

**Standard Operating Procedures for
approval and monitoring of Recognised
Medical Institutions in Kerala**

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P.K.SREEMATHI TEACHER
MINISTER FOR HEALTH & SOCIAL WELFARE

MESSAGE

I am happy to see that Arogyakeralam Palliative Care Project is publishing the Standard Operating Procedures for the Recognised Medical Institutions (RMI). This document will serve the important function of guiding palliative care units in the state on the procedure for acquiring and maintaining Recognised Medical Institution status.

A large number of new palliative care units are coming up in Kerala following the governments palliative care policy. Arogyakeralam palliative care project has been facilitating this process by encouraging the development of home care programs by local self government institutions with community participation and in collaboration with the primary health care system in the state. Publication of standard operating procedures for RMI will be of good use to these initiatives.

I hope that like other initiatives in palliative care in Kerala, this important step will also get replicated in other states in near future.

(S/d)

P.K. Sreemathi Teacher

S/12451/09/DC
21/03/2009

Office of the
Drugs Controller
Thiruvananthapuram

CIRCULAR

Sub: Standard Operating Procedures for Recognised Medical Institutions

Kerala Government has simplified the procedure for making available morphine at pain and palliative care centres vide GO (Ms) No. 165/99/TD dated, Thiruvananthapuram, 26th Nov 1999 (Kerala Gazette notification dated 29 Nov 1999). The Drugs Control Department of Kerala State is taking all efforts to make morphine available for pain relief, at the same time taking adequate measures to prevent its abuse and diversion to illicit uses.

The Department is bringing out this standard Operating Procedures (SOP) for the information of all concerned for easy understanding and application of the rules by the institutions providing pain and palliative care services in Kerala.

(s/d)

M.P. George
Drugs Controller, Kerala

FOREWORD

Kerala has made great strides in the area of palliative care. A force of committed volunteers and professional and very supportive community and government have made this possible.

Availability of medicines is a key component of developing palliative care services. The principles of palliative care are about taking care of the suffering of the patients with incurable diseases and their families by improving quality of life, by employing what is called active total care , treating pain and other symptoms, at the same time offering social, emotional and spiritual support.

The World Health Organisation in 2002 defined palliative care as an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

Though availability of medicines in general is an important issue, some medications like opioids needs special mention as procuring, stocking and dispensing these medications are controlled by strict rules. In India the Narcotic and Psychotropic Substance Act (1985) has the rules and regulations governing the transactions of opioid medications including morphine. The rules and regulations, made to prevent the abuse of narcotic and psychotropic preparations were so strict that availability of these medicines for genuine use by patients was also affected at times.

Kerala was one of the first states to modify these rules to simplify the process of procuring, stocking and dispensing opioids for medical use following a series of consultations at national and state level with officials and law makers. The notification by the Government of Kerala (G.O. (Ms.) No. 165/99/TD, *Dated, Thiruvananthapuram, 26th Nov 1999*) amending the Kerala Narcotic Drugs and Psychotropic Substances Rules, 1985 was an important milestone in the development of palliative care in Kerala. With the modified rules the whole process of getting the licence and procuring and dispensing oral morphine become simple and the issue of non availability of oral morphine due to strict rules almost become a non issue in Kerala. The palliative care centres were given Recognised Medical Institution (RMI) status if they satisfy the minimum mandatory requirement (MMR) laid out by the notification.

The Palliative Care Policy of the Government of Kerala (G.O. (P) No: 109/2008 H&FWD, *Dated Thiruvananthapuram, 15.04.2008*), another land mark achievement which has shown the commitment of the government towards the care of chronically and incurably ill in the state, aims at strengthening the palliative care services in the state. The policy proposes to build the capacity in the community and various levels of the health services and develop palliative care services in all the panchayats. It also observes that “a palliative care programme cannot exist unless it is based on a rational drug policy. Persons with incurable and other chronic illnesses need medicines for prolonged periods, which they may not be able to afford”, (Section 5.1) For improving the availability of medicines including opioids, the policy envisages to establish a palliative care service, with availability of essential drugs including oral morphine and with at least one trained doctor and trained nurse, in all government medical college hospitals in the state and in district hospitals in districts without Medical College. (Section 2.2.a.7) and to make essential medicines for palliative care available to patients covered by palliative care services through palliative care units / Primary Health Centres/other government hospitals. (Section 2.2.a.9).

The policy also sets the guidelines on training doctors which will enable them to be in charge of the RMIs and prescribe oral morphine. (See Appendix VI).

At the moment there are around 110 RMIs in Kerala, the highest in India. Many new services are applying for RMI status. The Drugs Controller, Kerala, to stream line the whole process, has issued a circular (S/12451/09/DC dated 21/03/2009) explaining the Standard Operating Procedures (SOP) involved in applying for RMI status, procuring, stocking and dispensing oral morphine by RMIs. The Palliative Care Project of Aarogyakeralam is publishing this circular which will be useful to existing RMIs as well as palliative care services aspiring to be RMIs in future.

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 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;
- e) 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.

11. 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 I

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. 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.
Pin: 682 026
Phone: +91 94460 33050
Email: palliation@aims.amrita.edu
- 5. Palliative Care Division**
Regional Cancer Centre, Thiruvananthapuram.
Pin: 695 011
Phone: +91 471 2522436, 2522272
Email: cheriankoshi@yahoo.co.in

6. Trivandrum Institute of Palliative Science
PJRRR 65, Santhi, Pothujanam Road,
Kumarapuram, Thiruvananthapuram. Pin 695 011
Phone: +91 471 325 7400, 3257400, +91 938 860 5681
Email: pallium.india@gmail.com

Appendix II

Members of the Advisory Panel to the Drugs Controller, Kerala

Co-ordinator

1. Dr. M.R Rajagopal
PJRRR 65, Santhi, Pothujanam Road,
Kumarapuram, Thiruvananthapuram. Pin 695011
Phone: +91 471 3257400 (O), +91 93886 05681 (M)
email: pallium.india@gmail.com

South Zone

(Thiruvananthapuram, Kollam, Kotayam, Pathanamthitta Districts)

2. Dr.Cherian Koshy
Palliative Care Division
Regional Cancer Centre, Thiruvananthapuram. 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, Kozhikode. Pin 673 008
Phone: 9447853340
Email.anilpaleri@gmail.com

Appendix III

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,
Thiruvananthapuram Pin 695 011

Appendix IV
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

Appendix V

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:

doctors and nurses identified as trainers should be kept protected for the training activities.

The trainer doctor:

Should be a qualified doctor with Indian medical council Registration. She/He should have the experience of at least one year as a full time Palliative Care Physician at a centre described above.

Or

She / He should have six months experience as a full time Palliative Care Physician at a centre described above after successful completion of a minimum of six weeks training in Palliative Care at a recognised training centre

It should be mandatory for the recognised training centres to submit a report of training activities to the government every year.

The Government will notify the training programmes conducted by the Recognised Training Centres.