PUBLIC HEALTH REGULATION DIVISION - MALTA

SUBJECT: Controlled Drugs: Supply, Storage and Administration

POLICY NUMBER: C – 1 **FIRST ISSUED: 2nd January 2006** Dates reviewed: June 2007 and September 2010. Re-issued on 1 July 2007.	**EFFECTIVE DATE: 18th October 2010** **REVIEW DATE: 1st July 2013**
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1. SCOPE AND PURPOSE

The objective of this policy is to in so far as possible, prevent misuse of narcotic drugs and psychotropic substances in a health-care setting. This is concomitant to the Dangerous Drugs Ordinance (Cap. 101) as well as the Drugs (Control) Regulations (Cap. 31.18)[1]. These substances are herein referred to as **controlled drugs**. The supply of controlled drugs is regulated in accordance with the Dangerous Drugs Ordinance and the Drugs (Control) Regulations. The basis for this policy for controlled drugs is that each drug (injection, tablets mixture or other drug formulation) should be accounted for and an audit trail maintained. Non-adherence with this policy entails disciplinary as well as criminal action, due to professional misconduct.

[1] http://www.justice.gov.mt/ - Legal Services – Laws of Malta – Main and Subsidiary

2 INFORMATION AND DEFINITIONS

For the purpose of this policy:

2.1 **Supply** refers to the drugs ordered and stock given by the pharmacy to wards and departments.

2.2 A **nurse** means either a licensed midwife, or a first level nurse or a second level nurse whose name is entered in the register held by the Council for Nurses and Midwives.

2.3 The **nurse in charge** means the senior nurse by grade or seniority, or a nurse delegated to be in charge of the ward or unit by the administration.

2.4 A **unit** means any care area where controlled drugs are stored and administered.

2.5 The **witness** to the administration of controlled drugs means a nurse, midwife or doctor.

2.6 **Drug Administration** means the actual removal of the controlled drug form the patient controlled drug cupboard, the preparation and giving of thereof to the right patient, all the required documentation as requested by this policy in para 3.4.1 – 3.4.7 and disposition of any in administered quantities of the drug.

3. INSTRUCTIONS AND PROCEDURES

3.1 Ordering

3.1.1 Each hospital unit is to have a Controlled Drugs cupboard and a stock of controlled drugs is to be kept therein.

3.1.2 Each unit should establish the minimum stock level to hold prior to ordering and should also indicate the maximum level to hold on the unit.

3.1.3 Controlled drugs ordered for a specific unit should only be used for identified patients of that unit.

3.1.4 Unless stocks are ordered electronically, stocks should be obtained by the use of a special duplicate numbered order form signed by the nurses in charge **(Annex 1)**. The form should be on Controlled Drugs Order Book that should be numbered and the name, strength, dosage form and quantity of drugs to be supplied is indicated. The ordering book should be kept locked in the Controlled Drugs cupboard. Records, whether on paper

or electronically stored, should be kept on the ward for ten years from the date of the last entry by the nurse in charge .

3.1.5 The nurse in charge is responsible for the controlled drug cupboard and should hold an audit trail of all controlled drugs available on the ward. Only nurses are allowed access to the controlled drug cupboard.

3.1.6 Requests for controlled drugs should be in duplicate and filled in ink. The name and surname of the nurse in charge in block letters should be entered on the order form, which will also indicate the date the drugs were requested.

3.1.7 At the point of dispensing, the pharmacist issuing the controlled drugs must sign name and surname in block letters and write the date of issue.

3.1.8 Request forms should clearly indicate the form of preparation and its strength. If the formulation dispensed is in any way different from what was requested (e.g. Different volumes) this should be clearly specified.

3.1.9 Controlled drugs for use in wards or units shall be under the direct responsibility of the nurse in charge of the ward or unit.

3.1.9.1 Stock of controlled drugs supplied by the pharmacy for use in wards or units shall be handed directly to the person authorised by the nurse in charge of the ward or unit, to collect controlled drugs. This authorised person shall check that the drug, strength, volume and dosage form dispensed matches what is documented as dispensed, and sign at the point of dispensing.

3.1.9.2 Controlled drugs brought from pharmacy shall be handed to the nurse in charge who shall check the controlled drugs against the requisition, including the number ordered and received.

3.1.9.3 If the supply is intact and correct, then the Controlled Drug Order Book shall be signed by the nurse in charge in the “received by” section.

3.1.9.4 The nurse in charge shall place the controlled drugs in the controlled drugs cupboard as soon as possible after being brought to the ward or unit and shall complete immediately the necessary record keeping requirements.

3.1.10 The new stock is to be entered in the Controlled Drug register **(Annex 2)**. All entries in the register should be double-checked and signed by the nurse who brought the stock and the witness. Only controlled drugs as per First Schedule of the Dangerous Drugs Ordinance can be kept in stock for administration.

3.2 Storage

3.2.1 Storage of controlled drugs should be in a cupboard solely and specifically designed for the purpose under double lock and key.

3.2.2 The controlled drugs cupboard should be placed in the treatment room firmly secured to a wall. In the absence of a treatment room, the controlled drugs cupboard should be kept in a controlled area. The controlled area should be secure, with limited access and entry restricted to authorized persons only.

