Providing Partnership Services in Bedfordshire, Essex and Luton

PROCEDURAL GUIDELINES FOR THE SAFE AND SECURE HANDLING OF MEDICINES

PROCEDURE NUMBER:	
VERSION NUMBER:	
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CONSULTATION:	
IMPLEMENTATION DATE:	
AMENDMENT DATE(S):	
LAST REVIEW DATE:	
NEXT REVIEW DATE:	
APPROVAL BY EXECUTIVE TEAM DATE:	

The Director responsible for monitoring and reviewing this policy is

The Executive Director for Clinical Governance and Quality

TABLE OF CONTENTS

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURAL GUIDELINE ON THE SAFE AND SECURE HANDLING OF MEDICINES

Assurance Statement

The purpose of this procedural guideline is to ensure South Essex Partnership University NHS Foundation Trust has operational procedures in place to minimise the risks associated with the management and use of medicines. It defines the systems that are in place for the safe and secure handling of medicines, including ordering, supply, storage, transportation, prescribing, dispensing, administration and disposal.

1. INTRODUCTION

1.1. South Essex Partnership University NHS Foundation Trust (SEPT) is required to establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner. This document and its associated appendices define the operational procedures for the ordering, prescribing supply, storage, transportation, dispensing, administration and disposal of medicines needed to achieve this. The document is laid out in the chronological order that medicines are managed.

1.2. In order to achieve this, it is necessary for the Trust to comply with a variety of legislation and best practice guidance. This document is based upon statutory requirements and guidance issued by various official bodies. These include:

- The Medicines Act (1968)
- The Misuse of Drugs Act (1971) / Misuse of Drugs Regulations (2001)
- Royal Pharmaceutical Society of Great Britain *The Safe and Secure Handling of Medicines* (The 'Duthie Report') (2005)
- General Pharmaceutical Council *Standards of conduct, ethics and performance* (2010)
- General Medical Council *Good Medical Practice (2006)*
- General Medical Council *Good Practice in Prescribing Medicines* (2008)
- Nursing and Midwifery Council *Standards for Medicines Management* (2010)
- Nursing and Midwifery Council *Standards of conduct, performance and ethics for nurses and midwives* (2008)
- Care Quality Commission *Essential Requirements for Quality and Safety* (Outcome 9: Management of Medicines)

1.3. Although primarily directed at nursing and medical staff who are responsible for the prescribing and administration of the majority of medicines, references are also made to the many other professions who may be involved in these activities. The requirements of this procedural guideline apply to all staff who handled medicines.

1.4. For convenience and by custom the feminine pronoun is used throughout to refer to nurses and the male pronoun to doctors and patients. All statements can refer equally to men and women.

1.5. This document is intended for use in conjunction with the current edition of the British National Formulary (BNF) and the SEPT 'Formulary and Prescribing Guidelines'.

1.6. Where wards or services develop local protocols for any element of the pathway relating to medicines they must conform with the requirements of this procedural guideline and be authorised by the Lead Clinical Pharmacist for the relevant area of the Trust. If there is any doubt about the appropriateness of such local protocols they will need to be discussed by the Medicines Management Committee.

2. SCOPE

2.1. All staff working within SEPT who are involved in the prescribing, ordering or administration of medicines are required to familiarise themselves with the contents of this procedural guideline, its appendices and related documents.

3. DEFINITIONS

3.1. For the purpose of this document:

3.1.1. The term 'medicines' encompasses the following

- All medicines and medicinal products prepared for administration to patients and which are subject to the requirements of the Medicines Act, 1968. This includes all products designated as 'prescription-only' (POM) medicines 'pharmacy' (P) medicines, and 'general sales list' (GSL) medicines. It also includes products such as vaccines, medical gases and X-ray contrast media.
- Controlled Drugs (CDs), as defined within the Misuse of Drugs Act, 1971.
- Complementary medicines, e.g. aromatherapy oils, herbal remedies and homeopathic preparations.
- Medicated dressings, disinfectants, reagents and similar products.

3.1.2. A controlled drug is any substance controlled by the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001. Certain

drugs may be designated locally to be treated in the same way as controlled drugs, where authorised by the Chief Pharmacist.

3.1.3. The term "Appointed Nurse in Charge" is a registered nurse who is shown to be competent in the administration of medicines as determined by the competencies laid down by the Trust, and carries overall responsibility for a ward, unit or community setting (e.g. ward sister, charge nurse, clinical ward/team manager).

3.1.4. The term “Nurse in Charge” is the senior nurse on duty for the ward or department who has been identified as the Nurse in Charge at a particular point in time (e.g. for that shift).

3.1.5. The term “Manager” refers to ward managers of wards, units and community teams, and those who manage wards, units and community teams.

3.1.6. The term “Nurse” is used in its generic sense to include a registered nurse, on all parts of the register. The term “associate practitioner” is a qualified practitioner approved by South Essex Partnership NHS Foundation Trust and universities with which the Trust contracts to provide such training, having achieved the competencies outlined in the curriculum.

3.1.7. The term “First Level Nurse” is a nurse whose name appears in Part One of the register.

3.1.8. The term “Clinical Area” means a ward or department in which patients are treated or a group of such wards or departments which form a single management unit. This includes residential units operated by the Trust and community team bases.

3.1.9. The term “Prescriber” means a registered medical doctor or dentist, or a nurse, pharmacist or other allied health professional, who have undergone a specified training course in supplementary and independent prescribing and have been registered by their professional body. (See CLP53 *Policy on Non-Medical Prescribing*).

3.1.10. The term “Pharmacist” means a registered pharmacist employed directly by SEPT or providing pharmaceutical services to SEPT under the terms of a service level agreement (SLA) or contract.

3.1.11. The term “Community Pharmacist” refers to a pharmacist working in primary care in a pharmacy providing pharmacy services defined in the NHS (Pharmaceutical Services) Regulations 2005.

4. RESPONSIBILITIES

4.1. Responsibility for reviewing this document in relation to medicines management rests with the Chief Pharmacist working through the Medicines Management Committee.

4.2. Responsibility for establishing and maintaining a system for the secure and safe handling of medicines rests with the Chief Pharmacist in consultation with appropriate medical, nursing and administrative staff.

4.3. Responsibility of Prescribers

4.3.1. All prescriptions must be written by a suitably qualified practitioner. See also section 7.

4.3.2. A record listing the name, position and specimen signature of all prescribers, including locums, must be notified to the Trust Chief Pharmacist (or designated senior pharmacist) by the Medical Staffing Department using the form shown at Appendix 1. Any changes to this list must also be notified.

4.4. Responsibilities of Line Managers and New Staff

4.4.1. It is the responsibility of a manager to identify all new staff whose duties include the prescribing, handling or administration of medicines, and to provide such staff with a copy of the medicines policy and this procedural guideline to read during their induction period.

4.4.2. It is the responsibility of a manager to identify to new staff the key aspects of this procedural guideline that relate to their areas of work.

4.4.3. It is the responsibility of a manager to ensure that members of staff whose duties include responsibility for medication-related procedures have received relevant training and experience and are competent to undertake these procedures.

4.4.4. A record listing the name, position and specimen signature of all nurses authorised to order medicines, including controlled drugs, must be notified to the Trust Chief Pharmacist (or designated senior pharmacist) by managers using the form shown at Appendix 2.

4.4.5. It is the responsibility of a new member of staff to read and familiarise themselves with this procedural guideline prior to dealing with medication for the first time in their new role, and to adhere to it as it applies to their duties.

4.5. Responsibilities of the Appointed Nurse in Charge

4.5.1. All wards, units and other Trust sites shall at all times have a designated member of staff who assumes overall responsibility for the ordering, storage and administration of medicines at that site. This will be the Appointed Nurse in Charge, although another member of staff may be the designated person if more appropriate.

4.5.2. The Appointed Nurse in Charge carries responsibility for the security of medicines held at the site, for ensuring that stocks of Controlled Drugs correspond with the CD record book, and for ensuring that the medicines policy and procedural guideline is followed by all members of staff.

4.5.3. The process of medicines administration and other medicines-related activities may be delegated by the Appointed Nurse in Charge to another suitably trained member of staff. The tasks that may be delegated, and the grades of staff who may undertake such tasks, are indicated within this document. All members of staff, including locums, agency staff and care bank staff, must be aware of the tasks that they may or may not perform.

4.6. Responsibilities of Nurses

4.6.1. All Registered Nurses, Midwives and Health Visitors are personally responsible for their own actions and omissions, and shall adhere to the current NMC Code of Practice.

4.6.2. In administering any medication, or assisting or overseeing the self-administration of medication, nurses must exercise their professional judgement and apply their knowledge and skill in the given situation.

4.7. Responsibilities of Pharmacists

4.7.1. Responsibility for establishing systems for the safe and secure handling of medicines rests with the Chief Pharmacist in consultation with appropriate medical, nursing and administrative staff.

4.7.2. Pharmacists working for, or on behalf of, the Trust have a responsibility to ensure that the requirements set out in the medicines policy and procedural guideline are followed. Pharmacists are required to carry out their duties in accordance with the standards for conduct, ethics and performance set out by the General Pharmaceutical Council (GPhC).

4.7.3. Pharmacists are responsible for the stock of medicines held in the pharmacy departments, their manipulation and preparation into user-ready presentations, and for their supply to wards,

departments and outpatients. They are also responsible for monitoring prescriptions and for advising on the safe, effective and economic use of medicines. This includes advising practitioners on the storage of medicines in clinical areas.

4.7.4. Pharmacy staff may inspect the stocks of medicines held on wards, units and at other Trust sites (and at non-Trust sites where Trust staff are responsible for care provision) at any time, to ensure that the medicines are in date and are being stored under the correct legal and environmental conditions. Stocks of medicines in clinical areas will be checked by a member of pharmacy staff at regular, frequent intervals not exceeding six months.

5. MEDICINES SAFETY

5.1. The Trust is committed to the safe management of medicines and takes a lead from The National Patient Safety Agency (NPSA)[*]. The NPSA leads and contributes to improved, safe patient care by informing, supporting and influencing the health sector. It issues Patient Safety Alerts and Rapid Response Reports as safety issues with medicines arise.

5.2. These are reproduced in the Medicines Management section in the Library on the intranet. All staff involved in the management of medicines must be familiar with these publications, and ensure that they implement the actions recommended in them.

5.3. Medicines reconciliation

5.3.1. When a patient is first admitted to a ward, a medicines history must be completed in accordance with the CLP63, *Policy for Medicines Reconciliation on Admission to Hospital* and CLPG63, *Procedural Guideline for Medicines Reconciliation on Admission to Hospital*.

5.3.2. This is to ensure that medicines prescribed correspond to those that the patient was taking prior to admission and to reduce medication errors commonly associated with the transfer of patients from one area to another.

5.3.3. On admission to inpatient services the medication of high priority patients will be reconciled by the pharmacy team. Basic reconciliation will take place for all patients via the clerking process.

5.3.4. When taking over the care of a patient, the healthcare professional responsible should check that information about the

[*] Note: the safety function of the NPSA will transfer to the NHS National Commissioning Board by April 2013

patient's medicines has been accurately received, recorded and acted upon.

5.4. Rapid tranquilisation

5.4.1. The pharmacological treatment of acutely disturbed patients (rapid tranquilisation) shall be undertaken in line with RMPG05 *Procedural Guidelines for Preventing and Managing Violence and Aggression*, CLPG52 *Rapid Tranquilisation Procedure*, and the Trust *Formulary and Prescribing Guidelines*.

5.5. Treatment of anaphylactic shock

5.5.1. All inpatient areas will hold a stock of adrenaline for the treatment of life-threatening anaphylactic shock. All inpatient nursing staff are expected to have undertaken training in enhanced emergency skills. Staff must be familiar with CLPG27, *Procedural Guidelines for Anaphylaxis.*

6. PROCUREMENT AND RECEIPT OF MEDICINES

6.1. Medicines may only be purchased and received from manufacturers and wholesalers by pharmacy staff acting in accordance with local standard operating procedures or ward staff where arrangements have been made by the pharmacy team for direct delivery to a clinical area. No other staff are authorised to order or receive medicines on behalf of the Trust.

6.2. Samples, free stock, or clinical trial material may be accepted only by the pharmacy department, for issue as appropriate. Representatives wishing to leave samples must be directed to the appropriate hospital pharmacy department. If left in a clinical area by a company representative such medicines shall be sent immediately to the pharmacy department. Samples must not be used for the treatment of patients. (See also policy CLP51 *Policy on Hospitality and Sponsorship provided by the Pharmaceutical Industry, and contact with Representatives*).

6.3. As Home Office requirements specify that an organisation may only maintain one controlled drug register that records external receipts and supplies, Controlled Drugs cannot legally be received by anyone other than the pharmacy department.

7. PRESCRIBING

7.1. Authority to prescribe

7.1.1. Medicines will be prescribed by medical staff and non-medical prescribers according to their professional registration restrictions and competency.

7.1.2. Nurses, pharmacists and certain other professional groups who have successfully completed an accredited non-medical

prescribing course, and have been annotated to the appropriate professional register, may prescribe certain medicines provided they have been approved to do so within their employment setting (see CLP53, *Policy for Non-medical Prescribing* and CLPG53, *Procedural Guideline for Non-Medical Prescribing*).

7.1.3. Provisionally registered medical staff may prescribe for in-patients including prescriptions for leave or discharge. They may not prescribe for out-patients. Unregistered medical locums (e.g. medical students) do not have the authority to prescribe.

7.1.4. If a prescriber considers it unwise for a patient to receive medicines in accordance with a Patient Group Direction, that fact shall be recorded in the patient's healthcare record and on the prescription chart.

7.1.5. All staff who are authorised to prescribe shall provide a specimen of their signature to the pharmacy department of each hospital and clinical area in which they may work (see Appendix 1).

7.1.6. In certain circumstances a pharmacist may alter the formulation or dose of a prescribed medicine to clarify the correct meaning and facilitate administration. A pharmacist may also alter a prescription written by a prescriber in accordance with therapeutic substitution which has been agreed by the Medicines Management Committee (See *Formulary and Prescribing Guidelines*).

7.1.7. In some clinical areas, nurses and members of other professions may have the authority to administer and supply certain medicines at their own discretion. This is not prescribing and the precise circumstances in which this is permitted will be defined in a Patient Group Direction (see section 8).

7.2. Scope of prescribing

7.2.1. **Registered Medical Practitioners** are permitted to prescribe any medicines listed in the BNF, other than those marked as not allowable within the NHS.

7.2.2. **Non-medical prescribers** are permitted to prescribe within their area(s) of competence and from their permitted range of medicines. Such practitioners are responsible for ensuring that they only prescribe within these requirements.

7.2.3. The following points should also be noted by all prescribers:

- For **mental health conditions** prescribing should be from within the range of products listed in the Trust *Formulary and Prescribing Guidelines*. Products that have not been approved by the Medicines Management Committee for use

within the Trust are not listed in the Formulary and should not be prescribed without gaining appropriate permission from the Committee (see below).

- **Non-psychiatric treatments** initiated by a patient's GP may be prescribed as continuing therapy. If it is necessary to initiate inpatient treatment for a non-psychiatric condition, prescribing should be from within the formulary which applies at the local acute trust/PCT.
- When prescribing **Controlled Drugs**, additional requirements apply. Refer to Appendix 3 for further information:
- **Unlicensed medicines**, or licensed medicines for unlicensed indications, require approval from the Medicines Management Committee. Prescribers shall refer to the Trust procedure for prescribing unlicensed medicines; see Appendix 4 for details.
- **New products** that have not previously been used within the Trust require approval from the Medicines Management Committee before they can be purchased. The procedure for requesting a new medicine shall be followed; see Appendix 5.
- **Clinical trial drugs** must be prescribed in accordance with the trial protocol. For inpatients, the drug and dosage details on the pack label shall be transcribed onto the prescription chart. All clinical trials must be approved by the Trust Research Governance Group (RGG) as well as the Local Research Ethics Committee (LREC).
- **Complementary therapies** encompass a variety of *non-systemic* therapies such as aromatherapy, body massage, reflexology, head massage, etc. These therapies are intended to be used alongside (i.e. to complement) conventional medical and psychological therapies. Refer to the Trust policy CLP12 on complementary therapies for further information.
- In contrast, the term **alternative therapies** is used to describe treatments that are used *instead of* conventional approaches, e.g. homeopathy. Any member of staff wishing to use an 'alternative' therapy instead of conventional treatments must seek prior authorisation from the Trust Medicines Management Committee. The therapy must be an integrated part of the individual patient's care plan.

7.3. All prescriptions must be written on the appropriate Trust stationery (Medicines Prescription and Administration Chart', outpatient prescription form, or FP10 prescription form), and be signed and dated by the prescriber. (See also section 20 on controlled stationery).

7.4. All prescriptions must be written by an authorised prescriber who works for the Trust. GPs may prescribe for Trust patients in Fountains Court, Bedford but must use their own prescription pads and not prescribe on Trust forms.

7.5. All prescriptions shall be written in block capitals with black ink, and must be legible.

7.6. *It is the responsibility of the prescriber to ensure that all prescriptions comply with the requirements detailed in this procedural guideline.*

7.7. Prescribing for in-patients

7.7.1. Prescriptions for in-patients shall be written on the Trust's Medicines Prescription and Administration Chart (see Appendix 6). Supplementary cards are available to reduce risk in certain specialist situations e.g. for clozapine initiation and insulin and must be attached to the main prescription chart. Where these exist they shall be used.

7.7.2. It is essential that prescribers provide clear and complete written instructions to staff responsible for administering the medicines. These instructions shall be written in the appropriate section of the chart.

7.7.3. All prescriptions shall be dated and signed by the prescriber and endorsed with the prescriber's name in block capitals.

7.7.4. For inpatients, Controlled Drugs can be prescribed in the same way as all other medicines.

7.8. Completing a Medicines Prescription and Administration Chart

7.8.1. **Patient Details**: All sections on the front page of the Medicines Prescription and Administration Chart* must be completed. Addressograph labels shall be used whenever possible. Details required are as follows:

- Patient's full name and NHS number (required on all pages of the chart)
- Date of birth
- Name of patient's consultant
- Ward / unit name (required on all pages of the chart)
- Drug sensitivities (allergies)
- Consent to Treatment - Form T2/T3 in use

* * generally referred to as the 'prescription chart' 'drug chart' or 'chart'

When more than nine medicines are being prescribed regularly, a second prescription chart will be required. In this event, both charts must clearly indicate that another chart is in use by marking them '1 of 2' and '2 of 2' on every page.

7.8.2. **Drug sensitivities/allergies:** The prescriber is responsible for entering any known drug sensitivities/allergies in the appropriate box on the front page of the chart. **This box must not be left blank**. If no allergies are known, the abbreviation 'NKDA' (no known drug allergies) shall be entered. If the patient has multiple charts, this box must be completed on all the charts, and must also be completed when a chart needs to be re-written.

7.8.3. **Consent:** When patients are subject to treatment under the Mental Health Act, all relevant consent documentation must be completed and reviewed as required by the Act (see also section 15.18). If a Form T2 or T3 is in effect, the relevant box on the front of the prescription chart shall be ticked, and a copy of the Form T2/T3 shall be kept in the folder together with the patient's prescription chart.

7.8.4. **Drug Name:** The full approved name of the drug (as per BNF) shall be written clearly in BLOCK CAPITALS. If the medicine is a compound product with multiple ingredients and has no BNF approved name, the brand name shall be written. Non-approved abbreviations, such as CBZ for carbamazepine, must never be used.

