs Controller shall convene meeting of the advisory panel every year in the month of December before the annual estimates are approved and whenever necessary.

4. Procedure of application

a) Application for approval as RMI shall be submitted to the member of the advisory panel in the respective region, in duplicate. The application shall contain:

i. A covering letter addressed to the Drugs Controller with court fee stamp worth Rs 5/- (Rupees Five only) affixed on the original set of application. The covering letter should be signed by the managing partner, managing director, managing trustee etc of the institution

Ii.Annexure I, duly filled and signed by the managing partner, managing director, managing trustee etc of the institution.

iii. Annexure III, duly filled and signed by the designated Medical Officer in charge. The name of the Medical Officer shall be written in the application as shown in the Registration with Medical Council.

iv. Attested copies of the following certificates of the medical officer in charge

a. MBBS or equivalent degree

b. Registration with Medical Council.

c. Training in Palliative Care (Minimum of 10 days of "hands on" training) from a training centre approved by the Drugs Controller.

d. Attested copies of the ownership details of the applicant institution like partnership deed, Articles of Association and Memorandum of association of Companies, bye-laws of Societies, trusts or other bodies, etc.

e. A self-addressed stamped envelope (stamp worth Rs 27/).

4. Procedure of scrutiny

a)The member of the panel who receives the application shall inspect / cause inspection of the institution within one month from the date of receipt of the application and verify the MMR. The panel member shall not receive any remuneration or allowances from the applicant.

b)After the inspection, the panel member shall forward the original application to the Drugs Controller along with Inspection Report recommending / rejecting the approval. If the MMR are not satisfied or if there are reasons to believe that the applicant is engaged in practices that violate safe and effective use of morphine, the same shall be noted in the Inspection Report. A copy of the forwarding letter shall be forwarded to the coordinator.

5. Approval of RMI

a) The Drugs Controller after verifying the application and the reports received by him shall issue RMI Certificate along with allotment of specified quantity of morphine for the year to the applicant within two months.

b) A copy of the communication shall be sent each to the manufacturer/supplier and to the Drugs Controller of the State of supply.

6.Duties and responsibilities of Medical Officer in charge.

The Medical Officer in charge shall:

a)endeavor to ensure that the stock of morphine is adequate for patients' needs;

b)ensure that morphine is kept under safe custody;

c)maintain a record of all receipts and disbursements of morphine in the format as specified in Annexure II;

d)ensure that estimates, and other details are sent to the Drugs Controller in time;

b)ensure adequate supervision over prescription of morphine by other Medical Officers.

7. Application for Supplementary Quota of Morphine

If the allotted quota of morphine for the year is inadequate, the institution shall apply for a supplementary quota along with the estimate in Annexure III to the Drugs Controller. The Drugs Controller shall consider it and either approve, modify or reject the estimate and inform the applicant within one month.

8. Renewal of Annual Quota of Morphine

a)All RMIs shall submit the annual return before 30th November every year even if they have not used any morphine in the preceding year.

b) The annual estimate in Annexure III signed by the medical officer in charge shall be forwarded to the Drugs Controller along with utilization statement from 1st November to 31st October, every year before 30th November.

c)The Drugs Controller shall consider it and either approve, modify or reject the estimate and inform the applicant before 31st of December. A copy of the communication shall be sent each to the manufacturer/supplier and to the Drugs Controller of the State of supply.

9.Purchase and Transport of Morphine

a) The recognized medical institution shall place orders for purchase of Morphine to a manufacturer /supplier enclosing the following:

i. Annexure IV duly filled up and signed by the approved medical officer in charge.

ii. The estimate approved by the Drugs Controller ; Copy of RMI certificate in case of first purchase.

b) A copy of the purchase order shall be sent to the Drugs Controller and the Narcotics Commissioner of India.

c)The manufacturer/Supplier shall send morphine to the RMI only on the basis of the **RMI Certificate** and the estimates approved by the drugs Controller.

d)The manufacturer/supplier shall dispatch morphine to the RMI along with a consignment note in quintuplicate in the format given in Annexure V.

e)The manufacturer/supplier shall send copies of the consignment note to the Drugs Controller of the state where the manufacturer/supplier is located, the drugs controller of the State in which RMI is located and the Narcotics Commissioner of India. The manufacturer shall also keep a copy of the consignment note.

f)On receipt of the consignment, the RMI shall enter the quantity received with date in all the copies of the consignment note, retain the original consignment note, send the duplicate to the supplier, triplicate to the Drugs Controller, the quadruplicate to the to the drugs Controller of State (in cases in which the consignment originated outside the State) in which the supplier is located and the quintuplicate to the Narcotic Commissioner of India.

10. Revoking the recognition

If it comes to the notice of the Drugs Controller that morphine obtained by the RMI was supplied for non-medical use or that any of the provisions under part IV A of the Kerala NDPS Rules, 1985 is violated, for reasons to be recorded in writing and after hearing the party, the Drugs controller may revoke the recognition accorded under these Rules.

d) Appeal

Any person aggrieved by any decision or order passed by the Drugs Controller relating to recognition or revocation of recognition of RMI or allotment of estimates may appeal to the Secretary to Government, Department of Health and Family Welfare, Government Secretariat, Thiruvananthapuram, within ninety days from the date of receipt of such decision or order.