3.2.3 The controlled drugs cupboard should be placed in an area which is not subject to substantial variations in temperature e.g. not in direct sunlight or over a radiator.

3.2.4 The keys should be kept at all times by the nurse in charge or any other nurse delegated for the day by the nurse in charge.

3.2.5 Fridge items, which need a temperature between 2 to 8 degrees Celsius, should be stored in the fridge for medications in the treatment room. Units making use of fridge items should have a lockable fixed space in the fridge where controlled drugs are stored.

3.2.6 All controlled drugs containers should be clearly labeled. Printed labels should always be used. The expiry date should also be clear.

3.2.7 Regular stock checks should be carried out weekly by the nurse in charge or senior nurse to ensure adequate stock and that the stock is not expired.

3.2.8 Where standard hospital policy warrants that controlled drugs need to be stored in an emergency trolley, the quantity maintained should be two of each item and kept under seal. Provisions stipulated in sections 3.3 and 3.4 also apply.

3.3 Record Keeping

3.3.1 A register is to be kept by the unit of all ordered and administered controlled drugs **(Annex 2)**. The pages of the register should be numbered and no pages should be missing. The ordering booklet and register in use is kept in the first lock of the controlled drugs cupboard.

3.3.2 The name of the drug to be registered is to be filled clearly at the top of the page in the space provided. A new page must be set for each drug, form of preparation and strength of drug.

3.3.3 The serial number of the page of the Controlled Drug Order Book is written on the register whenever a new stock is brought from the pharmacy together with the date and amount of drugs brought from the pharmacy. E.g. “New stock of XX amount of XY drug brought from Pharmacy.” The new balance is to be written down in the space provided for the balance and counter signed by another nurse.

3.4 Administration

3.4.1 Controlled drugs should be written and signed on the treatment chart by a doctor, and then only be administered to patients, by a nurse, midwife or doctor in that unit where prescribed. Except in exceptional circumstances drug administration is to be witnessed by a witness. These exceptional circumstances include those wards and shifts whereby administration is not in a position to provide a witness. These circumstances are to be documented by the hospital management a priori. If this is the case, then the nurse in charge of the shift is to double check the drug administration him/herself.

3.4.1.1 Student nurses are allowed to administer controlled drugs, only under the direct supervision of the nurse and a witness.

3.4.2 When a drug is taken from the controlled drugs cupboard for administration, it should be entered under the appropriate heading of the register and the following columns of the register for controlled drugs are to be filled **(Annex 2)**:

3.4.2.1 Date when the drug is removed from controlled drugs cupboard for administration,

3.4.2.2 Time of taking drug out of cupboard and its administration,

3.4.2.3 Patient’s name and surname to whom the drug is being administered,

3.4.2.4 Identity card number of the patient receiving the drug,

3.4.2.5 Name of doctor prescribing the drug,

3.4.2.6 Amount of the drug given and amount of the drug discarded if any, this disposal is witnessed and signed by the witness. If a controlled drug is taken out of the cupboard but is then not used, the drug should be registered back as a return into the controlled drug cupboard.

3.4.2.7 Signature of the nurse, midwife or doctor administering the drug together with the full name in block letters,

3.4.2.8 Signature of the person acting as witness to the whole process of the drug administration together with the full name in block letters.

3.4.2.9 When a phial/ampoule of controlled drug is accidentally broken, syrup spilled, or tablet crumbled, it should be registered by the nurse involved and double signed by the witness.

3.4.3 Completed registers are to be kept in the ward for 10 years from the date of the last entry.

3.4.4 The stock balance is to be written down after the drug has been administered. Any discrepancies in the balance should be immediately reported to the nurse in charge. An official incident report is to be written immediately which should be handed to the. immediate nursing manager or any other delegated authority, and the entity / medical administrator or its equivalent.

3.4.5 No cancellations or obliteration of an entry should be made. Corrections should be made by neatly crossing a line across the part being corrected and dated and signed.

3.4.6 Once the drug is administered, the prescription chart should be clearly signed or initialised in the space provided by the authorised person administering the medication. The only official prescription chart in the hospital is the patients' treatment chart.

3.4.7 All entries should be clearly legible.

3.5 Stock Checking

3.5.1 The nurse in charge or any other nurse delegated for the day by the nurse in charge should hand over stocks of controlled drugs at the end of each shift to the nurse in charge of the next shift, and vice versa **(Annex 3)**. Any discrepancies should be reported immediately as outlined in No. 3.4.4.

3.6 Expired Items

3.6.1 The removal of unwanted, unused or expired controlled drugs must always be recorded on the Controlled Drug Register. The nurse in charge and his/her deputy must both sign the

entry. On no account should out of date or damaged controlled drugs be destroyed on the ward. Their disposal should follow the established hospital policy.

3.7 Issuing controlled drugs on discharge

3.7.1 Following discharge the patient should have the prescription for controlled drugs on the 'Prescription for Narcotic Drugs' and Psychotropic Substances available on green forms. Discharge supply should be in accordance with the hospital's policy for discharge.

3.7.2 When patients require long-term treatment with a controlled drug, the appropriate application (DH 680-ii) should be filled in and sent to the Drug Control Unit, so that a Control Card for narcotic drugs/psychotropic substances could be issued.