If the required drug has special release properties, this should clearly be indicated on the chart, in order to differentiate it from plain formulations of the same drug (e.g. venlafaxine MR, olanzapine orodispersible).

For drugs where there are important bioavailability differences between brands (particularly lithium and anticonvulsants), the brand name shall be written, e.g. Priadel rather than lithium carbonate MR.

7.8.5. **Dose:** Medication errors arising from incorrect interpretation of the intended dose are common. Whenever possible, doses shall be written in whole numbers rather than in forms that require decimal points. This particularly applies to doses in the form '0.xxx', and these shall always be converted to the whole number equivalent. For example:

- 0.125 mg shall be written as 125 micrograms
- 0.25 g shall be written as 250 mg

The word 'micrograms' must always be written in full, and never abbreviated to 'mcg', in order to avoid confusion with milligrams ('mg'). Only the following abbreviations may be used:

- milligram mg
- gram g
- millilitre ml
- millimole mmol

It is acceptable to write doses in a form which includes the decimal point if this is the convention for the drug, e.g. venlafaxine 37.5mg.

The word 'unit' shall always be written in full, and not abbreviated to 'u' or 'iu', e.g. 'insulin 20 units' rather than 'insulin 20u'. Insulin should be written on the dedicated insulin chart where the word 'units' is already included, not on the main prescription chart.

If a medication does not have a strength (e.g. compound preparations), the dose shall be written in the form '1 tab', '2 caps', etc.

Roman numerals (e.g. i, ii) are a common cause of medication errors, and shall not be used.

Exact doses shall be specified for regular medications. Instructions such as '10-20mg' or '1-2 tabs' shall only be used for 'as required' medications (see also section 7.11).

For liquid medicines and injections, the actual dose (in mg) must be written on the chart – the dose MUST NOT be written as a volume*. This is because a number of products are available in more than one strength (e.g. 5mg/ml and 20mg/ml), with the risk that an incorrect dose could be administered if the wrong strength product is used. Pharmacists will annotate the prescription chart with the appropriate strength and the volume to be administered in cases where there is potential ambiguity.

7.8.6. **Route:** The intended route of administration shall be specified in full or using only the abbreviations below:

- Oral PO
- Intramuscular IM
- Subcutaneous SC
- Rectal PR
- Topical TOP
- Inhalation INH
- Sublingual SL

* except laxatives and simple linctus

- Nebuliser NEB
- Intravenous IV

Separate prescriptions shall be written if the same drug is to be given by two different routes. Instructions such as 'PO/IM' must not be used, as certain drugs have different doses depending on the route of administration.

7.8.7. **Frequency:** The interval between doses shall be specified, using conventional abbreviations such as BD, TDS, QDS or specifying in full, e.g. 'alternate days', 'every 2/52'.

7.8.8. **Date Drug Started:** Indicates the date the treatment commenced or the date of admission. This start date must be carried forward if the chart needs to be re-written. A change of dose or frequency must be written as a new prescription with a new start date, and not by alteration of existing instructions.

7.8.9. **Prescriber's Signature:** Each prescription must be validated by the full signature of the prescriber. Initials or abbreviated signatures alone are not acceptable, although these may also be included (in brackets) if they assist in identifying the prescriber.

7.8.10. **Pharmacy:** This box is intended for use by Pharmacy staff, and should not be used by the prescriber. Pharmacists may add such instructions to the chart (in green ink) where appropriate, for example when additional administration instructions are required, e.g. 'with/after food'.

7.8.11. **Times of Administration:** The intended time(s) of administration shall be clearly circled. If the intended administration time is not pre-printed on the chart, the required time of the dose shall be written in by hand.

7.8.12. **Discontinuation of treatment:** When treatment is to be discontinued the prescriber must cancel the prescription by drawing a diagonal line through it and dating and initialling the cancellation.

A vertical line shall also be drawn after the last signature in the administration recording boxes to ensure no further doses can be given. A 'cancelled' or 'discontinued' stamp may be used, but if so, it is important that the original prescription details are not obliterated.

If it is necessary to change the route or dose of the medicine the prescription must be cancelled and rewritten.

7.9. Prescribing 'once only' medication

7.9.1. Medications that are intended to be given as a single dose shall be written in the 'Once Only Medication' section on the front page of the chart.

7.10. Prescribing 'regular' medication

7.10.1. Medicines written in the 'Regular Medication' section of the prescription chart will be given every day at the times specified, until the prescription is cancelled or instructions are given to the contrary.

7.10.2. Treatment shall be kept under regular review and cancelled when no longer required.

7.10.3. If the drug is intended to be given for a fixed course, e.g. 5 days of an antibiotic this must be specified and a vertical line drawn through the administration recording boxes at the end of this period to ensure no further doses can be given.

7.10.4. Prescriptions for systemic antimicrobial therapy should always state the period for which treatment is to be given. Pharmacists will automatically stop a prescription for antimicrobials after 7 days unless specifically prescribed for longer. If treatment needs to be continued after this time, the prescription should be rewritten.

7.10.5. Prescription charts shall be rewritten by an approved prescriber once the administration record columns have been filled. A pharmacy medicines management technician may rewrite a prescription chart, but no doses may be administered until it has been signed by the prescriber.

7.11. Prescribing 'as required (PRN) medication

7.11.1. Prescriptions for 'as required' (PRN) medications shall be written in the 'As Required (PRN) Medication section of the chart.

7.11.2. In addition to standard prescription writing requirement, the prescriber shall specify:

- the intended indication (e.g. 'for pain', 'for nausea'),
- the minimum interval between doses (e.g. '6-hourly')
- the maximum number of doses that may be given within 24 hours (e.g. 'max. 3 doses in 24 hours' or 'max. 4mg in 24 hours').

7.11.3. Due consideration should be given to the BNF maximum daily dose for the drug, and the dosage instructions should normally ensure that this maximum cannot be exceeded. If it is considered

necessary to prescribe a 'PRN' dose which could potentially exceed the BNF maximum daily dose, this must be discussed with the patient and/or their representative and the rationale documented in the patient's healthcare record.

7.11.4. Alternative routes of administration for the same drug shall be written as separate prescriptions – the practice of writing the route as 'PO/IM' or 'PO/PR' is not acceptable.

7.11.5. Prescriptions for 'PRN' medication should take into account any regular doses of the same medication that the patient has also been prescribed. If the combination of the regular dose and the maximum daily permitted 'PRN' dose exceeds the BNF maximum daily dose for the drug, this must be discussed with the patient and/or their representative and the rationale documented in the healthcare record (see also Appendix 7 on prescribing antipsychotic medication above BNF limits).

7.11.6. The maximum number of doses to be administered and/or maximum duration of treatment should be stated where relevant.

7.11.7. **Review of 'PRN' medications:** The administration records for 'PRN' medications, and the patient's on-going need for these items to remain on the chart, must be reviewed at least every 7 days, or more frequently if clinically appropriate. The dates of such reviews must be documented in the patient's healthcare record.

If the review of the administration record indicates that a 'PRN' medication is being given on a regular basis, the clinical rationale for the treatment should be reviewed. If appropriate, the treatment shall be re-written in the 'regular medication' section of the chart.

If the review of the administration record indicates that the patient has not required any doses of a 'PRN' medication, consideration should be given to cancelling the prescription for the item.

7.11.8. **Record-keeping for 'PRN' medications:** Every 'PRN' dose of medication administered must be recorded on the chart with the date and time of administration. A corresponding entry must be made in the patient's healthcare record detailing the reason why the 'PRN' dose was given, and the date and time of administration.

7.12. Prescribing 'Variable Dose' medication

7.12.1. Prescriptions for medication requiring continuing changes of doses (i.e. chlordiazepoxide reducing regime) should be prescribed in the main section of the prescription chart.

7.12.2. A Clozapine starting regime should be prescribed on the supplementary chart designed for this purpose.

7.13. Prescribing medicines to take home

7.13.1. Different paperwork is used in Bedfordshire, Essex and Luton for obtaining discharge and leave medication.

In Bedfordshire and Luton: medication for leave or discharge should be prescribed on an outpatient prescription form.

In Essex: medication for leave must be prescribed in the relevant section of the prescription chart. Medicines prescribed for patients at the time of discharge must be written on separate four-copy discharge prescription form. All four copies of this form must be sent to the pharmacy when dispensing is requested. Three will be returned to the ward with the medicines - the white copy should be handed to the patient, the pink copy sent to the patient's GP and yellow copy filed in the patient's healthcare record. The green copy is retained by the pharmacy.

7.13.2. **Leave medication**: The period of leave must be specified in order to provide the correct quantity of regular medications. For 'as required' medication, the exact quantity to be supplied must be specified, e.g. 20 tablets, 200ml etc.

7.13.3. **Discharge medication**:

Normal duration of supply of medicines to take home should be 28 days. Duration for less time shall be clearly specified by the prescriber.

For 'as required' medication, the exact quantity to be supplied must be specified, e.g. 20 tablets, 200ml etc.

Patients with a history of self-harm in the last three months, and considered to be at high risk of taking an overdose of medication should receive no more than 14 day's supply. In this event, the care co-ordinator must make arrangements for the patient to be provided with further supplies of suitable duration until such a time as it is considered safe for the GP to take over prescribing responsibility.

7.13.4. Administration instructions shall be given to the patient or their carer by the doctor, pharmacist or nurse. Information leaflets should also be offered to the patient. A manufacturer's Patient Information Leaflet (PIL) for all medicines to be taken home will be issued by the pharmacy.

7.13.5. In some cases a period of training for the patient may be necessary prior to discharge.

7.13.6. **Monitored Dose Systems (MDSs):** Medicines may only be supplied in an MDS if their use has been agreed as part of the discharge planning process and the pharmacist is satisfied that adequate arrangements are in place for refilling (see also section 16.7).

7.13.7. **Fixed Courses:** For fixed courses of treatment, e.g. antibiotics, the prescription shall specify the number of days treatment required to complete the course.

7.13.8. **Clozapine**: It is normal for clozapine to be issued as part of discharge medication in a quantity sufficient to last until the patient's next blood test is due. If the correct quantity of clozapine labelled with dosage instructions was supplied whilst on the ward this may be issued from the ward.

The pharmacy must be informed of discharge so that the patient's contact details can be updated and an outpatient prescription written. Arrangements must also be made with the patient, community team and pharmacy regarding future blood tests and medication supply.

7.13.9. **Controlled Drugs:** Leave and discharge prescriptions for Controlled Drugs must comply with the requirements of the Misuse of Drugs Act, which are more stringent than for inpatient prescriptions. See Appendix 3 for further details.

It is an offence in law for a prescription for a controlled drug to be dispensed unless it is complete in every detail. Prescriptions not correctly written cannot therefore be dispensed and will lead to delay and inconvenience.

7.14. Remote prescription / direction to administer (verbal orders)

7.14.1. In exceptional circumstances, where medication is **currently prescribed** but where changes to the dose are considered necessary, the use of information technology, such as fax or email is acceptable to obtain confirmation of a change to the original prescription.

A verbal order is not acceptable on its own. The fax or email must be attached to the patient's prescription chart until the prescriber can confirm and sign the change on the chart. It is the responsibility of the prescriber to amend the prescription as soon as possible and in any case within twenty-four hours of giving the verbal order. The fax or email providing a verbal direction to administer must then be filed in the patient's healthcare record.

In an emergency, when no other form of communication is possible (i.e. no fax or email), a verbal order for dose changes may be accepted but must be witnessed by a second nurse.

This shall be written in the "once only" section of the patient's prescription chart in black ink by the nurse in charge, and then read back to the prescriber checking the patient's full name and date of birth, the name of the medicine, dose and route.

The nurse shall endorse the prescription "dose change instruction by telephone" and enter the date, time, name of the prescriber, her own name and signature and the name and signature of the witness. It is the responsibility of the prescriber to countersign the prescription as soon as possible and in any case within twenty-four hours of giving the verbal order.

If necessary, the doctor should also write up a new regular/PRN prescription for the medication. Under no circumstances should nursing staff write a new regular/PRN prescription for the drug on the patient's chart in anticipation of the doctor's signature. After the doctor has signed the patient's chart (and if necessary, written a new regular/PRN prescription), the nurse should record that this has happened in the patient's healthcare record.

7.14.2. Verbal orders for the administration of a **previously un-prescribed substance** are not normally acceptable. However, an exception may be made for short-acting sedation for highly agitated patients (e.g. lorazepam) that is required as a matter of urgency in a high risk situation, although a verbal order for such therapy can only be taken in exceptional circumstances and must be confirmed by either a fax or email from the prescriber before the dose is given.

The nurse shall endorse the prescription "dose instruction by telephone" and enter the date, time, name of the prescriber, her own name and signature and the name and signature of the witness. It is the responsibility of the prescriber to countersign the prescription as soon as possible and in any case within twenty-four hours of giving the verbal order.

The patient must be reviewed by the Consultant or their representative as soon as practicable.

7.14.3. Controlled Drugs cannot be administered on a verbal instruction.

7.14.4. A verbal order to administer is valid for one dose.

7.14.5. Text messages may not be used to confirm verbal orders, as no record can be retained.

7.14.6. Verbal orders are not permitted when the patient is under the age of eighteen years.

7.15. Prescribing for out-patients

7.15.1. When prescribing for out-patients, the following types of prescription forms shall be used within the Trust:

- 'in house' prescription forms (SEPT, Bedford Hospital or Luton & Dunstable Hospital)
- FP10HP prescription forms (green)
- Instalment FP10MDA forms (blue - only used within Substance Misuse Services)

7.15.2. Prescriptions for out-patients shall contain all relevant information as detailed in section 7.8.

7.15.3. A record should be made in the patient's healthcare record of what has been prescribed including the drug, dose, form and quantity.

7.15.4. **In-house prescription forms**: These can only be dispensed at the hospital pharmacy named on the form, and in Bedfordshire and Luton may be used for leave/discharge prescriptions as well as outpatient prescribing. (Leave and discharge prescriptions in Essex must be written on the appropriate stationery – see section 7.13.1)

7.15.5. The normal quantity to be ordered is 28 day's supply. Shorter duration should be specified by the prescriber. Patients with a history of self-harm in the last three months should receive no more than 14 days' supply.

7.15.6. **FP10HP forms:** These prescription forms can be dispensed at any community pharmacy. It is essential that these prescriptions are completed correctly and in full to avoid inconveniencing patients. If in doubt, prescribers should check the section on prescribing in the British National Formulary.

The normal quantity to be ordered is 28 day's supply. Shorter duration should be specified by the prescriber. Patients with a history of self-harm in the last three months should receive no more than 14 days' supply. Larger quantities may be prescribed if the product is one that GPs are unwilling to prescribe.

Only medication pertaining to the patient's mental health condition should be prescribed; other medications should be obtained from the patient's GP.

The only drugs which should be prescribed are those listed in the Trust Formulary or ones that have been specifically approved by the Medicines Management Committee for use (new and/or unlicensed products). FP10HP forms shall not be used to circumvent any restrictions on the prescribing of particular drugs.

Prescribing on FP10HP forms will be audited on a regular basis. Any apparent inappropriate use of these forms will be brought to the attention of the relevant Clinical Director

FP10HP forms may not be used for private patients or for staff prescriptions.

7.15.7. **FP10MDA forms:** These forms are only available within Substance Misuse Services for use when clients are required to obtain their medication on an instalment basis, e.g. daily methadone. The forms may be computer generated and a copy should be kept in the patient's healthcare record.

Other non-instalment prescribing within these services should be undertaken on the normal FP10HP form.

7.15.8. **Controlled Drugs:** outpatient prescriptions for Controlled Drugs must comply with the requirements of the Misuse of Drugs Act, which are more stringent than for inpatient prescriptions. See Appendix 3 for further details.

7.15.9. FP10HP and FP10MDA prescription forms are controlled stationery which must be kept securely. Refer to Appendix 8 for further information.

7.16. Prescribing for personal use

7.16.1. No prescriber shall issue a prescription for themselves, members of staff or family and friends.

7.16.2. Members of staff, including medical staff, shall obtain any medication they require for their own treatment from their GP, or over the counter from a community pharmacy.

7.16.3. In the event of illness occurring whilst on duty, the Occupational Health Service should be contacted.

7.16.4. Medicines held on wards are for the treatment of Trust patients only, and must never be given to staff or visitors.

8. PATIENT GROUP DIRECTIONS

8.1. Patient Group Directions (PGDs) permit nurses and members of some other healthcare professions to supply or administer medicines in specific circumstances without the need for a valid prescription.

8.2. A PGD is a written instruction for the administration of named medicines in specified clinical circumstances. PGDs apply to groups of patients or other service users who do not need to be individually identified prior to presentation for treatment.

8.3. If it is felt that a PGD is required to meet a specific need, this should initially be discussed with the Chief Pharmacist. If it is decided that a PGD is the most appropriate solution, the Chief Pharmacist will arrange for the preparation of a draft PGD.

8.4. Each Patient Group Direction shall be drawn up by an appropriate group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. The PGD must be prepared using the Trust template (see Appendix 9) which provides notes for completion. It shall be valid only if approved by all of the following:

- A senior doctor involved in developing the PGD
- A senior pharmacist involved in developing the PGD
- A Lead Nurse / Allied Health Professional representing those who will supply under the PGD
- The Medicines Management Committee
- Clinical Governance lead on behalf of the Trust

8.5. Each Patient Group Direction shall include details of the clinical situation in which it applies, including: -

- criteria for confirming the clinical condition
- clinical criteria under which patients are excluded

8.6. Each Patient Group Direction shall include details of staff who are authorised to act in accordance with it, including: -

- the professional qualification required (PIN Number)
- any specialist qualification, training or experience required
- requirements for continuing training or education

8.7. Each Patient Group Direction shall include details of the medicines which it covers including: -

- the name, form and strength of the medicine which may be administered or supplied
- the dose(s) which may be administered and the criteria for choice of dose.
- the route(s) of administration which is permitted the frequency of administration which is permitted and the total number of doses which may be given within a stated time period
- details of any follow-up treatment which is required
- details of information or advice to be given to the patient
- instruction for identifying and managing any adverse outcomes

- arrangements for referral to medical advice contra-indications to administration or supply of the medicines, including concurrent medication

8.8. Each Patient Group Direction shall include the following:

- the names of the persons involved in drawing it up
- the signatures of the managers approving it in accordance with section 8.4
- the date on which it was approved and an expiry date, after which is no longer valid

8.9. Any patient excluded from treatment under a Patient Group Direction shall be referred to a doctor so that appropriate medicines may be prescribed.

8.10. All medicines administered or supplied under a Patient Group Direction shall be recorded in the healthcare record and signed and dated by the practitioner.

8.11. Any health professional authorised to act in accordance with a Patient Group Direction shall: -

- have the written authority of the head of their profession or nominated deputy
- satisfy the head of his/her profession that he is competent and has received appropriate training
- sign a copy of the relevant Patient Group Direction to confirm that s/he has understood its content
- be aware of the need for vigilance in reporting any adverse outcomes
- be experienced with patients being treated in accordance with the Patient Group Direction.

8.12. The master copy of each Patient Group Direction will be held by the Director of Clinical Governance & Quality. Copies of Patient Group Directions will be held by the Chief Pharmacist.

8.13. Records of staff authorised to act in accordance with Patient Group Directions shall be held by the Director of Clinical Governance & Quality. A list shall be provided to the Chief Pharmacist.