Appendix II

List of approved Palliative Care training centers in Kerala (as of Jan 2009)

1. Institute of Palliative Medicine

   Medical College PO, Kozhikkode. Pin 673 008

   Phone: +91 495 2554897

   Email: palliativecare@gmail.com

2. Community Resource Centre in Palliative Care,

   Palliative Care Clinic, Valiyattiparamba Road,

   Manjeri, Malappuram(D), Pin 676 121

   Phone: +91 4832 767367 +91 94464 44667
   Email: painclinic@sify.com

3. Institute of Palliative Care,

   District Hospital, Round East, Trissur Pin 680 001

   Phone: +91 0487 2425733 +91 94473 08707
   Email: edivakaran@gmail.com

4. Department of Palliative Medicine,

   Amrita Institute of Medical Sciences and Research Centre,

Amrita Lane, Elamakkara PO. Ernakulam Dist. Pin 682 026

Phone: +91 94460 33050

Email: palliation@aims.amrita.edu

5. Palliative Care Division

Regional Cancer Centre

Thiruvanathapuram. Pin 695 011

Phone: +91 471 2522436, 2522272

Email: cheriankoshi@yahoo.co.in

5. Trivandrum Institute of Palliative Science

PJRRA 65, Santhi, Pothujanam Road,

Kumarapuram, Thiruvanathapuram. Pin 695 011

Phone: +91 471 325 7400, 3257400 +91 938 860 5681

Email: pallium.india@gmail.com

Appendix III

Members of the Advisory Panel to the Drugs Controller, Kerala

Co-ordinator

1. Dr. M.R Rajagopal

PJRRA 65, Santhi

Pothujanam Road, Kumarapuram

Thiruvanathapuram. Pin 695011

Phone: +91 471 3257400 (O)

+91 93886 05681 (mobile)

email: pallium.india@gmail.com

South Zone (TVM, Kollam, Kotayam, Pathanamthitta Districts)

2. Dr.Cherian Koshy

Palliative Care Division

Regional Cancer Centre

Thiruvanathapuram. Pin 695011

Phone: **+91 4712522436, D2522272**
Email: cheriankoshi@yahoo.co.in

Central Zone (Alapuzha, Ernakulam, Palakkad, Thrissur Districts)

3. Dr.Divakaran

Institute of Palliative Care,

District Hospital, Round East,

Trissur-680001

Phone: 9447308707

Email: edivakaran@gmail.com

North Zone (Kasargode, Kannur, Wynad, Calicut, Malappuram Districts)

4. Dr.Anil Kumar Paleri

Pain and Palliative Care Society, Medical College PO

Kozhikkode. Pin 673 008

Phone: 9447853340

Email.anilpaleri@gmail.com

Appendix IV

List of Manufacturers and Suppliers of Morphine Tablets in Kerala

1. Lisie Hospital Pharmaceuticals
   Ernakulam . Kochi. Pin 692 018
   Contact Person: Mrs. Nini Babu,
   Phone: +91 484 2401102
2. College of Pharmaceutical sciences,
   Medical College P.O
   Thiruvanathapuram Pin 695 011

Appendix V

Some Important Addresses

1. Hon Minister of Health and family Welfare **Smt. Sreemathi Teacher**

   Government of Kerala.
   Thiruvananthapuram, Kerala

2. Secretary to the Government **Dr. Vishwas Mehta**
   Health and Family Welfare Department,
   Secretariat,
   Thiruvananthapuram Pin 695 001

3. The Drug Controller, Kerala **Sri. M.P George**
   Red Cross Road,
   Thiruvananthapuram pin 695 035

4. Narcotic Commission of India,
   Central Bureau of Narcotics
   19, The Mall, Morar
   Gwalior. Madhya Pradesh Pin 474 006

Proforma Inspection Report of Recognized Medical Institutions

1. Name of institution with full postal address

   Phone: EMAIL:

2. Date of inspection :

3. Name of inspecting officer :

4. Name of applicant:

5. Nature of Institution: Hospital / Hospice /Palliative Care Services / Home care

6. Nature of the ownership of the facility: Society/Trust/ Other (specify)

7. Name of the medical officer in charge :

8. Facilities for treating patients (specify)

9. No.of patients treated during previous year :

10. Requirement of oral morphine of the current year with justification :

11. Details of any other license to hold morphine :

12. Storage facilities for storing oral Morphine :

13. Register for morphine documentation :

14. Remarks :

15. Signature of inspecting officer:

Recommendation of the Member of the Advisory Panel to the Drugs Controller, Kerala

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:

Place: Name:

Address:

Changes needed in the G.O. (Ms.) No. 165/99/TD ***Dated, Thiruvananthapuram, 26th Nov 1999.*** **(Kerala Gazette notification dated 29 November 1999)**

1		Part IV A 57 F (b) (b) The manufacturer/supplier shall dispatch the morphine consignment along with a consignment note in **quadruplicate** in the format given in Annexure V. Copies of the consignment note shall be sent by the manufacturer/supplier is located, the Drugs Controller of the State in which the recognised medical institution is located and the Narcotics Commissioner of India. He shall also keep a copy of the consignment note.	To be changed to: (b) The manufacturer/supplier shall dispatch the morphine consignment along with a consignment note in **duplicate** in the format given in Annexure V. He shall also keep a copy of the consignment note.
3		Part IV A57 F (c) (c)…. triplicate to the Drugs Controller, the quadruplicate to the to the drugs Controller of State (in cases in which the consignment originated outside the State) in which the supplier is located and the quadruplicate to the Narcotic Commissioner of India.	(c) To be deleted
4		5 Annexure I Whether the hospital has facilities **to treat cancer patients:** 6. No. of cancer patients treated during previous calendar year : Inpatient/Out patient	Whether the hospital has facilities **for pain relief and palliative care**: **To be deleted**
6		Annexure II	To add a column for signature of the medical officer in charge to sign.
7		Annexure V 6. Signature of the **Consignor**)	6. Signature of the **Consignee**
8		Explanatory note	**To be included non cancer patients as well.**

To be added: definition of palliative care. The WHO definition of palliative care is to be appended

We can also quote state palliative care policy.