9. SUPPLY OF MEDICINES BY PHARMACY

9.1. Stock items

9.1.1. Medicines and other pharmacy items that are regularly used in each clinical unit will be included on a stock list. This shall be agreed between the appropriate ward/team manager and pharmacy department. Each ward/unit should keep a copy of its

current stock list in a readily accessible place such as the treatment room.

9.1.2. These medicines may only be administered to a patient by a nurse and never issued to them to be self-administered. Stock items are retained on the ward/unit regardless of whether they are currently being used for the treatment of patients.

9.1.3. Patterns of medicines usage change over time, and stock lists should be reviewed annually. Alterations to the stock list and/or stock levels may only be implemented after discussion between the ward/unit manager and a pharmacist or pharmacy technician.

9.1.4. Where a pharmacy 'top-up' service is in operation, a member of pharmacy staff will restock clinical areas on a regular basis. The ward/team manager remains responsible for identifying fluctuations in medicines requirements, ordering appropriately and notifying pharmacy when it becomes necessary to review the current stock list.

9.1.5. Where a 'top-up' service is not in operation, computer-generated stock sheets will be completed and signed by the nurse in charge and sent to the pharmacy. This system may need to be used for all wards in the event of an emergency such as a ‘flu pandemic.

9.1.6. Inevitably, situations will arise where a ward/unit runs low on stock of an item before the next pharmacy ‘top-up’ visit is due. In this event, the product(s) required shall be requested in writing, signed dated and sent or faxed to the pharmacy.

9.1.7. For units supplied from Bedford Hospital where duplicated stock books are used, the original top copy of the requisition should still be sent to the pharmacy (clearly marked ‘Faxed to pharmacy on …. (date)….’).

9.1.8. Some Community Mental Health Teams (CMHTs) in Bedfordshire and Luton use ‘stock order cards’ for ordering medicines from the pharmacy. The quantity of each medicine required should be entered on the appropriate card, and the cards sent to the pharmacy together with the pharmacy box.

9.1.9. A delivery note will be issued by the pharmacy when stock medicines are supplied. The nurse in charge/team manager or their deputy must check and sign this and notify the pharmacy of any discrepancies immediately.

9.2. Controlled drugs

9.2.1. Controlled drugs shall be ordered by the nurse in charge or her deputy in the appropriate requisition book. A separate page must be completed for each preparation and the name of the drug shall be written in full.

9.2.2. Any nurse who is authorised to requisition controlled drugs shall provide a specimen of her signature to the pharmacy department of any hospital in which she may work.

9.2.3. On receipt the nurse in charge shall check the drugs, sign the copy of the requisition and immediately record the receipt of Schedule 2 controlled drugs, and any locally required Schedule 3 drugs, in the controlled drugs record book (see Annex 1 of Appendix 1). The receipt shall be witnessed by a second nurse, who shall also sign the controlled drugs record book

9.2.4. The controlled drug record book and order books must be retained in the clinical area for two years after the date of the last entry. It may be destroyed after this period.

9.2.5. Detailed procedures for the handling of controlled drugs are set out in Appendix 3. These must be followed at all times.

9.3. Items for individual patients

9.3.1. Medicines that are not used sufficiently frequently to warrant inclusion on the stock list will be supplied by pharmacy on an individual-patient basis or as 'temporary stock' items (usually where there is more than one patient on the ward requiring that medicine). These will be supplied in containers labelled with the name of the product, the patient's name or 'temporary stock', and the date of supply.

9.3.2. Non-stock items including items dispensed for individual patients and temporary stock will be endorsed as such on the prescription chart by the ward pharmacist.

9.3.3. These medicines should only be held on a ward/unit whilst there is a patient requiring treatment with them, although they may be retained on the ward for patients who are on short periods of leave. Once the patient has been discharged, any remaining temporary stock medicines will be removed by pharmacy staff (Essex only) or disposed of as pharmaceutical waste on the ward (Bedfordshire and Luton).

9.3.4. Those labelled as 'temporary stock' may be used for other patients prescribed the same drug on the same ward. Items labelled with a patient's name may not be used for another patient.

9.3.5. If a patient is started on treatment with a non-stock medicine, it is the responsibility of the ward/unit to initiate a supply from the pharmacy (except for wards that receive a daily ward pharmacist visit, when the pharmacist will usually initiate the supply). When items are required urgently, after a pharmacist's ward visit or where a pharmacist does not routinely visit, non-stock medicines

should be ordered by sending or faxing the original prescription chart to the pharmacy, with a clear indication of which item(s) are required.

9.3.6. Prescriptions may be faxed from clinical areas on a site remote from a pharmacy. A copy of the complete prescription chart together with a requisition signed by the nurse in charge should be faxed, including copies of every page of the chart should be sent, with the exception of any unused administration record pages. A copy of the 'as required' page must be included, even if no 'as required' medications have been given. Original prescriptions should be seen by a pharmacist within 7 days of supply, where possible.

9.3.7. Once a supply of a temporary stock medicine has been initiated, any further supplies that are required will usually be arranged by the pharmacy staff. However, if a patient runs out of a temporary stock medicine, the prescription chart (or a faxed copy) should be sent to the pharmacy as described above, with a clear indication of which item(s) are required (see section 9.3.5).

9.4. Patients' own medicines

9.4.1. Patients are encouraged to bring their own medication into hospital at admission, as this can assist in the identification of the treatments they are currently taking. The Department of Health also encourages the continued use of patients' own medicines whenever appropriate, as this can help to reduce wastage in the NHS.

9.4.2. Medicines brought into hospital or other clinical areas remain the patient's property and all medicines retained on a ward/unit must be recorded in the patient's healthcare record by a member of the nursing or pharmacy staff, and as part of the patient's property.

9.4.3. If the medicines are not required they may, with the patient's consent, be disposed of on the ward in accordance with Appendix 10. Consent must be recorded in the patient's healthcare record using the form provided as part of Appendix 11. Alternatively, the medicines shall be stored in a locked medicines cupboard on the ward to return to the patient on discharge or returned to a relative or carer for safe keeping.

When the medicines are removed from the clinical area details of disposal or onward transfer should also be recorded in the healthcare record.

9.4.4. Patients' own medicines may only be used when they can be positively identified and have been approved for use. In Essex this will be undertaken by a pharmacist or pharmacy technician.

In Bedfordshire and Luton nursing staff currently undertake this role and will continue to do so, until such time as pharmacy services are able to take on this role.

9.4.5. Assessment shall include checking that medicines are in appropriate containers and clearly labelled, following the algorithm in Appendix 11. The suitability of these medicines shall be recorded in the patient's healthcare records

9.4.6. If a patient's own medicines have been assessed as suitable for continued use, they may be used for the future treatment of that patient only, with their written consent. This should be obtained by using the form provided as part of Appendix 11). A patient's own medication must never be used to treat other patients.

Patients' own medicines that are being used for inpatient treatment will be endorsed on the prescription chart by the ward pharmacist. Patients' own medicines shall be kept in a locked medicines trolley or medicines cupboard.

If a patient is self-administering his medicines, he may continue to use his own medicines during an in-patient stay if the consultant agrees to this.

9.4.7. If patients' own controlled drugs are to be used a record of each administration must be kept in the ward controlled drug record book. A separate page must be used for each drug held for individual patients. As soon as these controlled drugs are removed from the ward a line shall be drawn through the remainder of the page to prevent it being used again. Refer also to Appendix 3 which explains the entries required in the CD Register for the receipt and administration of a patient's own CDs

9.4.8. If a newly-admitted patient has not been seen by a prescriber before the time that a dose of their own medication is due, the patient should be permitted to self-medicate provided the nurse is satisfied that:

- the correct medicine has been brought in by the patient
- the medicine is in a suitable condition to use
- the treatment is still necessary for the patient's well-being

9.4.9. Before permitting self-medication the nurse should check with the prescriber responsible for the patient that the treatment is clinically appropriate, and record the prescriber's advice in the patient's healthcare record.

9.4.10. At discharge, a patient's own medicines may be returned to the patient provided the dosage instructions have not changed. If only a few days of medication are left, an additional supply

should be ordered as part of the discharge prescription (see section 7.13).

9.4.11. If a medicine has been discontinued, or the dosage changed, the patient's consent should be sought to retain their medicines on the ward/unit rather than returning them. Any such medicines should then be disposed of in accordance with Appendix 10.

9.4.12. A patient's own homeopathic, herbal and over-the-counter medicines may be retained on the ward and administered to the patient provided they have been prescribed on the prescription chart and have been assessed as fit to use.

Prescribers shall only prescribe such products if it is within their knowledge and competence to do so. Any such medicines must be clearly marked with the patient's name, and must never be administered to other patients. If the patient requires further supplies of such treatments, family or friends will need to be asked to purchase these on the patient's behalf.

9.4.13. Patients admitted through the Accident and Emergency department must have their medicines sent to the clinical area, together with documentation of any doses administered in that department.

9.4.14. Community teams may store medicines for patients who are at risk of self-harm. When a patient uses his own medicines during an in-patient stay or under the care of a community team, pharmacy or nursing staff must ensure that a reasonable quantity is supplied on discharge. This will normally be four weeks supply but must be at least two weeks, unless the patient has a history of self-harm and the prescriber indicates that a smaller supply is required.

Full details of medicines brought into a community team base and stored on behalf of a patient must be recorded in a book/folder and kept with the medication in a locked medicines cupboard. When the medicines are removed from the clinical area details of disposal or onward transfer should also be recorded in the same book/folder.

9.5. Medicines supplied for leave / discharge

9.5.1. Medicines for leave or discharge supplied by the pharmacy shall be locked in a medicines cabinet immediately upon receipt.

9.5.2. All medicines given to a patient on discharge, except patient's own drugs which they brought with them at admission which may be returned, shall be individually dispensed by the pharmacy department for that patient. It is not necessary to provide a new supply of any medicines, if the pharmacist considers that the

patient has a sufficient quantity which is still appropriate to his needs.

9.5.3. If a patient is going on leave an individual supply of medicines shall be dispensed by the pharmacy for the duration of the leave. Where individual patients have a supply labelled with full directions, this may be issued to the patient for leave with the agreement of the multidisciplinary team. Under no circumstances must stock medicines ever be issued to a patient for leave. If patients' relatives or carers collect the medicines from the pharmacy or ward in the absence of the patient, ID must be confirmed.

9.5.4. Before the patient leaves the ward, the leave/discharge medication should be checked against the prescription chart to confirm that all details are correct, in case there have been recent changes to the treatment. Details to be checked include:

- the patient's name
- the name and strength of the medicine
- the dose
- the directions
- the quantity

9.5.5. This check should be done by a registered nurse in conjunction with the patient. Any discrepancies should be reported to the pharmacy immediately. It is also important that the patient receives adequate information about their medicines prior to discharge. The patient should know the purpose of their medicines, how to take them, and for how long they are to be taken. It is the responsibility of the nurse overseeing the discharge process for the patient to ensure that adequate information has been provided.

9.5.6. Healthcare professionals should ensure that all necessary information about the patient's medicines is accurately recorded and transferred with the patient, and that responsibility for on-going prescribing is clear.

9.5.7. Ordering, delivery and receipt of Controlled Drugs for leave/discharge is the same as for other leave/discharge medicines (i.e. the CD Order Book does not need to be used). However, when the ward/unit receives a patient's leave/ discharge medication which includes a CD, the medicines shall be stored in the CD cupboard until they are ready to be handed over to the patient. **NB.** It is not necessary to enter leave/discharge CDs in the ward's CD Record Book.

9.5.8. With the agreement of the Chief Pharmacist, Consultant(s) and the Appointed Nurse in Charge, certain clinical areas may be issued with a limited range of preparations ready packed for patients to take home/use at home. These packs must:

- be provided by the pharmacy department
- be issued only in accordance with a prescription written by a registered prescriber
- have the label endorsed with the patient's name and the date of supply.
- be labelled with clear directions for use.
- no alteration may be made to the label or the contents.

9.5.9. A register must be kept of all pre-packs issued. This register will be issued by the pharmacy and must be held in the clinical area at all times. Details to be recorded are patient's name, time, date, name of medicine, quantity issued and signature of two members of staff, one of whom shall be a first level nurse or registered prescriber.

9.6. Obtaining medicines when pharmacy is closed

9.6.1. Whenever feasible, the medicines required by a ward/unit shall be ordered via a hospital pharmacy during normal opening hours. However, it is recognised that it may occasionally be necessary to obtain urgently-required medications when the pharmacy is closed.

9.6.2. In an emergency, a medicine, other than a controlled drug may be borrowed from another clinical area provided that it is transferred in the original, fully labelled pack, and the transfer has been authorised by the nurses in charge of both wards.

9.6.3. Such medicines must be transferred in their original packaging, as supplied by pharmacy, and not decanted into other containers. A signed record must be kept on both wards involved in any transfers of stock drugs, in the ward diary. Individual strips of medicines must not be removed from the original package and transferred. The nurse in charge must inform the pharmacy department as soon as it reopens, so that supplies can be replenished to the issuing ward.

9.6.4. Individually-dispensed medicines (including 'temporary stocks') must not be transferred between wards unless the patient is being transferred (see section 9.7),

9.6.5. If a Controlled Drug needs to be administered as a matter of urgency and the ward/unit does not have the drug in stock, a **single dose** may be obtained from another ward/unit that does

have the drug, provided this is authorised by both the nurses in charge. The procedure set out in Appendix 3 MUST be followed.

9.6.6. **In Essex:** Medicines may be obtained from the emergency drug cupboards at either Basildon Mental Health unit, Brockfield House or Rochford Hospital. There is a stock list on the outside of each cupboard and the key can be obtained from the site officer/unit coordinator. If a medicine is required urgently and is not available from another clinical area or the emergency drug cupboard, the doctor or nurse in charge should telephone the on-call pharmacist via the Contact Centre (0300 123 0808), who either will advise of a suitable alternative or make arrangements to dispense the medicine.

9.6.7. **In Bedfordshire and Luton:** Pharmacy services are not provided by the Trust and the service level agreements do not include provision of an on-call service. In wholly exceptional circumstances, when all other avenues have been explored it may be possible to obtain an urgently-needed medicines via the on-call pharmacy service at Bedford Hospital or the Luton and Dunstable Hospital. The doctor or nurse in charge should telephone the Contact Centre (0300 123 0808) who will arrange to contact the relevant hospital.

9.7. Transfer of medicines when a patient moves ward

9.7.1. If a patient moves from one ward to another medicines that have been individually dispensed for the patient must be sent to the new ward along with his other property.

9.7.2. If a patient is transferred to another ward/unit, any individually-dispensed medicines bearing the patient's name must be transferred.

9.7.3. Stock items should not generally be transferred between wards, but this is permissible if the ward receiving a transferred patient does not keep the drug in stock and there is likely to be a delay in obtaining a supply from the pharmacy. In this event, the medicine must be transferred in its original packaging, as supplied by pharmacy, and not decanted into other containers.

9.7.4. The pharmacy must be notified at the earliest opportunity that medicines have been transferred with a patient, so that stocks can be replenished as necessary.

9.8. Transfer of medicines when a patient moves to another healthcare setting

9.8.1. If a patient is transferred to another healthcare setting, for example to an acute hospital or care home, a copy of the prescription chart, discharge note or other record of current

medication should accompany them. Healthcare professionals should ensure that all necessary information about the patient's medicines is accurately recorded and transferred with the patient, and that responsibility for on-going prescribing is clear.

9.8.2. Wherever possible, medicines should also be transferred to ensure continuity of treatment. This will only be possible for medicines that have been dispensed specifically for that patient and are labelled with full directions for administration. Stock medicines, and medicines that are not labelled with full directions, must not be transferred to another healthcare setting.

9.8.3. Where a transfer is planned, discharge medication should be ordered from the pharmacy to be transferred with the patient.

10. DISPENSING

10.1. Dispensing and the supply of medicines will be undertaken by a pharmacy department within the Trust or via a service level agreement with another appropriate organisation.

10.2. Pharmacy services will be provided in accordance with Standard Operating Procedures (SOPs) approved by the Chief Pharmacist of the relevant organisation. These will be regularly reviewed and updated in response to any event that may affect patient safety, or when new legislation or guidance is issued which affects what is included within a particular SOP.

10.3. When dispensing medication a pharmacist will check that:

- the prescription is clearly and correctly written to avoid misunderstanding and error
- the medicines prescribed are appropriate for the patient
- the dose prescribed is appropriate for the patient.

10.4. A prescription may be amended by a pharmacist following verbal consultation with the prescriber. Such alterations shall be initialled by the pharmacist and endorsed 'PC' ('prescriber contacted').

10.5. Amendments to the prescription which are made and signed by the pharmacist in accordance with procedures previously agreed by the Medicines Management Committee are acceptable.

10.6. At the discretion of the pharmacist, and in the absence of facilities to fax or email, a prescription may be dispensed following a verbal order from a prescriber. Full details must be given including drug allergies and concurrent medication, and the age and weight of the patient if a child. A signed prescription must be provided within twenty four hours.

10.7. Pharmacy staff are also responsible for:

- ensuring the quality, efficacy and safety of all medicines used within the Trust
- advising on security and storage of medicines
- compounding medicines in a form suitable for administration to the patient
- annotating prescriptions to render them accurate and providing any relevant additional information on container labels, or in the form of a patient information leaflet.

10.8. Approved names shall be used for prescribing, dispensing and labelling of medicines. Pharmacists will normally supply the most appropriate branded or generic product bearing in mind the clinical needs of the patient, the quality, efficacy and safety of the medicine and any financial implications.

10.9. Prescription Charges

10.9.1. Prescription charges are payable in respect of drugs supplied to out-patients and day-hospital attenders.

10.9.2. Prescription charges are not payable in respect of drugs supplied on discharge to in-patients or in respect of any drugs administered whilst the patient is on health service premises. Patients treated under the terms of supervised Community Treatment Orders (CTO) are also exempt, provided they receive their medicines from a hospital pharmacy.

10.9.3. Prescription charges normally shall be collected by the pharmacy department, but staff who issue medicines from other departments, including supply under a PGD, are responsible for ensuring that the appropriate charge is collected.

10.9.4. If a patient requires medicines for immediate treatment and has no cash, staff may issue an invoice in respect of the prescription charge.

10.9.5. The prescription charge is not refundable unless it has been levied incorrectly or if no proof of exemption can be supplied. If this is the case an NHS receipt form FP57 can be issued by the pharmacy for reclaiming the prescription charge (only at the time the prescription charge is paid).

10.9.6. Credit is not possible in respect of medicines returned by the patient at a later date.

11. TRANSPORT OF MEDICINES

11.1. Medicines may only be transported by authorised courier services, portering services or members of Trust staff.

11.2. Following a pharmacy 'top-up' visit, supplies of stock items will be transported to the ward/unit in a sealed pharmacy ward box. Small quantities of medications ordered on a day-to-day basis will be transported in sealed, tamper-evident bags. The courier/porter will be asked to sign for the collection of such containers from the pharmacy.

11.3. A consignment note stating the number of sealed containers to be transported shall be completed by pharmacy staff and accompany each load. A signature shall be obtained each time the consignment changes hands.

11.4. Members of staff may collect medication from pharmacy. This task may be delegated to any member of staff by the nurse in charge, but the person collecting the medicines must be prepared to show their Trust ID card. The pharmacy may refuse to release medicines to staff who cannot produce identification

11.5. **Transport of Controlled Drugs**

11.5.1. **In Essex:** Controlled drugs may be delivered to the appropriate clinical area by a member of Trust staff, Trust transport services or authorised courier services, in a tamper-evident package, provided that a signature is obtained on the appropriate document each time the package changes hands. The completed documentation will be archived in pharmacy. Upon delivery to the clinical area the package shall be handed to the nurse in charge who shall sign to acknowledge acceptance. The messenger must be a person employed on Trust business.

11.5.2. **In Bedfordshire and Luton:** Controlled Drugs may be transported to wards/units by portering services or collected from the pharmacy by a member of the nursing staff. They may not be transported by courier services. Refer to Appendix 3 for further information.

11.6. Any vehicle used to transport medicines shall be kept locked at all times.

11.7. Nursing staff shall carry medicines in a locked bag when transporting them in the community. This shall be transported in the locked boot of a vehicle and any remaining medicines must be returned to Trust premises at the end of a shift.

11.8. When a member of community staff delivers medicines to a patient's home they must be handed over in person to the named recipient or a nominated representative named in their care plan. They must not be put through a letter box.

12. RECEIVING MEDICINES FROM PHARMACY

12.1. All medicines will be delivered from pharmacy in a sealed box or tamper-evident bag.

12.2. A registered nurse must check the medicines received against the delivery note and report any discrepancies to the pharmacy at the earliest opportunity. Delivery notes must be signed and retained for two years for audit purposes.

12.3. All medicines must immediately be transferred to a locked medicines cabinet or trolley.

12.4. Controlled Drugs must be signed as received in the CD Order Book, and immediately be entered into the CD Record Book. Refer to Appendix 3 for further information.

13. STORAGE AND SECURITY OF MEDICINES IN CLINICAL AREAS

13.1. The Appointed Nurse in Charge is responsible for the safe and secure storage of all medicines held on their ward/unit.

13.2. The design and location of all medicines cabinets and trolleys must be approved by the Chief Pharmacist or a designated senior pharmacist.

13.3. The following general principles for medicines storage shall apply:

- All medicines shall be stored in a secure area that is not accessible to patients or the public, such as a locked clinical room. If no such area is available for storing the medicines trolley, it must be securely chained to a wall whenever it is not in use.
- All medicines cabinets, fridges and trolleys must be kept locked whenever they are not in use. Medicines cabinets must be securely attached to a wall and comply with the requirements of BS2881-1989.
- All medicines (including dressings) shall be stored in conditions that minimise the risk of deterioration due to humidity, light, extremes of temperature or exposure to other substances.
- Medicines packaging shall be checked for any special storage requirements, such as the need for refrigeration. Medicines suitable for storage at room temperature must be stored at or below 25°C.
- The temperature of the room in which medicines are being stored must be monitored on a daily basis. If the temperature cannot be maintained at 25°C or below, the ward manager must contact the Estates Department to arrange for a temporary or permanent solution to be installed. Please refer to Appendix 12 for further guidance on temperature monitoring.
- Items such as food, patients' valuables or personal property must not be stored in medicines cabinets or fridges under any circumstances.

13.4. All medicines shall be stored in one of the following locked cupboards, as appropriate: -

13.4.1. **Internal medicines cupboard**: To be used for the storage of internal medicines such as tablets, capsules, internal liquids, inhalers and injections, with the exception of Controlled Drugs and items that require refrigeration. Externally-applied medicines that are intended to have a systemic effect, e.g. hormone replacement patches, glyceryl trinitrate patches, should be treated as internal medicines.

13.4.2. **External medicines cupboard**: To be used for the storage of medicines intended for external application, e.g. creams, ointments, lotions etc.

13.4.3. **Reagent / disinfectants cupboard**: To be used for the storage of urine-testing products and antiseptic/disinfectant products

13.4.4. **Controlled drugs cupboard**: To be used solely for the storage of medicines subject to the Misuse of Drugs Act, 1971. The CD cupboard must meet the requirements of the Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007, and be securely attached to a wall with at least two rag-bolts. It must be separate from other medicines cabinets or located inside an internal medicines cabinet. All CD cupboards must have their own unique 7 lever, key-retaining mortice lock.

13.4.5. **Medicines refrigerator**: To be used only for the storage of medicines requiring refrigeration. Enteral feeding products requiring refrigeration may be stored in the medicines refrigerator if there is insufficient storage space in a general-purpose refrigerator.

13.5. Where separate cupboards are not available, internal and external medicines shall be stored on separate shelves in a locked cupboard. Any new medicines cupboards must comply with BS2881-1989 or the Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007, as relevant.

13.6. Medicines in current use may be stored in a portable, lockable medicine trolley. When not being used for a medicines administration round, the medicines trolley shall be kept locked and either securely chained to a wall or locked in a secure area such as a clinical room. The medicines trolley must never be left unattended at any time when unlocked.

13.7. A limited range of medicines for life-threatening emergencies may be kept on a resuscitation trolley or in an emergency drugs box.

13.8. Medicines which have been individually dispensed for self-administration by a named patient or for those wards where “one-stop dispensing” takes place may be kept in a locked cabinet within the vicinity of the patient’s bed.

13.9. Medicines must never be transferred from one container to another. Once a dose of any medicine has been removed from its container it shall never be returned. If not required it must be discarded, by placing in a sharp's container or pharmaceutical waste bin. Where half a tablet from a blister pack is needed for a dose, the remaining half shall be discarded. (See special requirements for controlled drugs, Appendix 3).

13.10. Custody of keys

13.10.1. The Appointed Nurse in Charge is entirely responsible for the custody of the medicines on their ward/unit, and this includes responsibility for the keys to medicines cabinets, trolleys, etc. This responsibility may be delegated to another registered nurse (e.g. the nurse in charge for a shift), but no other person shall have access to the medicines cabinets and keys unless authorised by the Appointed Nurse in Charge. The keys must not be handed over to medical staff.

13.10.2. All medicine cupboards and refrigerators shall be kept locked. The keys shall be held on the person of the nurse in charge of the clinical area or her designated deputy. The keys to medicines cabinets, trolleys, etc. must be kept together on a single key ring reserved solely for these keys, and each key should be clearly labelled.

13.10.3. The keys to the controlled drugs cupboard shall be kept on a separate bunch to the keys for other medicines storage facilities.

13.10.4. Consultant Practitioners and Team Managers should securely store a spare set of keys for each of the clinical areas under their management. Spare keys are not held by pharmacy or estates departments.

13.10.5. At shift changeover, the nurse in charge must ensure that the keys are passed on to the nurse in charge of the incoming shift. In the event of no suitably qualified person being present on the ward/unit, the keys must be handed over for safe keeping to the nurse in charge on a nearby ward. This information must be made known to the staff on the ward.

13.10.6. Loss of medicine cupboard keys will be reported to the appropriate Manager and pharmacist immediately.

13.11. Temperature monitoring

13.11.1. The temperature of all areas where medicines are stored, including medicines refrigerators, shall be monitored on a daily basis and temperatures recorded. Temperatures above 25°C for rooms and outside the range 2-8°C for refrigerators shall be reported to the Consultant Practitioner or Team Manager and to pharmacy, who will advise on the action to be taken.

13.11.2. Medicines refrigerators must be regularly defrosted (if not self-defrosting) and be kept clean and locked. Daily records of fridge temperature shall be maintained, using a maximum/minimum thermometer. Please refer to Appendix 12 for further guidance on fridge temperature monitoring.

13.11.3. If the fridge temperature falls outside the range 2-8°C, any medicines shall immediately be transferred to another medicines fridge until the fault has been investigated and rectified. The Estates Department should be contacted to investigate the fault, and advice should be sought from a pharmacist about the suitability for future use of any medicines that had been stored in the faulty fridge. Medicines shall be quarantined until this has been obtained and must not be administered until released by a pharmacist as suitable for future use.

13.12. Stock rotation

13.12.1. Stocks of medicines must be used in rotation and expiry dates checked regularly to avoid wastage. Nursing staff will inspect ward/unit medicines cabinets at regular intervals to ensure that medicines are in date and are being stored correctly. Cupboards shall be kept neat and tidy to facilitate this process.

13.13. Controlled Drugs

13.13.1. All Schedule 2 and 3 Controlled drugs must be stored in a locked controlled drug cupboard. Any new cupboards must comply with the Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007. It is recommended good practice that all controlled drugs cupboards conform to these standards.

13.13.2. All stocks of Schedule 2 controlled drugs, and any drugs required locally to be recorded in the CD record book, shall be checked by nursing staff at least once a week. Refer to Appendix 3 for further information on the process required.

13.14. Advice to patients

13.14.1. Nurses should advise patients on the safe storage of their medicines at home, seeking advice from pharmacy as necessary.

13.15. Losses and discrepancies

13.15.1. The loss of any medicines from a clinical area must be notified to the nurse in charge who will notify the appropriate senior manager and pharmacy manager. The manager and pharmacist will decide the appropriate action required.

13.15.2. If the missing items cannot immediately be found CPG3 *Adverse Incident Procedural Guidelines* shall be followed.

13.15.3. In the event of a discrepancy in the stock balance of a Controlled Drug, the nurse in charge must immediately investigate the reason for the discrepancy. An incorrect or missing entry in the CD Record Book must be sought, but if this is not found, the discrepancy must be reported immediately to the senior manager responsible for the ward/unit, to the pharmacy and to the Accountable Officer for controlled drugs. Refer to Appendix 3 for further information.

13.16. Closure of a ward or unit

13.16.1. If a ward or unit is to close, arrangements must be made with a pharmacist for any Controlled Drugs to be returned to the pharmacy (Essex only), destroyed or transferred to another ward/unit.

13.16.2. If a ward/unit is to close for only a few days, other medicines may, with the agreement of a pharmacist, remain on the ward provided there is adequate security to prevent unauthorised access.

13.16.3. If a ward/unit is to close for a longer period, arrangements should be made with a pharmacist for the stock of medicines to be returned to the pharmacy (Essex only), destroyed or transferred to another ward/unit.

14. PREPARATION OF MEDICINES FOR ADMINISTRATION

14.1. Wherever possible, medicines will be supplied by pharmacy in a form suitable for direct administration to the patient.

14.2. When medicines have to be measured, mixed or reconstituted in a clinical area prior to administration, this shall be undertaken in a designated clean area, i.e. clinical room.

15. ADMINISTRATION OF MEDICINES

15.1. Medicines shall only be administered in accordance with an official written order (a prescription chart or prescription form) which has been signed by a suitably-qualified prescriber, or in accordance with a Patient Group Direction (see section 8). See section 7.14 for information on remote prescription or direction to administer (verbal orders).

15.2. Medicines may only be administered by suitably qualified nursing staff, or staff who have undergone appropriate training and assessment (see section 22). Staff who are authorised to prescribe are also authorised to administer medicines.

15.3. Nursing staff who administer medicines are professionally accountable for their actions or omissions. The standards that apply to the administration of medicines are contained in:

- NMC Code of Professional Conduct
- NMC Standards for Medicines Management

A nurse bears professional accountability for every action taken. A registered nurse may therefore decline to administer a medication if she feels that to do so would be outside the limits of her knowledge or competence, and that to do so would be unsafe. However, she must be prepared to justify her reasons for taking such action.

15.4. Ward/unit managers have a responsibility to ensure that all staff who administer medicines are suitably qualified and trained to do so, and are familiar with the relevant sections of this procedural guideline.

15.5. Ideally, two people should be involved in the medicines administration process, but it is accepted that at certain times and in certain circumstances, this may not be feasible. Where two persons are involved the responsibility for the accuracy of the administration is attached to the senior registered nurse, who shall sign the administration record. However, both shall check each step of the administration process.

15.6. Medicines must be administered directly from the labelled container in which they were received from pharmacy and never transferred into another container prior to administration.

15.7. Medication shall normally be administered in the form in which it is supplied. If this is not possible for physical reasons then the advice of a pharmacist should be sought on appropriate alternatives.

15.8. If a syringe is required to administer an oral liquid medicine it must be a specific oral syringe. Under no circumstance must an intravenous syringe be used for this purpose.

15.9. The administration of medication must be recorded on the patient's prescription chart immediately after administration. Failure to record administration will be considered an adverse incident and must be reported in line with CLP3. Non-administration must be recorded on the prescription chart using the appropriate reason code.

15.10. If a patient has specific concerns regarding their medicines a summary of the discussion between them and a healthcare worker should be made in the patient's health care record.

15.11. Situations requiring specific care

15.11.1. **Anticoagulants:** If anticoagulants (e.g. heparin and warfarin) are to be administered the nurse must check that the patient's blood clotting (e.g. INR for oral anticoagulants) is being monitored regularly and refer to the patient's anticoagulant clinic card as appropriate. (See also NPSA Patient Safety Alert 18 *Anticoagulants: 'Actions that can make anticoagulant therapy safer'*).

15.11.2. **Insulin:** If insulin is being administered the nurse must check that the patient's blood glucose levels are being monitored regularly and refer to the patient's 'insulin passport' as appropriate.

15.11.3. **Once weekly preparations:** Certain medicines are only administered once weekly. This includes **methotrexate,** which is also used for rheumatoid arthritis and psoriasis**.** If administered daily when intended to be administered weekly methotrexate can cause considerable harm. (See also NPSA Patient Safety Alert 13 *Improving compliance with oral methotrexate guidelines*). Some bisphosphonate preparations for bone metabolism (including alendronate and risedronate) may be given once weekly. The prescriber must strike out the six days of the week when a dose must not be administered.

15.11.4. **Antibiotics:** penicillin allergy affects about 10 per cent of the population. It is important to check the allergy status of patients before administering antibiotics.

15.12. Nursing staff permitted to administer medicines

15.12.1. **Registered Nurses (first level)**: May administer medicines alone, provided they are competent to do so, with the following exceptions which require a second person to be involved:

- Intramuscular and subcutaneous injections apart from depot antipsychotics, short-acting sedation, anticholinergics and subcutaneous insulin (see also section 15.15.3)
- Intravenous injections; intravenous and subcutaneous infusions such as insulin infusion pumps (see also section 15.15.4)
- Any dose of medication which requires a calculation, e.g. doses based on body weight (mg/kg), where the dose has not already been calculated by the prescriber
- Controlled Drugs (see also section 15.16)

15.12.2. **Registered Nurses (second level) / Associate Practitioners**: Subject to the exceptions listed in section 15.12.1, second level nurses may administer medicines alone provided:

- They have received additional instructions relevant to the medications likely to be encountered in the clinical area where they are working.
- They have completed a practical assessment approved by the Trust and signed by the ward/unit manager (or have completed a similar assessment with an educational institution or another Trust).

15.12.3. **Agency nurses**: Agency nurses are registered nurses responsible for their own actions. Registered first level agency nurses may administer medicines alone provided they are familiar with the Trust medicines procedural guideline, subject to the exceptions listed in section 15.12.1. Second level agency nurses may not administer medicines alone unless they are familiar with the Trust medicines procedural guideline and have undergone assessment as explained in section 15.12.2.

15.12.4. **Student nurses**: Nurses in training should be given every opportunity to become proficient in the administration of medicines. Student nurses may administer medicines where accompanied and supervised by a registered nurse. In this situation, both the student and the supervisor shall sign the administration chart.

15.12.5. **Support Workers**: In an inpatient setting where there is 24-hour nursing cover, nursing support workers who have successfully completed the Trust competency-based assessment* may be authorised by the Trust to assist a registered nurse to perform the following:

- Administer oral and topical medicines to a patient, including inhalers, eye and ear drops, once these have been prepared and checked by a registered nurse.
- Check Controlled Drugs with a registered nurse (only if a second registered healthcare professional is not available).
- Check the patient's name and NHS number against the prescription chart with a registered nurse.
- Check discharge medicines against a discharge prescription with a registered nurse.
- Witness the self-administration of medicines following patient-specific assessment and training by a registered nurse.

Duties that cannot be performed by support workers:

- Preparation and supply of medicines
- Administration of medicines by injection or infusion
- Administration of Controlled Drugs
- Administration of 'as required' medication
- Administration to children
- Supply of discharge medication

* 'Learning Tool for Staff assisting the Administration of Medicines'

15.13. Process for administering medication

15.13.1. Not all sites use Trust prescription charts. Some sites use Medicine Administration Record (MAR) sheets that are provided by a community pharmacy for recording medicines that have been prescribed by a GP. All other sites, including day-hospitals, must administer against directions written on the Trust Medicines Prescription and Administration Chart or supplementary cards (see section 7.7.1).

15.13.2. Medicines should be administered in a quiet area to allow patients to discuss their medicines if necessary. The nurse administering medicines should ensure that she is not disturbed throughout the process. See also Appendix 13.

15.13.3. The therapeutic purpose of the patient's medication and its possible side-effects, interactions and contra-indications should be carefully considered. Reference should be made to the BNF for such information if necessary. If there are any concerns about drug interactions or contra-indications, contact the prescriber or a pharmacist.

15.13.4. If the dose that has been prescribed is above the BNF upper limit, the reason for doing so must be documented in the patient's healthcare record by the prescriber. If not documented the dose must be confirmed with the prescriber before administration.

15.13.5. If contra-indications to a medicine are observed, the dose shall be withheld and the appropriate prescriber informed without delay. A record should be made in the patient's healthcare record.

15.13.6. Always wash hands before administering medicines, or use an alcohol-based preparation if hand-wash facilities are not available, for example in a patient's home.

15.13.7. If a staff member is pregnant, thinks she may be pregnant or has sensitivities or allergies to particular drugs, contact pharmacy for advice before handling medicines.

15.13.8. Read the prescription carefully and ascertain that the dose has not already been given. If the patient has more than one prescription chart, ensure that all charts are available.

15.13.9. Check the entry for allergies on the first page of the prescription chart. If there is reason to suspect that the patient may be allergic to a prescribed medicine, refer to the prescriber or pharmacy.

15.13.10. Select the medicine required, check the label with the prescription and note the expiry date. If there is any doubt about the identity of the medicine, e.g. ambiguous / illegible wording on

the chart or unclear labelling, withhold the medicine and contact the prescriber and/or pharmacy immediately.

For injections and liquid medicines (except laxatives and simple linctus) the dose must be written as milligrams, micrograms, grams or units and not as a number of millilitres (see section 7.8.5). If this is not the case, contact the prescriber to verify what dose is intended.

15.13.11. Prepare the medicines and check the prescription and/or prescription chart with:

- the name of the patient
- the patient's NHS number where appropriate
- the medicine including dose and route of administration
- the calculation, if any (ideally with a second person)
- the measured dose
- the expiry date
- the time of administration
- the dosage instructions and compare with the label on the container
- that the prescription has been signed

15.13.12. Take the measured dose and prescription chart to the patient, checking his identity. Care shall be taken to ensure that the patient's identity is positively confirmed by visual recognition and/or verbal questioning. If medicines are being administered by a nurse unfamiliar with the patient, a competent second person may need to assist with identification.

15.13.13. Ensure that the patient knows what the medicine is and has given valid consent. If the patient is detained under the Mental Health Act and a Form T2 or Form T3 is in effect, check that the prescribed medicine is in line with the details on the form. If there is any discrepancy, this should be brought to the prescriber's attention immediately, and the dose of medication withheld.

15.13.14. Administer or supervise the administration of the medicine. Remain with the patient until the medicine has been taken, or longer if required by the patient's care plan.

15.13.15. Immediately sign the prescription chart to confirm that administration has taken place. An entry shall be made on the prescription chart to indicate when doses are either refused or omitted using the codes on the front of the card. The prescriber shall be informed and a record made in the patient's healthcare record. Where necessary, e.g. students under supervision, the

prescription chart should be countersigned. *Failure to sign the prescription chart following administration may be regarded as an administration error – see section 15.20*.

15.13.16. If treatment is refused, professional judgement will be used to determine the level of persuasion necessary to induce the patient to accept.

15.14. Administration of medicines prescribed 'as required' (PRN)

15.14.1. These are medicines prescribed to be used only when necessary, in addition to the patient's regular medication. The minimum interval between doses and the maximum total daily dose should be stated on the prescription chart. The clinical indication for which the medicine is to be used should also be stated.

15.14.2. 'As required' medicines should be administered at the discretion of a registered nurse, e.g. for pain relief or to reduce anxiety. When administered a note should be made in the healthcare record stating the reason the medicine was given and the outcome.

15.14.3. It is essential to check whether an 'as required' drug has also been prescribed on the 'regular medication' section of the chart, to ensure that the maximum daily dose is not exceeded. This is particularly important with products such as paracetamol and compound analgesics, which are frequently prescribed as both regular medication and for PRN pain relief.

15.14.4. If an 'as required' medicine is being given on a regular basis, it is the responsibility of the nursing staff to bring this to the attention of the prescriber. If appropriate, the prescriber should consider re-prescribing the medicine on the 'regular medication' section of the chart. The continuing need for 'as required' medicines should be reviewed on a regular basis (see section 7.11.7 for further information on the review of PRN medications).

15.15. Administration by injection

15.15.1. Injections are to be administered in accordance with the procedures for administration of injections (see Appendix 14). Before administering any medicine by injection, staff must be familiar with its contents on the preparation and administration of injections.

15.15.2. Practitioners must never administer any substance by injection that has been prepared in advance by another practitioner.

15.15.3. **Subcutaneous and intramuscular injections:** The administration of subcutaneous and intramuscular injections should be checked by two nurses whenever possible. However,

the following products are exempted from the requirement for a second nurse to check:

- depot antipsychotics
- short-acting sedation
- anticholinergics
- subcutaneous insulin

15.15.4. **Intravenous injections, infusions and subcutaneous infusions:** The administration of medicines by the intravenous (IV) route is associated with numerous risks, and should be avoided whenever a drug can be given effectively by an alternative route. Nursing staff should not administer injection by these routes unless they have undergone appropriate additional training and have a current and up-to-date IV certificate.

15.15.5. **Vaccines:** Nursing staff should not administer vaccines unless they have undergone appropriate additional training in immunisation and in the recognition and treatment of anaphylaxis.

15.16. Administration of Controlled Drugs

15.16.1. The administration of a controlled drug must be witnessed by a second practitioner, one of whom must be a registered nurse or doctor. In addition to the normal steps of the administration process described in section 15.13 an entry must be made in the CD Record Book, including:

- the date and time of administration
- the name of the patient
- the dose administered
- the **full** signatures of both the witness and the person administering the drug

15.16.2. The quantity of stock remaining shall be checked and recorded in the CD Record Book.

15.16.3. If the controlled drug is only partially used or wasted, it shall be destroyed by placing it in a pharmaceutical waste or sharps container in the presence of a witness and a record made in the CD Record Book. For more detailed information on the administration, recording and disposal of Controlled Drugs, refer to Appendix 3.

15.17. Delayed and omitted doses

15.17.1. There are a variety of reasons why a dose of medication may not have been administered. These include:

- Drug not available on ward/unit
- Prescription illegible, illegal or ambiguous,
- Patient not available
- Patient asleep
- Patient unable to take drug
- Patient refuses to take drug

15.17.2. It is essential that the reason for the non-administration of a medicine is documented. Codes for the above circumstances are listed on the prescription chart, and the appropriate code shall be entered on the chart in the box for the date/time that the medicine was due.

15.17.3. If no appropriate code is available, code 7 (other) shall be entered on the chart and the reason for the missed dose documented in the patient's healthcare record. *Failure to document the reason for a missed dose may be regarded as an administration error – see section 15.20.*

15.17.4. Following issue of an NPSA alert on delayed and omitted doses a list of 'critical medicines' has been drawn up. A short version is available on each ward and a longer version on the Medicines Management web pages of the Trust intranet. This provides advice on the action to the taken if a dose is delayed or omitted.

15.18. Administration of medicines to patients detained under the Mental Health Act

15.18.1. Medication for mental health disorders can be prescribed for, and administered to, certain categories of patients detained under the Mental Health Act without their consent, for a period of three months from the day on which such medication was first commenced (the 'three month rule').

15.18.2. Once the three month period has expired, such medication can only be administered to detained patients provided the safeguards referred to in Section 58 of the Act have been observed. These require that a Form T2 (patient consents to treatment) or Form T3 (patient does not or cannot consent to treatment) must be completed. These forms document what medications can be administered and need to be used in conjunction with the patient's prescription chart. A patient's T2 or T3 and prescription chart must be kept together at all times.

15.18.3. 'As required' (PRN) medication for the treatment of a mental disorder, or side effects of a treatment for a mental disorder shall be included on the Form T2 or T3.

15.18.4. In addition to completing Forms T2 or T3, the Responsible Clinician or Second Opinion Appointed Doctor (SOAD) should document in the patient's healthcare record the treatment plan and the process followed for considering consent.

15.18.5. The front page of the prescription chart contains a section which must be completed to indicate that a Form T2 or T3 is in effect.

15.18.6. Section 62 of the Act provides for urgent treatment to be administered pending compliance with Section 58.

15.18.7. Further guidance from the Care Quality Commission in relation to the administration of medicines for mental disorder and the Mental Health Act can be found on the CQC website. Further information is also contained in the Trusts Mental Health Act policies and procedures.

15.19. Covert administration of medicines

15.19.1. If it is felt that to disguise medication in food or drink can be justified in the best interests of the patient, the nurse must ensure before doing so that she:

- has made every effort to obtain the consent of the patient to receive the medicines in the normal way
- has discussed the issue with other members of the health care team, including the pharmacist and, if possible, with the patients carers and relatives
- document these discussions in the patient's healthcare record and provides a detailed account of the disguised administration.

15.19.2. If it is possible to obtain the written consent of carers and relatives this should be done and the consent retained with the records. Further information is provided in Appendix 15 including a checklist (**Annex 1**) and review form (**Annex 2**) for documenting the process.

15.20. Medication errors, incidents and near misses

15.20.1. A medication error is a preventable incident associated with the use of medicines which may put the patient at risk. Such incidents may be related to any step in the medicines use process, including prescribing, dispensing, preparation and administration. Examples include:

- administration of a medicine to the wrong patient

- administration of the wrong medicine
- administration of the wrong dose
- the wrong route of administration used
- failure to administer a medicine without due reason (i.e. no 'missed dose' code recorded on the chart
- failure to record administration on the chart
- a medicine incorrectly prescribed
- failure to sign and/or date the prescription
- a medicine incorrectly dispensed

15.20.2. In the event of an incident occurring, the well-being of the patient is of prime importance. The designated nurse in charge of the ward/unit must:

- ensure the patient is safe, and carry out any necessary physical observations
- inform the ward/unit manager or on-call manager and the doctor responsible for the patient (or deputy).
- conform with the CPG3, *Adverse Incident Procedural Guidelines.*
- document the incident in the patient's healthcare record

15.20.3. In the event of an error in administration, the nurse in charge shall inform the appropriate doctor, manager and pharmacist. The Consultant must be informed of the error at the earliest opportunity. In the case of a serious error the Consultant on-call must be informed.

15.20.4. Medication errors will be investigated in line with the CP3, *Adverse Incident Policy* and CPG3, *Adverse Incident Procedural Guidelines.*

15.20.5. The primary objective of the reporting system is improvement in care and not the disciplining of staff. It is only via the reporting of errors and near misses that managers can identify shortcomings in systems which need to rectified.

15.20.6. Disciplinary action will only be taken in respect of a medication error where there is continual or general concern about a person's competence to practice. Punitive measures tend to create a culture of concealment, and operate against a spirit of openness, co-operation and mutual trust.

15.20.7. **Near misses**: The Trust encourages the reporting of 'near misses', which are defined as medication incident that are detected up to and including the point at which the medicine is

handed over or administered to the patient, i.e. an error that could have occurred but did not, because of an appropriate intervention.

The purpose of 'near miss' reports is to use them as a learning tool and for identifying training needs. Near misses should be reported in the same way as medication incidents.

15.21. Adverse drug reactions

15.21.1. Healthcare professionals must be alert to the possibility of adverse reactions to medicines, and all suspected reactions must be reported to the patient's doctor and pharmacist. These can be reported by the patient, nurse, doctor, carer or other health professional. All suspected adverse drug reactions should be documented in the patient's healthcare record giving details of the suspected adverse reaction and any action taken.

15.21.2. The detection of previously un-recognised adverse drug reactions depends largely on the receipt of reports when adverse drug reactions are suspected. The MHRA 'Yellow Card' system is designed to collect national data on suspected adverse drug reactions.

15.21.3. Hard copy 'Yellow Cards' for reporting adverse reactions can be found at the back of the BNF. Alternatively, they can be reported electronically via www.yellowcard.gov.uk. Medical, nursing and pharmacy staff are required to submit yellow card reports, especially for the following types of adverse reaction:

- unusual reactions to established medicines (including vaccines), i.e. reactions that are not listed in the BNF as recognised side effects of the drug.
- serious or potentially-life-threatening reactions, even if it is well-known that these may occasionally occur with the medicine.
- any suspected adverse reaction to a recently introduced 'black triangle' medicine (marked ▼ in the BNF), even if the reaction is already listed under 'side effects' in the BNF.
- any suspected adverse reaction involving a person under 18 years of age.

15.22. Defective Medicines

15.22.1. If a medicine is found to be defective, or is suspected of being defective, the following procedure should be applied:

- if the product has been administered to a patient, inform the prescriber responsible for the patient and record the defects in the patient's healthcare record.

- report the incident to the ward/unit manager.
- inform the appropriate pharmacy department, who will advise on all reporting, recording and investigation of the defect.
- retain any remaining product and associated packaging for inspection by a pharmacist.

15.22.2. Outside pharmacy opening hours the site officer must be informed and will notify the on-call pharmacist and senior clinical on-call person.

15.22.3. A local recall, or action required following receipt of a Drug Alert notifying of a defective medicine, will be instigated by the pharmacy department.

16. SELF-ADMINISTRATION OF MEDICATION

16.1. Self-administration of medication occurs when a patient on a ward or unit keeps and administers their own medication, which may be either brought in from home or dispensed by a hospital pharmacy.

16.2. The process is undertaken in the interests of improving patient care and should be consistent with the philosophy of care at the site where the scheme is operating. It should be made clear to the patient that inability to reach the later stage(s) of the scheme is not failure, and that any progress made is valuable.

16.3. The scheme must not be used as a response to staffing and other operational problems.

16.4. Patients wishing to take responsibility for their own medicines shall be entered on the Trust's self-medication programme. The programme may be started at any stage depending on the patient's ability. This must be recorded on the front of the prescription chart and dated.

16.5. Before any patient is started on the self-medication programme there must be agreement from the multidisciplinary team (MDT) that the patient is suitable for the programme and an entry stating this made in the patient's healthcare records.

16.6. Further details on operating self-administration are given in Appendix 16) including the risk assessment and monitoring forms to be used.

16.7. Compliance Aids

16.7.1. Non-adherence (also known as non-compliance or non-concordance) with prescribed medication is a major cause of relapse and admission to hospital. There are many factors which can lead to non-compliance, including:

- a poor understanding of the need for medicines

- a poor understanding of how to take medicines
- forgetfulness
- inability to open containers
- poor eyesight
- a complicated medication regimen

16.7.2. For some people, a compliance aid* may assist them to continue self-medication and remain out of hospital. The need for a compliance aid should be discussed and agreed by the multidisciplinary team, and this should include input from a pharmacist. The decision to use a compliance aid and the outcome of the assessment and evaluation must be documented in the patient's care plan.

16.7.3. A full assessment of the reason(s) for potential non-compliance should take place, as the provision of medicines in a compliance aid may not be of benefit in all cases. Patients should be assessed for their ability to:

- remember the time when medicines are due
- open the device
- select the right compartment
- remove medicines from the device

The assessment tool at Appendix 17 should be used.

16.7.4. Not all medicines will be suitable for inclusion in a compliance aid. Only medicines which are sufficiently stable may be used in a compliance aid, as exposure to other medicines, moisture and light may affect efficacy. A pharmacist should assess the suitability of a patient's medicines to be supplied in this type of container. Do not keep medicines in a device for longer than two weeks. The assessment tool at Appendix 17 should be used.

16.7.5. Most compliance aids need to be filled at a pharmacy with the appropriate equipment for dispensing, labelling and sealing the container. Compliance aids should only be considered if arrangements can be made for a community pharmacy to supply medication in a compliance aid on a continuing basis once the patient is discharged. Not all pharmacies provide this service, so it is essential to confirm that a local pharmacy is willing to provide a patient's medication in a compliance aid.

16.7.6. Patients should be encouraged to self-administer medication from their compliance aid.

* also known as a Monitored Dosage System (MDS)

16.7.7. Patients shall be monitored and re-assessed at least once every 3 months or when prescribed medicines are changed.

16.7.8. A nurse or pharmacist should explain to the patient the role of each person providing medication support to him or her.

16.7.9. A registered nurse may enable patients to fill and label their own MDS. In exceptional circumstances, where it is not possible to find a pharmacist to fill the MDS, the patient or carer is not able to fill it and the assessment of the patient has shown that a MDS is essential, a registered nurse may fill the device.

16.7.10. A device containing a maximum of one week's supply can be filled by a nurse. Ideally daily devices only should be filled by nurses. When filling the device care should be taken that it is filled in accordance with the directions on the boxes and bottles supplied by a pharmacist and in line with advice on whether each item is stable in this form of container.

16.7.11. Nursing or other non-pharmacy staff must not fill compliance aids from bulk or stock packs of medication.

16.7.12. A compliance aid must be labelled with:

- Patients full name
- Quantity, name and strength of medicine and prescribed dose.
- The date filled
- The name of the person filling it

16.7.13. The same details of filling must also be recorded in the patient's healthcare records.

16.7.14. The compliance aid shall be re-labelled each time there is a change in prescribed medication.

16.7.15. Medicines shall only be removed from the compliance aid at the time of administration.

16.7.16. If one medicine is no longer prescribed the whole contents of the compliance aid should be returned to the Pharmacy and refilled with the correct medicine. A nurse must never attempt to identify and remove individual discontinued medicines.

17. DISPOSAL OF MEDICINES

17.1. A dose of a medicine prepared for administration within a ward or clinic and subsequently not used must be disposed of safely by placing in pharmaceutical waste container or sharps container as relevant. It shall not be returned to its original container.

17.2. Due to differing arrangements for the provision of pharmaceutical services within Bedfordshire, Essex and Luton pharmaceutical waste must be handled differently in each area.

17.3. Essex

17.3.1. Spoiled doses and patient's own medicines which are not required should be disposed of on the ward.

17.3.2. Other medicines which are no longer required (including CDs) must be returned to the hospital pharmacy as soon as possible. Medicines returned to pharmacy for disposal will be handled in accordance with the relevant pharmacy standard operating procedure.

17.4. Bedfordshire and Luton

17.4.1. **Stock drugs and individually-dispensed drugs (except CDs):** All out-of-date medicines and in-date medicines that are no longer required must be disposed of in accordance with Appendix 10.

Unwanted medicines must NOT be sent back to the hospital pharmacy for disposal. All Trust sites where medicines are handled must keep suitable pharmaceutical waste bins, which must be removed by the Trust's approved waste contractor when full.

17.4.2. **Controlled Drugs**: Unwanted Controlled Drugs held at inpatient sites must be denatured by an approved person in the presence of a suitable witness before they can be disposed of. Refer to Appendix 3 for further information on the disposal of CDs.

17.5. Patients' own medicines

17.5.1. All medicines brought into hospital by patients remain their own property, and should not be destroyed or disposed of without their permission (or if this is not possible, the permission of a family member or carer).

17.5.2. Medicines brought into hospital shall be reviewed by the admitting doctor, as part of the process of Medicines Reconciliation, who will decide whether the treatment(s) should be continued (see CLP63, *Policy for Medicines Reconciliation on Admission to Hospital* and CLPG63, *Procedural Guideline for Medicines Reconciliation on Admission to Hospital*).

17.5.3. If to be continued, the patient's medicines may be taken into the custody of the ward, and, if fit for use, used to treat the patient (refer to section 9.4 and Appendix 11).

17.5.4. If a patient's own medicines are not required because the admitting doctor decides to discontinue the treatment, permission should be sought for the medicines to be disposed. If such permission is not granted, the medicines should be sent home in the same way as any other property not required by the patient.

17.5.5. If a patient's own medicines are assessed as unfit for use (by application of Appendix 11), permission should be sought for the medicines to be disposed of. These should be disposed of in the same way as unwanted stock drugs (see section 17.4.1).

17.5.6. In a community setting, patients' own medicines (including CDs) that have been dispensed by a community pharmacy can be taken to any community pharmacy for disposal.

18. DAY CARE FACILITIES

18.1. Patients attending day care / day hospital facilities will normally bring their own medicines with them if they require to take any during their time at the facility. Nursing staff should check with the GP or Consultant Psychiatrist the current medicines prescribed.

18.2. If the patient is able, they may keep their own medicines with them and self-administer at the appropriate times. Staff must ensure that the patient will store their medicines safely and not allow other less able patients access to the medicines.

18.3. If staff are not confident that the medicines are in a suitable condition for administration to the patient, or they are unsure of the identity of the medicines, then an alternative supply must be obtained from the hospital pharmacy. This supply must be made against a hospital prescription or prescription chart.

18.4. If it is felt that patients are not able to take their own medicines, then staff may administer them. The patient must bring their medicines with them fully labelled with name and directions for use. The medicines will be stored in a locked medicines cupboard for the duration of the patient's visit.

18.5. If staff are administering medicines to a patient then all medicines need to be prescribed on a prescription chart and all doses administered signed for. Omitted doses should also be recorded in the same way as for an inpatient.

18.6. There shall be a locked cupboard for the storage of medicines which complies with the requirements of section 13.

19. MANAGEMENT OF MEDICINES BY SECONDED LOCAL AUTHORITY STAFF

19.1. This guidance must be used in conjunction with the individual policies and procedures of each Local Authority.

19.2. All local authority staff managing medicines on behalf of South Essex Partnership University NHS Foundation Trust must have completed the Trust medicines management training for social care staff and nursing support workers.

19.3. Any medicines related tasks expected to be carried out by staff will be documented as part of the risk assessment and managed through the CPA care plan and be under the continuing supervision of a registered nurse.

19.4. Managing medicines will be limited to prompting patients to take their medicines correctly. This must be carried out with the permission of the patient, which must be recorded in the healthcare record. In cases of severe dementia staff may administer medicines in line with individual local authority guidelines.

19.5. Staff must not purchase or offer advice on non-prescribed medicines for the patient.

19.6. Any concerns relating to medicines, either raised by the patient, carer or staff member, should be reported to the CPA care coordinator.

19.7. Any interventions relating to medicines must be recorded in the patient's healthcare record.

20. CONTROLLED STATIONERY

20.1. All versions of FP10 prescription forms, Pharmacy requisition books, and outpatient prescriptions, shall be regarded as controlled stationery. All these shall be serially numbered.

20.2. Controlled stationary shall be kept in the pharmacy department or other designated area.

20.3. A record shall be kept of the date, ward or department and signature of the recipient whenever controlled stationary is issued.

20.4. FP10 pads are the responsibility of the prescriber who signed for their collection. No FP10 prescription forms shall be destroyed by prescribers or administrative staff. If spoiled the form shall be crossed through and retained with the pad. These forms shall be returned to the administrator / pharmacy of origin for destruction. See Appendix 8 for further information on the security and safe handling of FP10s.

20.5. White trust prescription forms are used in outpatient clinics and in Bedfordshire and Luton for obtaining leave/discharge medication from the hospital pharmacy. They cannot be used to obtain medicines from community pharmacies, and can only be dispensed at the hospital of origin.

20.6. For this reason, hospital prescription forms do not pose the same security risk as FP10 forms, and do not warrant the same level of record-keeping. Nevertheless, the good practice guidelines (section 13 of Appendix 8) should

still be followed, and any losses or thefts should be reported and the appropriate Trust Chief Pharmacist.

20.7. Prescription charts are not treated as controlled stationery. However, the following precautions shall be observed: -

- unused charts shall be kept securely in wards and departments and issued only to staff who have authority to prescribe medicines.
- used charts shall be retained as part of the patient's healthcare records.
- a file of specimen signatures of all staff authorised to prescribe shall be kept in each pharmacy department.

20.8. Other forms used for ordering medicines are not treated as controlled stationery but the following precautions shall be observed:-

- unused forms shall be kept securely and issued only to staff who have authority to order medicines.
- used forms shall be retained in the pharmacy after dispensing.
- a file of specimen signatures of all staff authorised to order medicines shall be kept in each pharmacy department.

20.9. Stationery used for ordering or prescribing medicines shall not be taken away from NHS premises except in the custody of an authorised member of staff who shall be responsible for its safe keeping.

20.10. FP10 prescription forms may be issued to an individual prescriber for their use. The prescriber must sign to accept responsibility for the forms. When a trainee doctor leaves the Trust or move to another part of the rota it is the responsibility of the consultant to make sure that any remaining FP10 forms are returned to the department of origin.

20.11. Loss of FP10 forms should be reported immediately to the department of origin and the relevant Primary Care Trust (PCT).

21. SUSPECTED ILLICIT SUBSTANCES

21.1. Where a suspected illicit substance is brought onto Trust premises by a patient, as soon as it is discovered it shall be removed from the area in which it was found and stored in the ward controlled drugs cupboard. An entry shall be made in the ward CD Record Book stating "small quantity of brown substance" etc. The entry shall be signed by two members of staff (preferably qualified nurses). A separate page at the back of the CD Record Book should be reserved for entering details of suspected illicit substances.

21.2. Whilst being stored in the CD cupboard, the substance shall be placed into a suitable container, e.g. sealed plastic bag or envelope, and labelled with:

- a brief description of the item
- the quantity

- where it was found
- the date

21.3. The police Controlled Drug Liaison Officer (CDLO)[*] should be contacted immediately by the ward/team manager concerning illicit substances. The CDLO will attend the ward/unit to destroy the illicit substance in conjunction with the ward/team manager.

21.4. All incidents involving illicit substances should be recorded as an adverse incident using the Trust reporting system. The Accountable Officer for controlled drugs should be informed if more than two doses are recovered.

21.5. Staff shall not transport suspected illicit substances from a service user's home to the team base unless police are contacted prior to transportation. This is to prevent staff from being in possession of a drug covered by the Misuse of Drugs Act and unwittingly committing an offence.

22. TRAINING

23.1. Through the Trust analysis of training needs it has been agreed that medicines management is a core practice training requirement for all qualified nursing staff within mental health, learning disability and CAMH services. Staff are expected to attend medicines management training on a 3-yearly update cycle. All mandatory/core practice training is managed by the Workforce Development and Training Department.

Core Practice Training	Update Interval	Staff Category	Delivery Method
Medicines Management	Three yearly	All qualified nursing staff (MH, LD, CAMHS)	Direct learning with competency assessment by observation and e-test

23.2. Training includes coverage of the Trust policy and procedural guidelines for the safe and secure handling of medicines, and the direct learning element is provided by the pharmacy team.

23.3. The Workforce Development and Training Department will report monthly on compliance levels for mandatory training to the Trust Executive Team, Workforce and Business Support Service Board and Risk Management Committee. Compliance for all mandatory/ core practice training is set at a minimum of 75%. The Trust has an agreed target figure that is adjusted to account for sickness/absence, maternity leave etc.

23.4. Staff who are booked onto mandatory/core practice training that do not attend will receive a letter from the information department informing them of their non-attendance, which will be copied to the appropriate Line Manager.

[*] Contact Details can be found on the Medicines Management web pages on the intranet under 'Forms and Resources'

Non-attendees will be automatically rebooked onto another course by the information department.

23.5. Monthly mapping reports will also be sent to operational managers and directors identifying which of their staff are up-to-date with their training and when they are approaching update deadlines. Non-attendance of courses will also be recorded. It is the line manager's responsibility to ensure all their staff have attended appropriate training as identified in the Trust's training needs analysis.

23. MONITORING

24.1. The prescribing and administration of medication at inpatient wards and units is monitored by pharmacists via regular reviews of all the prescription charts. The frequency of pharmacist monitoring is determined by the nature of the ward/unit.

24.2. Compliance with key elements of the safe and secure handling of medicines policy is monitored through a programme of regular quarterly and six-monthly audits conducted by the pharmacy staff. Additional medication-related audits are agreed via the Medicines Management Committee as part of a three-yearly medicines management audit programme, or occur as part of the POMH-UK audit programme.

24.3. Aspects of the procedural guidelines which are audited via these programmes include:

- Controlled Drug storage and safekeeping, including stock reconciliation
- Fridge temperature monitoring
- Compliance with prescribing standards (prescription chart audits)
- Medicines reconciliation
- Medication transfers
- Transport of medicines
- Supply of medicines to wards and departments
- Self-medication
- High dose antipsychotic prescribing
- Safe and secure storage of medications

24.4. The findings of these audits, and recommendations for action, are presented to the Medicines Management Committee. Where re-audit identifies a lack of progress, the findings and recommendations are escalated to the appropriate senior managers and/or committees.

24.5. The Risk Management department collates details of all incidents involving the prescribing and administration of medication. Reports of these are available to the Chief Pharmacist. A summary report of medication-related

incidents is a standing item on the agenda of the Medicines Management Committee

Appendices

Providing Partnership Services in Bedfordshire, Essex and Luton

PRESCRIBING STAFF SPECIMEN SIGNATURES

1. Each pharmacy department must be familiar with the signatures of all the prescribers whose prescriptions it may encounter. Specimen signatures are also required in order to check a doctor's countersignature on Controlled Drug Orders*.

2. The Medical Staffing office provides the hospital pharmacy departments with specimen signatures for newly-appointed medical staff. Permanent medical staff and non-medical prescribers should provide a new specimen signature every 2 years, using this form.

3. Please send or fax completed copies of this form to the relevant hospital pharmacy.

4. The pharmacy departments reserve the right to query any unknown signatures and may refuse to dispense a prescription or supply Controlled Drugs if the signature cannot be recognised.

Name:			
Position:	Directorate:		
Full signature:		Initials used:	Date:
Trust e-mail address:			
GMC / NMC / GPhC registration number:			
Date of appointment:	Locum / permanent	Expected finish date (locums):	
Name of Consultant (if applicable):			
Full signature of Consultant:		Date:	
Please send or fax a copy of this form to the hospital pharmacy that supplies medication to the ward / unit where you work: • Pharmacy Dept., Bedford Hospital: Fax: 01234 795930 • Pharmacy Dept., Rochford Hospital Fax: 01702 538226 • Pharmacy Dept., Luton & Dunstable Hospital: Fax: 01582 497364			

* Legislation require that orders to the hospital pharmacy of another organisation for stock supplies of Controlled Drugs must be countersigned by a doctor

Providing Partnership Services in Bedfordshire, Essex and Luton

NURSES AUTHORISED TO ORDER, RECEIVE AND ADMINISTER MEDICINES INCLUDING CONTROLLED DRUGS

SPECIMEN SIGNATURES

1. Each hospital pharmacy department that supplies the Trust must be familiar with the signatures of all the nurses who order medication. Please send or fax completed copies of this form to the relevant hospital pharmacy.

2. The registered nurse in charge of a ward or unit is responsible for providing specimen signatures for all nursing staff who are authorised to order medication from the pharmacy. These staff must be permanent employees of the Trust.

3. The pharmacy departments reserve the right to query any unknown signatures and may refuse to dispense Controlled Drugs if the authorised nurse cannot be identified.

Name:		
Position:		
Full signature:	Initials used:	Date:
Trust e-mail address:		
NMC registration number:		
Ward / Unit where you usually work:	Date of appointment:	
Name of the registered nurse in charge of the ward / unit where you work:		
Full signature of the registered nurse in charge of the ward unit		Date:
This member of staff is authorised to order, receive and administer controlled drugs (nurse in charge to circle)		Yes No
Please send or fax a copy of this form to the hospital pharmacy that supplies medication to the ward / unit where you work: • Pharmacy Dept., Bedford Hospital: Fax: 01234 795930 • Pharmacy Dept., Rochford Hospital Fax: 01702 538226 • Pharmacy Dept., Luton & Dunstable Hospital: Fax: 01582 497364		

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURES FOR THE SAFE MANAGEMENT AND USE OF CONTROLLED DRUGS

1. INTRODUCTION

1.1. Following the Shipman Inquiry, the Government introduced strengthened monitoring and inspection arrangements for Controlled Drugs (CDs) to minimise the risk to patient safety of the inappropriate use of controlled drugs. These were incorporated into the Health Act 2006, and in England, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 which came into force in January 2007.

1.2. Each NHS organisation is required to appoint an Accountable Officer (AO) with overall responsibility for the safe use and management of CDs within the organisation. The Accountable Officer for this Trust is the Chief Pharmacist. The AO is responsible for ensuring that there are standard operating procedures for the management of CDs within all areas of the Trust, and that these procedures are amended and updated as necessary, and reviewed regularly. The AO is ultimately accountable for all systems for the safe management of CDs.

1.3. This document reflects the above legislation and closely reflects interpretative guidance issued by the Department of Health in October 2007 (*Safer Management of Controlled Drug: a guide to good practice in secondary care*). It sets out the procedures which must be followed for the management of controlled drugs on wards and other units.

2. WHAT ARE CONTROLLED DRUGS?

2.1. Controlled Drugs (CDs) are any substance (medicinal or otherwise) which may be addictive and/or subject to misuse, as defined in the Misuse of Drugs Act 1971, which divides CDs in to classes which will affect the culpability of the person in possession of them. The use of controlled drugs in medicines is permitted by the Misuse of Drugs Regulations 2001, which divides CD into five schedules according to their level of control.

2.2. Schedule 1 CDs have virtually no therapeutic uses, and can only legally be in the possession of a person who has a licence from the Home Office. Examples of Schedule 1 CDs include cannabis, LSD and magic mushrooms. The only current exception is Sativex®, a cannabinoid-based medicine used in the treatment of severe spasticity in multiple sclerosis, for which the Home Office has granted an open general licence. In the event of needing to use this produce advice should be sought from the pharmacy team.

2.3. A summary of the CD regulations as they apply to Schedules 2 - 5 can be found in Annex 1. This table gives details of the prescription-writing, storage and record-keeping requirements that apply to the drugs in each Schedule.

2.4. Within the regulations, Trusts are permitted to treat non-CD medicines as CDs if they are considered to carry a risk of dependency or misuse; this may apply on a Trust-wide basis, or at an individual Trust site, and may be a temporary or permanent measure. Similarly, certain CDs may be subject to more stringent controls than is required by their Schedule. Details of the requirements as they apply to specific drugs within this Trust are included in the table in Annex 1.

2.5. Tables listing the most common CDs in Schedule 2, Schedule 3, and Schedule 4 Part I, can be found in Annex 2. Products are listed by generic name, with an indication of brand name(s) where these exist. Those CDs that are used most frequently within the Trust have been identified with an asterisk (*).

3. ACCOUNTABILITY AND RESPONSIBILITY

3.1. The Accountable Officer (AO) is responsible for ensuring that there are standard operating procedures for the management of CDs within all areas of the Trust, and that these procedures are amended and updated as necessary, and reviewed regularly. The AO is ultimately accountable for all the systems for the safe management of CDs.

3.2. The Appointed Nurse in Charge of a ward or unit is responsible for the safe and appropriate management of CDs in that area, by ensuring that all relevant procedures in this document are complied with. Where the person in charge is not a nurse, the responsibility for CDs rests with the most senior nurse permanently employed on the ward or unit. She can delegate control of access to the CD cupboard (i.e. key-holding) and other CD-related tasks to another registered nurse, but legal responsibility remains with the most senior nurse. See also section 5.2.

4. CONTROLLED DRUG STOCKS

4.1. In most cases CDs will be ordered as required for individual patient care. However, where CDs are routinely held as stock on a ward there should be a list detailing the quantities usually held. This list should be agreed between the pharmacist or pharmacy technician responsible for stock control for that ward and the registered nurse in charge, and should be reviewed at least annually.

4.2. Stocks of Schedule 2 and 3 Controlled Drugs (see Annex 1 and Annex 2) are not topped-up by the pharmacy service. They must be ordered from the pharmacy by the ward or unit, using a CD order book (see section 5).

4.3. Stock CDs should be kept to a minimum and unwanted or out of date stock items should be disposed of promptly (see sections 14 and 15).

5. REQUISITIONING CONTROLLED DRUGS

5.1. The registered nurse in charge of a ward or unit is responsible for ordering Schedule 2 and 3 Controlled Drugs for use in that area. Where the person in

charge is not a nurse, the responsibility for ordering CDs rests with the most senior nurse permanently employed on the ward or unit. This responsibility can be delegated to another registered nurse.

5.2. Nurses who are authorised to order and handle CDs must provide a specimen signature to the supplying pharmacy department, using the form shown in Appendix 2 of CLPG13. In addition, a list of the names and specimen signatures of all nurses authorised to order and handle CDs should be kept in the front of the ward/unit CD Record Book.

5.3. Schedule 2 and 3 CDs must be ordered from the pharmacy using a Controlled Drug Order Book with duplicate numbered pages. The order (requisition) must be signed by an authorised nurse.

5.4. Legislation requires that requisitions to another health body for the supply of CDs must be countersigned by a doctor employed by the Trust, as independent verification that the drugs ordered are required for use on the ward or unit.

In Bedfordshire and Luton only, the requisition must be countersigned by a doctor, because the Trust obtains its supplies of CDs from the pharmacy departments of other NHS trusts. The doctor who countersigns the CD order is not accountable for the management of CDs on the ward or unit; this responsibility remains with the Appointed Nurse in Charge.

5.5. All CD orders (requisitions) must state:

- Name of the Hospital
- Name of the ward or unit
- Drug name, form (e.g. tablets, capsules), strength and ampoule size (if applicable)
- The quantity required (CDs should be ordered as whole packs – check with the pharmacy if unsure what pack sizes are available)
- Signature and printed name of the registered nurse
- Date
- Signature and GMC number of the countersigning doctor (*Bedfordshire & Luton only*)

5.6. When writing an order in the CD Order Book it is important to ensure that the carbon paper is placed, the correct way up, between the order paired duplicate page, that both copies of the order carry the same serial number, and that a clear copy of the order is visible on the second page.

5.7. Once the order has been completed and signed, the CD Order Book should be sent to the pharmacy.

In Bedfordshire and Luton this should be accompanied by a lockable Controlled Drug box. This box must clearly state which ward or unit it belongs to.

In Essex this should be sent in a tamper evident bag accompanied by a consignment note.

5.8. A new CD Order Book can be obtained by sending a written order to the appropriate hospital pharmacy; this must be signed by a nurse who is authorised to order CDs. **In Essex** page 100 of each order book will be completed by pharmacy staff as the order for the next CD order book; this must be signed by a nurse who is authorised to order CDs.

6. TRANSPORT OF CONTROLLED DRUGS

6.1. Controlled Drugs must be transported from the pharmacy to the ward or unit in a locked or sealed, tamper evident container carried by an appropriate messenger, who is responsible for ensuring that the box is delivered intact. The messenger may be a member of the ward/unit staff, a member of the local portering services or Trust transport service. Courier/taxi services are not permitted to transport CD boxes from the pharmacy to Trust wards/units in Bedfordshire and Luton.

6.2. The messenger who collects the CD box from the pharmacy must carry a valid identification card; the pharmacy will not release CDs to messengers without appropriate ID.

6.3. The messenger will be required to sign the CD Order Book or a specific consignment record at the pharmacy. The top copy of the order will be removed and retained in the pharmacy, and the messenger will be given the CD Order Book to return to the ward/unit together with the locked or sealed, tamper evident container. The messenger may also be asked to sign the pharmacy CD Register to confirm collection.

6.4. On arrival at the Trust ward or unit, the messenger must give the locked or sealed, tamper evident container and CD Order Book to a registered nurse, who then assumes responsibility for the container and its contents. On no account must the container be left unattended.

6.5. At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

7. RECEIPT OF CONTROLLED DRUGS

7.1. Deliveries of CDs must be accepted by an authorised nurse whose name and signature have been notified to the pharmacy (see Appendix 2 of CLPG13)

7.2. The authorised nurse must immediately:

- check that the container is locked/sealed and intact

- open the container and check the contents (drug, strength, quantity) against the duplicate order page in the CD Order Book. If a CD has been supplied in a manufacturer's pack closed by an un-broken seal, the seal should not be broken in order to count the contents. If there is no tamper evident seal, or the seal is broken, the contents of the pack should be removed and counted.
- if the delivery is correct, sign the receipt section of the duplicate order page in the CD Order Book.
- enter the details of the received item(s) in the ward/unit CD Record Book and confirm that the stock balance is correct (see section 9.2).
- place the received items in the CD cupboard

7.3. The receipt shall be witnessed by a second nurse, who shall also sign the CD Record Book.

7.4. There is no need to record the receipt of Schedule 3 controlled drugs apart from buprenorphine and midazolam in the record book unless requested in a special case to do so by a Consultant Practitioner/Team Manager or the pharmacy department.

7.5. **Discrepancies on receipt**

7.5.1. If the delivery does not match the duplicate order page, or an item is missing, the details of the discrepancy must be reported to the supplying pharmacy immediately.

7.5.2. If the messenger who delivered the CD is able to return it to the pharmacy immediately, the receipt section of the duplicate order page should not be signed. The container and its contents should be re-locked/re-sealed and returned to the pharmacy together with the CD Order Book, to enable the pharmacy to rectify the problem.

7.5.3. If it is not possible to return the incorrect item to the pharmacy immediately, the duplicate order page should be endorsed with the details of what was actually received and the receipt section signed. The details of the received item should be entered into the CD Record Book and marked as 'received in error', and the item should then be stored in the CD cupboard pending resolution of the problem by pharmacy.

8. STORAGE OF CONTROLLED DRUGS

8.1. All controlled drugs (Schedule 2 and 3) must be stored in a locked controlled drug cupboard, which can only be opened by a person who can lawfully be in possession, such as the registered nurse in charge or a pharmacist, or a person working under their authority.

8.2. The Misuse of Drugs (Safe Custody) Regulations 1973 sets out standards for cabinets used to store controlled drugs. Any new cupboards must comply

with these requirements, and it is recommended that all CD cupboards conform to these standards. Ward CD cupboards should conform to BS2881 or be otherwise approved by the Chief Pharmacist or designated deputy as suitable for the storage of CDs.

8.3. Leave or discharge medication which includes CDs should be stored in the ward CD cupboard in a sealed bag until the time of discharge. These items should be segregated from the stock CDs that are used on the ward, and should not be entered into the CD Record Book. If a patient awaiting leave/discharge requires a dose of a CD before they leave the ward, this should normally be administered from stock and not from their discharge medication.

8.4. General measures for the storage of CDs include the following:

- The CD cupboard must be kept locked when not in use
- The lock must be unique (not the same as any other lock in the Trust)
- The keys for the CD cupboard must be kept separate from the other medicine keys and stay on the person of the keyholder all the time (not in a drawer or a key cupboard)
- Keys must only be available to authorised staff and the keyholder must be readily identifiable at all times; the keyholder for each shift should be named on the shift rota
- The CD cupboard must only be used for storing Schedule 2 and 3 CDs, plus any drug which the Trust requires to be treated as a Schedule 2 or 3 CD (see section 2.4 and Annex 1 and Annex 2)
- The CD cupboard must not be used for storing other items such a money and valuables.
- CDs must be locked away in the CD cupboard when not in use
- There must be adequate arrangements for keeping the keys secure in units which are not staffed 24 hours a day; in such cases, a standard operating procedure for the keys must be agreed with the Accountable Officer

8.5. **Responsibility for CD cupboard keys**

8.5.1. The registered nurse in charge of the ward or unit is responsible for the key to the CD cupboard.

8.5.2. Key-holding may be delegated to an authorised registered nurse whose signature is held by the pharmacy and whose name is listed in the CD Record Book (see section 5.2), but legal responsibility rest with the Appointed Nurse in Charge.

8.5.3. The keyholder named on the shift rota may give the CD cupboard key to another authorised member of staff if necessary (for example, a nurse administering medicines, a pharmacist or a

pharmacy technician) but it must be returned to her as soon as possible.

8.6. Missing CD cupboard keys

8.6.1. If the key to the CD cupboard cannot be found, urgent efforts must be made to retrieve it as soon as possible, e.g. by contacting the responsible staff who have recently gone off-duty or off-site.

8.6.2. The Appointed Nurse in Charge of the ward or unit must be informed immediately that the CD key is missing, and the pharmacy must be informed as soon as possible. If necessary, additional security measures must be implemented in order to preserve the security of the CD cupboard until the missing key has been found.

8.6.3. If the pharmacy does not hold a spare key, and a patient is due to receive a dose of a CD, the doctor should be called to assess whether the dose may be omitted without harm to the patient. If administration is essential, the required dose of the CD may be obtained from another nearby ward or unit within the Trust (by taking the patient to the other ward or unit and making an appropriate entry in their CD Record Book). The unit is responsible for arranging appropriate transport.

8.6.4. If no other nearby ward or unit has a stock of the required drug, a supply must be ordered from the pharmacy. The pharmacy will advise on the storage of such items until the CD key has been located.

8.6.5. If the keys cannot be found promptly, the Accountable Officer must be informed about missing CD keys during working hours. Out of hours, the on-call manager should be informed. Depending on the circumstances, it may also be appropriate to contact the Risk Management Department and the police.

8.6.6. An Adverse Incident Report must be submitted, and a copy must be sent to the Accountable Officer as well as the Risk Management Department.

9. RECORD KEEPING

9.1. Controlled Drug Record Book

9.1.1. Every ward or unit that holds Schedule 2 or 3 Controlled Drugs must keep a record of all CDs received and administered in a Controlled Drug Record Book. The Appointed Nurse in Charge is responsible for keeping the CD Record Book up to date and in good order.

9.1.2. All entries in the CD Record Book must be legible, made in indelible ink, and should be made in chronological order.

9.1.3. It is good practice to create an index at the front of the CD Record Book that states which pages are currently in use for each product. It is important that this index is updated whenever the running balance is transferred to a new page in the record book.

9.1.4. All entries in the CD Record Book (receipts and administration) should be signed by a registered nurse and should be witnessed by a second person, preferably another registered nurse. If a second registered nurse is not available, the transaction can be witnessed by another registered practitioner, e.g. a doctor, pharmacist, pharmacy technician, or by an appropriately trained healthcare assistant.

9.1.5. Each strength and form of a drug must be recorded on a separate page of the CD Record Book, e.g. morphine 10mg tablets, 20mg tablets and liquid require separate pages in the register. Every page in use in the CD Record Book must have a heading which clearly states:

- The **name** of the drug
- The **strength** of the drug
- The **form** of the drug, e.g. tablets, capsules. If the product is a special formulation, this should also be specified, together with the brand name, e.g. '*Morphine sulphate tablets MR 10mg (MST Continus 10)*'.

9.1.6. A running balance of the quantity in stock should be kept for each drug, and this balance should agree with the content of the CD cupboard. The running balance must be adjusted whenever a CD is received, administered or disposed of.

9.1.7. When all the available lines on a page have been used, the running balance must be transferred to the next available blank page in the CD Record Book (which will not necessarily be the next consecutively numbered page):

- **At the foot of the full page**: Write '*Balance transferred to page xx'*, giving the number of the new page. Date and sign the entry; obtain a witness signature if available.
- **On the new page**: Complete the heading (see section 9.1.5) and on the first line write '*Balance transferred from page xx'*, giving the number of the page containing the previous records for the drug. Write the running balance in the final column. Date and sign the entry; obtain a witness signature if available.

- **On the index page**: Cross out the previous page number and write in the new page number.

9.1.8. A new CD Record Book can be obtained by sending a written order to the appropriate hospital pharmacy; this must be signed by a nurse who is authorised to order CDs.

9.2. Recording receipt of stock CDs

9.2.1. If the drug supplied by the pharmacy already has a page in the CD Record Book, the receipt should be recorded on the next blank line. The entry in the record book must include (see sample below):

- Date of the entry in the record book
- Quantity (number) or volume of drug received, **in words**
- Name of the supplying pharmacy
- Serial number of the requisition (from the duplicate order page in the CD Order Book)
- Signature and printed name of the authorised person making the entry
- Signature and printed name of the witness
- New running balance of stock held

9.2.2. If the drug has not previously been used on the ward/unit, it will be necessary to create a new record page in the CD Record Book. This must be done on the next available blank page in the register. The new page should be given a heading as detailed in section 9.1.5, and the drug name and page number should be added to the index at the front of the Record Book.

The receipt should be entered on the first line of the newly created page, in the same format as shown below. The quantity supplied should be entered as the opening balance.

Figure 1: Sample receipt entry (stock)

NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate tablets MR 10mg (MST Continus 10)*										13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			01/01/11	19:15	Balance transferred from page 12				15 ✓*initial*	
Twenty	*18/04/11*	*Req. 24*	*18/04/11*	*14:30*	*Received from Rochford Pharmacy*		*Signature & name*	*Signature & name*	*31 ✓initial*	

9.3. Recording receipt of patients own CDs

9.3.1. Patients will occasionally bring their own supply of CD medication with them when admitted. Any CDs brought in by a

patient must be checked by two nurses and then stored in the CD cupboard. The details of a patient's own CDs must be entered in the back of the CD Record Book, starting at page 100 and working forwards, using a new page to record each CD for each patient. The patient's name and the page number should be added to the index page of the register.

9.3.2. The heading of the page should state the name of the drug, its form and strength, and the **name of the patient**. The quantity brought in should be entered on the first line in the following style:

Figure 2: Sample receipt entry (patient's own drug)

NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate tablets MR 10mg (MST Continus 10)* – Fred BLOGGS									100
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE
Twenty	*15/05/11*		*15/05/11*	*09:00*	*Brought in by patient*		*Signature & name*	*Signature & name*	*20 ✓initial*

9.3.3. Once the patient's CDs have been booked in and stored securely, a decision must be taken about whether they are to be used on the ward, returned home or disposed of – see section 13.

9.4. **Recording administration of CDs** – see section 12.5.

9.5. **Recording return or disposal of CDs** – see sections 14.4 (Essex only) for returns and 15.6.3 (Bedfordshire & Luton only) for disposal.

9.6. **Correcting errors**

9.6.1. If a mistake is made when making an entry in the record book, it **must not** be erased, crossed-out or obliterated; all entries must remain legible.

9.6.2. The incorrect entry should be bracketed, and '*error*' written next to the brackets. An appropriate footnote should be written at the bottom of the page explaining the error – this should be signed, dated and witnessed by a second practitioner (see section 9.1.4).

9.6.3. A new entry should then be made on the next blank line, the correct running balance inserted, and the entry witnessed by a second practitioner.

9.6.4. If an addition/subtraction error has been made with the running balance, resulting in several lines of the register being incorrect, a pharmacist should be contacted to investigate the error and make a correction to the register.

9.7. **Archiving Controlled Drugs Records**

9.7.1. Wards/units must retain all CD Order Books and CD Record Books for two years from the date of the last entry. All other CD-related documents, with the exception of CD denaturing/disposal records, should also be retained on the ward/unit for two years.

9.7.2. In Bedfordshire & Luton, records of the denaturing and disposal of CDs on the ward/unit (see section 15 and Annex 3) must be retained on the ward or unit for 7 years.

9.7.3. Completed CD Order Books and Record Books should be marked on the front cover with the date of the last entry and the date after which they can be destroyed (two years after the date of the last entry). CD Record Books contain patient-identifiable information and must be disposed of securely.

9.7.4. If a ward or unit closes, the CD records must be sent for archiving. The archived material must be clearly marked with the date of the last entry and the date after which it can be destroyed. The Accountable Officer must also be notified as soon as it is known that a ward/unit is planned to close (see section 16).

10. CONTROLLED DRUG STOCK CHECKS

10.1. The stock balance of all CDs entered in the CD Record Book should be checked against the contents of the CD cupboard by ward / unit staff on a weekly basis. If necessary, the Accountable Officer may require that a ward or unit carries out more frequent stock checks.

10.2. Ward / unit CD stock checks will also be carried out by pharmacy staff every three months.

10.3. **CD stock checks by ward/unit staff**

10.3.1. The Appointed Nurse in Charge of the ward or unit is responsible for ensuring that a weekly CD stock check is carried out. This check must be carried out even if no CDs are currently being administered to patients, in order to ensure that any stock is still present, correct and in date.

10.3.2. CDs that are unlikely to be used should be returned to pharmacy (Essex only) or disposed of (Bedfordshire & Luton only; see section 15.6.3), in order to eliminate the need for stock to be counted and recorded on a weekly basis.

10.3.3. Two registered nurses should carry out the stock check. Where possible, the staff undertaking the CD check should be rotated periodically, so the same people are not responsible every time.

10.3.4. The weekly check should take account of the following points:

- The balance of each drug in the CD Record Book should be checked against the physical stock in the CD cupboard, not the reverse, to ensure that all balances are checked.
- The CD cupboard should be checked to ensure that it does not contain anything that is not entered in the record book.
- Packs with intact tamper-evident seals should not be opened for stock checking.
- Stock balances of liquid medicines should be checked by visual inspection and estimation, in order to avoid contamination and loss through measuring. The balance in the record book and the physical quantity of liquid in stock must be reconciled when a bottle of liquid has been completed*.

10.3.5. For each item checked, an entry must be made in the CD Record Book stating '*Stock checked and correct'*, giving the date and time of the check. This entry must be signed by the two registered nurses who performed the check.

10.3.6. If the balance in the record book and stock count do not agree, other entries for that preparation should be checked for accuracy. If the problem is not found entries for other preparations in the CD Record Book should be checked.

10.3.7. Any errors should be marked in the CD Record Book as described in section 9.6.

10.3.8. If a discrepancy is found between the balance in the CD Record Book and the physical stock in the cupboard, it must be investigated without delay. The supplying pharmacy must be notified as soon as possible (not out of hours), if the discrepancy cannot be promptly rectified by the ward/unit.

10.3.9. If this is necessary, a pharmacist should investigate the discrepancy and carefully check the transactions in the CD Record Book and the contents of the CD cupboard. If an error or omission is traced, the pharmacist must make an appropriate entry in the record book stating the reason for the error/omission and correcting the running balance. This entry should be dated and signed by the pharmacist, and witnessed by an authorised member of the nursing staff.

10.3.10. If no error or omission can be traced to explain the discrepancy, an Adverse Incident must be submitted immediately by the Appointed Nurse in Charge of the ward or unit. A copy should be

* Note: Discrepancies often occur with liquid medicines. If the check shows that the stock exceeds the balance in the register, the excess must be disposed of by two authorised staff). If the check shows that the physical stock is less than the balance in the register, the supplying pharmacy should be contacted. If the discrepancy is large, the Accountable Officer should be contacted.

sent to the Accountable Officer as well as to the Risk Management Department, and both should be notified by telephone so that a decision can be taken on further investigative action.

10.4. **CD checks by pharmacy staff**

10.4.1. Staff from the pharmacy that supplies a ward/unit with CDs will carry out a stock check at 3-monthly intervals, and provide a summary report to the Appointed Nurse in Charge and to the Accountable Officer. The check will also cover other aspects of the requirements for the management and use of CDs on the ward/unit.

10.4.2. These stock checks should be carried out by a member of the pharmacy staff and an authorised member of the nursing staff, and should follow the same criteria as in section 10.3.4.

10.4.3. In the case of liquid preparations, the stock will be physically measured rather than estimated. Wards/units that hold stocks of liquid CDs should obtain small and large size glass pharmacy measuring cylinders for this purpose, e.g. 25ml and 2 x 250ml.

10.4.4. For each item checked, an entry must be made in the CD Record Book stating '*Quarterly stock check*', and giving the date and time of the check. This entry must be signed by the member of pharmacy staff and the authorised nurse who carried out the check.

10.5. **Stock checks at administration**

10.5.1. Whenever a CD is administered, the amount of remaining stock should be checked in order to confirm that the running balance in the CD Record Book is correct. Any discrepancy should be dealt with as in section 10.3.8.

11. PRESCRIBING CONTROLLED DRUGS

11.1. Prescribers must complete a signature form which includes their registration number – this form can be found at Appendix 1 of CLPG13.

11.2. **Prescribing CDs for inpatients**

11.2.1. CDs for inpatients should be prescribed on a standard inpatient Medicine Prescription & Administration Chart.

11.2.2. There are no special prescription-writing requirements when CDs are prescribed for inpatients. CDs should be prescribed in the same way as other medicines (see section 7.8 of CLPG13):

11.2.3. Inpatient prescription charts for Controlled Drugs will be endorsed 'CD' by the pharmacy.

11.3. Prescribing CDs for leave, discharge and outpatients

11.3.1. Prescriptions for Controlled Drugs for leave, discharge and outpatients must be written in accordance with all the requirements of the Misuse of Drugs Regulations, as detailed below. The prescription-writing requirements for CDs can also be found in the introductory pages of the BNF.

11.3.2. Prescriptions must be written on a Trust prescription form or a FP10 prescription form. The prescription must be written so as to be indelible, i.e. handwritten in ink, typed or computer-generated. With the exception of temazepam, prescriptions for all Schedule 2 and 3 CDs (see Annex 2) must contain the following details:

- The *prescriber's address*, i.e. the ward or unit, or the location of the clinic where the prescriber is based.
- The *patient's full name* and *address*, plus their NHS number
- The *name of the drug*
- The *form* of the preparation, e.g. tablets, capsules, liquid, patches, even if only one form exists
- The *strength* of the preparation
- The *dose* to be taken
- The *total quantity* of the preparation to be supplied, ***in both words and figures***, e.g. 'ten (10) tablets', 'one hundred ml (100ml)'.
- The *signature* of the prescriber. To aid identification, the prescriber should also print their name in block capitals, followed by their professional registration number.
- The *date* on which the prescription has been written

11.3.3. **Handwriting:** CD prescriptions no longer have to be handwritten – typed or computer-generated prescriptions are acceptable, but the *prescriber's signature must be in his/her own handwriting*. Any amendments to a CD prescription must be signed by the prescriber.

11.3.4. **Labels:** The use of pre-printed 'addressograph' labels containing patient details is not recommended for CD prescriptions. If the use of such labels is unavoidable, the prescriber should add a second signature, starting his/her signature on the label and extending it onto the prescription form, so that it is apparent at the time of dispensing if the label has been tampered with.

11.3.5. **Duration of supply:** Prescriptions for CDs should be for a maximum of 30 days supply. In exceptional circumstances a

prescriber may issue a CD prescription for more than 30 days supply of medication, but if this is to be done, the risk must be assessed and the reasons for doing so must be documented in the patient's healthcare record. CD prescriptions are only valid for 28 days from the date of writing.

11.3.6. **Leave/Discharge**: CDs MUST NOT be dispensed from ward stock for a period of home leave/discharge as this does not meet the legal requirements for the supply of CDs.

When authorising leave for a patient who is on regular treatment with a CD, medical and nursing staff must take into consideration the restrictions that apply to the prescribing and supply of CDs. If it is not feasible to obtain a supply of leave medication from the hospital pharmacy in time for a period of leave, the following options are permissible:

- If the ward is holding a supply of the patient's own CDs, these can be returned to the patient when they go on leave provided the dosage instructions have remained unchanged and they are still in date. The complete pack must be returned to the patient (see section 13.5); they must not be re-dispensed
- If the patient (or a relative/carer) confirms that they still have a supply of the medication at home, they can be instructed to use this while on leave, provided the dose has remained unchanged.
- The patient can be instructed to return to the ward on each day of leave for a dose of the CD to be administered from ward stock
- If the pharmacy is able to supply the medication by the following day, the patient can be instructed to return to the ward to collect the item.
- If the ward has access to FP10 prescription forms, the CD can be prescribed on one of these for dispensing via a community pharmacy (but note that most wards do not currently have access to FP10 forms).

If none of the above options is feasible but the provision of a supply of a CD is clinically essential, the patient's leave should be delayed until a supply can be obtained from the hospital pharmacy.

11.3.7. **Instalment prescriptions:** Community Drug and Alcohol Services may prescribe CDs for instalment dispensing using blue instalment prescription forms (FP10 MDA). The maximum supply permitted on these forms is 14 days.

11.4. **Non-medical prescribers**

11.4.1. Considerable restrictions apply to the circumstances in which non-medical prescribers can prescribe, administer and/or supply a controlled drug, whether acting as an independent prescriber or in accordance with the terms of an agreed individual clinical management plan as a supplementary prescriber.

11.4.2. Members of staff who have qualified as non-medical prescribers and who wish to prescribe Controlled Drugs as part of their role must contact the Accountable Officer to discuss the circumstances in which they are able to prescribe within current legislation.

11.5. **Patient Group Directions**

11.5.1. There are very limited circumstances in which certain CDs may be administered or supplied under a patient group direction (PGD) by certain named health professionals.

11.5.2. Members of staff who are considering using a PGD relating to CDs must contact the Accountable Officer to discuss the circumstances in which this is allowable within current legislation.

12. ADMINISTRATION OF CONTROLLED DRUGS

12.1. The administration of CDs must follow the Trust procedures for the administration of medicines, as detailed in procedural guideline CLPG13 (section 15), with the additional controls set out in this document.

12.2. The CD must be administered by a registered nurse or a doctor, and the administration must be witnessed by a second person, who should usually be a registered nurse (a nurse from a neighbouring ward/unit can act as the witness if a second nurse is not available). Alternatively, administration may be witnessed by a doctor, pharmacist or pharmacy technician.

12.3. Exceptionally, if there are routinely insufficient nursing staff available on a ward/unit to act as CD administration witnesses, the ward/unit manager must assign this role, and provide appropriate training, to suitable unqualified members of staff. These staff must sign the specimen signature sheet at the front of the CD Record Book (see section 5.2). Registered healthcare professionals should be used first.

12.4. The witness and the person administering the CD must be present for the whole of the procedure in order to confirm that:

- the prescription is complete and legible
- the medicine has not already been administered
- the correct CD is selected from the cupboard and is in date

- the stock level is correct against the last entry in the CD Record Book. Balances are to be checked, ticked and initiated every time an entry is made
- the medicine is prepared and/or measured correctly
- the dose is administered to the right patient by the right route in the right form
- the patient has actually taken the medicine and cannot retrieve it later
- any excess medicine which cannot be reused (for example, part of the contents of an ampoule, a dropped or spat out tablet, a dose prepared but refused) is destroyed appropriately (see sections 12.6 - 12.8 and 15.7).

12.5. Recording the administration of CDs

12.5.1. A record must be made in the CD Record Book whenever a CD is administered. The entry in the record book should contain the following details:

- date and time of administration
- name of the patient
- quantity administered (as the number of tablets or the volume of liquid administered, not as the number of mg)
- quantity wasted, if applicable (see section 12.6)
- form administered
- names and full signatures of the person administering and the person witnessing, for both administration and for the quantity wasted and destroyed, if applicable
- balance left in stock - to be checked, ticked and initiated every time an entry is made

Figure 3: Sample administration entry

NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate tablets MR 10mg (MST Continus 10)*									13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE
			01/01/11	19:15	Balance transferred from page 12				15
Twenty	*18/04/11*	*Req. 24*	*18/04/11*	*14:30*	*Received from Rochford Pharmacy*		*Signature & name*	*Signature & name*	*31 ✓initial*
			19/04/11	*16:15*	*John Smith*	*2 tablets*	*Signature & name*	*Signature & name*	*29 ✓initial*

12.6. Quantities wasted at administration

12.6.1. In the case of unit dose products (e.g. ampoules) for which the patient does not require the entire quantity in the ampoule, the

entry in the register should show the amount given and the amount wasted. For example, if 2.5ml was given from a 5ml ampoule, the entry should read '*2.5ml given, 2.5ml wasted*'. The quantity wasted should be destroyed as detailed in section 15.7.

12.7. **Doses prepared but not administered**

12.7.1. Doses prepared but not given, e.g. drug drawn up into a syringe but refused by the patient, should be destroyed as detailed in section 15.7. The reason for non-administration should be documented in the CD Record Book in the presence of the witness.

12.8. **Dropped items**

12.8.1. If a tablet or capsule is dropped on the floor, liquid spilled or an ampoule broken, an appropriate entry must be made in the CD Record Book and witnessed by a second practitioner. The running balance should then be adjusted to reflect the quantity lost. The quantity wasted should be destroyed as detailed in section 15.7.

12.8.2. Broken ampoules should be disposed of in a bin for sharps contaminated with pharmaceutical waste. Liquid spills should be mopped up with a paper towel, which should then be disposed of in the 'pharmaceutical waste' bin.

13. MANAGEMENT OF PATIENT'S OWN CONTROLLED DRUGS

13.1. A Controlled Drug brought into a ward or unit by a patient must be checked and entered onto a fresh page at the back of the CD Record Book as detailed in section 9.3.

13.2. If the patient's own CD is not labelled or boxed, it must be placed in a suitable container (clear plastic bag if available) and labelled with the name of the patient, the date of admission and the quantity of drug in the bag, in addition to making an entry in the record book.

13.3. If the patient's CD is not required for their treatment whilst an inpatient, one of the following procedures should be followed:

- If the patient agrees, the CD may be disposed of on the ward/unit. The patient should be asked to give their consent to the disposal of the item using the form at Annex 3 of Appendix 11 to CLPG13. The item should be clearly marked '*Awaiting disposal – consent obtained*' and an entry should be made on the appropriate page in the CD Record Book also stating '*Awaiting disposal – consent obtained*'. The consent form should be kept in the CD Record Book at the appropriate page until it can be removed to pharmacy (Essex) or disposed of securely on the ward (Bedfordshire & Luton; see section 15).

- If the patient wishes, and if it is appropriate to do so, the CD may be returned home with an identified responsible adult. This person must sign and date an entry in the CD Record Book when he takes responsibility for the CD. The entry must show the quantity returned home, and the running balance must then be changed to zero. If the item is not fit for use, or is no longer clinically appropriate, the patient and the patient's agent should be advised that the item should be taken to a community pharmacy for safe disposal.
- If the patient does not consent to disposal or to the item being returned home, it should be retained on the ward until the patient is ready to be discharged (see section 13.5).

13.4. **Use of a patient's own CDs on the ward/unit**

13.4.1. Ideally, a patient's own CDs should not be used for their treatment whilst an inpatient. Instead, a stock supply of the required medication should be ordered from the pharmacy as detailed in section 5.

13.4.2. However, in some circumstances it may be necessary to use a patient's own CDs until a stock supply can be obtained from the pharmacy, e.g. at weekends when the pharmacy is closed. If so, the item must be checked to ensure that it is fit for use (see Appendix 11 of CLPG13 for how to assess a patient's own drugs). Provided the item is fit for use, it can be administered and recorded in the back of the CD Record Book as detailed in section 12.5.

13.4.3. A patient's own CDs **must never** be used to treat another patient.

13.5. **Patients' own CDs at discharge**

13.5.1. If a patient continues to require treatment with a CD at discharge and has their own supply of medication in the CD cupboard, the item can be returned to them provided it is still suitable for use and the dosage instructions are still correct.

13.5.2. An entry must be made in the CD Record Book to indicate that the drugs were returned to the patient, and the register should be signed by the patient or their representative to confirm receipt. The running balance must then be changed to zero.

13.5.3. If a patient's CD treatment has been discontinued or altered but there is still a supply of their original medication in the CD cupboard, the patient's consent should be sought for the item to be removed to pharmacy (Essex) or disposed of securely on the ward (Bedfordshire & Luton).

13.5.4. A patient's own CDs remain their personal property until they consent to disposal. If a patient does not consent to the disposal

of a CD item that they no longer require for treatment, this item must be returned to them, and an entry made in the CD Record Book as in section 13.5.2. However, the patient should be advised to take the item to a community pharmacy for secure disposal because it is not required for their current treatment. The giving of this advice should be documented in the patient's healthcare record.

Figure 4: Sample entry (patient's own drug)

NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate tablets MR 10mg (MST Continus 10)* – Fred BLOGGS									100
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE
Twenty	*15/05/11*		*15/05/11*	*09:00*	*Brought in by patient*		*Signature & name*	*Signature & name*	*20 ✓initial*
			15/05/11	*10:00*	*Fred Bloggs*	*1 tablet*	*Signature & name*	*Signature & name*	*19 ✓initial*
			15/05/11	*16:00*	*Returned to patient Patient's signature*	*19 tablets*	*Signature & name*	*Signature & name*	*NIL ✓initial*

14. RETURN OF CONTROLLED DRUGS TO PHARMACY

14.1. Unused CD stock from wards or units may only be returned to the pharmacy where the pharmacy department is part of the same organisation. Therefore, different processes apply in Bedfordshire, Essex and Luton.

14.2. The only exception is the very small quantities of CDs that are wasted at the time of administration, e.g. part-used ampoules or doses that have been spat out (see section 15.7).

14.3. **Bedfordshire and Luton**: All unwanted CDs must be disposed of at ward / unit level (see section 15).

14.4. **Essex**: All unwanted CDs should be returned to the pharmacy for re-issue or safe destruction and onward disposal. This includes unused stock, CDs which are time-expired or otherwise unfit for use (e.g. opened liquids), and any other CDs no longer needed on the ward (i.e. patient's own CDs for disposal).

14.4.1. The ward or unit should keep a record of drugs returned to pharmacy. This should be in the form of a consignment note with duplicate pages so that both the pharmacy and ward / unit have a record of the transaction.

14.4.2. The following details should be recorded when CDs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Name and signature of registered nurse

14.4.3. An entry should be made on the relevant page of the ward / unit CD Record Book showing:

- Date
- Reason for return
- The names and full signatures of the registered nurse responsible for the return and the pharmacist or pharmacy technician witnessing
- Quantity removed
- Name, form and strength of drug
- Balance remaining

14.4.4. The CDs should be transferred to the pharmacy in a safe and secure manner by approved pharmacy staff.

Figure 5: Sample return entry

NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate tablets MR 10mg (MST Continus 10)*										13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			01/01/11	19:15	Balance transferred from page 12				15 ✓ *initial*	
Twenty	*18/04/11*	*Req. 24*	*18/04/11*	*14:30*	*Received from Rochford Pharmacy*		*Signature & name*	*Signature & name*	*31 ✓ initial*	
			19/04/11	*16:15*	*John Smith*	*2 tablets*	*Signature & name*	*Signature & name*	*29 ✓ initial*	
			20/04/11	*09:00*	*Returned to Pharmacy – no longer required*	*29 tablets*	*Signature & name*	*Signature & name*	*NIL ✓ initial*	

15. DISPOSAL OF CONTROLLED DRUGS

Sections 15.1 to 15.6 apply to Bedfordshire and Luton only

15.1. Disposal of CDs that are no longer required may only be undertaken on the ward or unit in Bedfordshire and Luton. In Essex all CDs should be returned to the pharmacy for safe denaturing and disposal.

15.2. All Schedule 2 and 3 Controlled Drugs that are no longer required by a ward or unit must be denatured (rendered unfit for use) before they can be disposed of. This denaturing process must be carried out on the ward or unit.

15.3. The denaturing of Schedule 2 and 3 CDs prior to their disposal must be witnessed by two people:

- An authorised nurse who works on the ward / unit (see section 5.2)
- A person authorised by the Accountable Officer to witness the destruction of Controlled Drugs on wards/units

15.4. The Accountable Officer is not permitted to personally witness the destruction of CDs, and pharmacy staff who visit Trust sites cannot carry out this role as they are also involved in the supply and audit of CDs. A member of the Trust's Clinical Governance & Quality Department is authorised to witness the destruction of CDs (contact Nikki Willmott, internal ext. 2234).

15.5. All staff who are authorised by the Accountable Officer to witness the destruction of CDs must have received appropriate training. They are accountable for this activity directly to the Accountable Officer, who will maintain a list of authorised 'CD destruction witnesses'.

15.6. **Process for denaturing and disposal of CDs**

15.6.1. When a ward or unit has unwanted CDs requiring disposal, they should first contact the Trust's authorised witness to arrange a suitable date and time for the disposal process to be carried out (see section 15.4).

15.6.2. Prior to carrying out the denaturing process, the authorised ward nurse and the witness should remove the unwanted CD (and any other stock of the same product) from the CD cupboard and check that the total quantity agrees with the running balance in the CD Record Book (if there is a discrepancy, refer to section 15.6.7)

15.6.3. An entry must then be made in the CD Record Book stating:

- The date and time of denaturing
- The quantity of drug denatured, e.g. '10 tablets', '35ml'
- The reason for denaturing, e.g. 'out of date', 'no longer required'
- In the case of a patient's own CDs, 'patient's consent obtained'
- The signatures of the authorised nurse and the authorised witness
- The remaining balance in stock, or NIL if the entire stock has been denatured. In the case of a patient's own CDs that have been denatured, the running balance should be zeroed and a line put through the remainder of the page.

15.6.4. A form for recording the denaturing and disposal of CDs must also be completed by the authorised nurse and witness – see Annex 3. The completed CD denaturing/disposal form, together with any relevant patient consent sheets, must be retained on the ward or unit with other CD records for 7 years from the date of disposal. The authorised witness must also forward a copy of the completed CD denaturing/disposal form to the Accountable Officer.

15.6.5. Once the entries in the CD Record Book and the record sheet have been completed, the authorised witness should carry out the denaturing process in the presence of the authorised nurse. The authorised witness will bring a suitable CD denaturing kit to the ward. Disposal will be undertaken by the authorised witness in accordance with the operational procedure in Annex 4**.**

15.6.6. When the contents of the denaturing kit have gelled, the container can be placed in the 'pharmaceutical waste' bin for disposal.

15.6.7. If there is a discrepancy between the running balance in the CD Record Book and the quantity in the CD cupboard, the actions detailed in sections 10.3.8 - 10.3.10 should be carried out before any stock is disposed of.

Sections 15.7 to 15.8 apply to Bedfordshire, Essex and Luton

15.7. **Disposal of very small amounts of CDs**

15.7.1. If small amounts of CDs are wasted at the time of administration (see sections 12.6 - 12.8), these can be disposed of by two authorised members of the ward staff, who should make an appropriately worded explanatory entry in the CD Record Book and ensure that the running balance is amended accordingly.

15.7.2. The wasted material, e.g. the remaining contents of an ampoule or vial, spat-out tablets, etc, should be placed in the pharmaceutical waste bin. Emptied ampoules and vials should be placed in a sharps bin suitable for the disposal of pharmaceutical waste.

15.8. **Disposal of Controlled Drugs belonging to deceased patients**

15.8.1. **Inpatients**: If a patient dies whilst an inpatient, any Controlled Drugs that were their personal property should be disposed of in accordance with section 15.6 of this procedure. These medications do not form part of the patient's estate and should not be returned to relatives or carers.

15.8.2. **Community**: If a patient dies in the community and has been in regular contact with community-based mental health services, the community staff have a responsibility to ensure that any dispensed medications (including CDs) are safety disposed of. CDs do not need to be treated any differently to other dispensed medications in this situation.

Ideally, the patient's relatives or carers should be advised to return the medicines to the community pharmacy that supplied them, so that they can be safely disposed of.

If the circumstances of the patient's death mean that this is not feasible, the community staff should remove the medications from the patient's home, recording in the patient's healthcare record the names and quantities of the drugs removed – this should be witnessed by a second person. The drugs should then be taken to a community pharmacy, and a receipt obtained to confirm that the drugs were handed to the pharmacy for disposal. This receipt should be filed in the healthcare record in case any questions are raised regarding the removal of the patient's medication.

16. WARD UNIT CLOSURES AND TRANSFERS

16.1. If a ward or unit is planned to be closed, either short-term or permanently, or if a ward/unit is to be transferred to another location, the Accountable Officer should be notified at the earliest possible opportunity.

16.2. The Accountable Officer will prepare a procedure for the management of Controlled Drugs during the closure or transfer, in consultation with senior ward staff.

17. OBTAINING CONTROLLED DRUGS OUT OF HOURS

17.1. If a patient requires treatment with a Controlled Drug that is not available on the ward/unit, a supply should be ordered from the appropriate hospital pharmacy. If the pharmacy is closed, it is acceptable to use the patient's own supply of medication until the pharmacy is next open (see section 13.4).

17.2. If the patient has not brought in a supply of their own CD medication, the doctor should be called to assess whether the dose may be omitted without harm to the patient.

17.3. If a Controlled Drug needs to be administered as a matter of urgency and the ward/unit does not have the drug in stock, a **single dose** may be obtained from another ward/unit that does have the drug in stock, provided it is authorised by the nurse in charge. In this situation, the CD Record Book of the ward supplying the CD must be taken, together with the container of the required drug, to the ward where the patient is located. This must be done by a member of the nursing staff of the ward supplying the CD. The administration details must be entered into the CD Record Book of the *supplying* ward and witnessed by nurses from *both* wards. The location of the patient must be recorded in the CD Record Book alongside the patient's name, and an entry made in the patient's healthcare record to indicate that the dose was supplied from another ward/unit. Any CD transfer must be notified to the pharmacy at the earliest opportunity.

17.4. If administration is essential but no nearby wards/units have any stock of the drug in question, the on-call pharmacist should be contacted for advice. Although there is no agreement between SEPT and the acute trusts in Bedfordshire and Luton for the on-call pharmacists to supply medications outside normal hours, they may be willing to do this in very exceptional

circumstances where a CD needs to be administered as a matter of clinical urgency. Alternatively, they may be able to arrange for the patient to be taken to A&E or one of the acute trust wards for a dose of the drug to be administered. See section 9.6 of CLPG13 for details of how to contact the on-call pharmacist.

18. POSTING CONTROLLED DRUG PRESCRIPTIONS

18.1. Under normal circumstances CD prescriptions should not be posted to service users, due to the potential for misuse if they should fall into the wrong hands. Prescription forms should always be given directly to the patient, or, in the case of children, to their parent or guardian.

18.2. In circumstances where posting a CD prescription is unavoidable, the following precautions should be taken:

- The prescription form should be posted to a community pharmacy nominated by the patient, and not sent to the patient's home address
- The prescription form should be sent to the nominated community pharmacy by recorded delivery. If the use of recorded delivery is not feasible, a system should be set up whereby the nominated pharmacy is notified when a prescription is being posted, with instructions to complete and fax back a form which confirms that the prescription has been received. Records of posted prescriptions must be maintained so that any losses in transit can be identified.

18.3. Any prescription forms that go missing in the post despite these precautions must be notified immediately to the Accountable Officer for CDs.

Annex 1

Legal requirements for Controlled Drug Schedules

Schedule:	**Schedule 2**	**Schedule 3**	**Schedule 4 Part I**	**Schedule 4 Part II**	**Schedule 5**
Designation:	**CD**	**CD No Reg**	**CD Benz**	**CD Anab**	**CD Inv**
Brief description:	Drugs which carry a severe risk of addiction but which may be used medicinally.	Must be stored in a CD cupboard in an institutional setting	Benzodiazepines and related drugs	Certain steroids and hormones liable to misuse	Low strength opiates
Examples:	Morphine and other strong opiates; methylphenidate and other major stimulants	Most barbiturates; buprenorphine, temazepam, midazolam	Diazepam, oxazepam chlordiazepoxide, and most other benzodiazepines; zolpidem	Anabolic steroids, growth hormone	Oramorph®
Storage in CD cupboard:	Yes	Yes, except phenobarbitone	No	No	No
Prescription writing requirements: (See section 11)	Yes	Yes, except temazepam	No	No	No
CD Requisitions needed:	Yes	Yes	No	No	No
Record in CD register:	Yes	No but required in SEPT for buprenorphine and midazolam	No	No	No but required in SEPT for Oramorph®
Pharmacist MUST ascertain the ID of the person collecting CD:	Yes	Yes	No	No	No
Emergency supplies allowed:	No	No, except phenobarbitone for epilepsy	Yes	Yes	Yes
Validity of prescription:	28 days	28 days	28 days	28 days	6 months (if POM)
Maximum duration that should be prescribed:	30 days	30 days	30 days	30 days as good practice	30 days as good practice

Note: Apart from the cannabinoid-based medicine Sativex®, drugs in **Schedule 1** (CD Lic) have no legitimate medical applications, and legal possession requires a licence from the Home Office. Examples include cannabis, LSD and magic mushrooms.

Annex 2

List of Common Controlled Drugs in Schedules 2 and 3

(The products most frequently used within the Trust are marked with an asterisk*)

Ordering: All Schedule 2 and Schedule 3 Controlled Drugs required for ward stock must be ordered using a CD Order Book.

Storage: All Schedule 2 CDs must be stored in a CD cupboard. Many Schedule 3 CDs are exempt from the legal requirement for storage in a CD cupboard, but within this Trust, **buprenorphine**, **temazepam** and **midazolam** must be stored in a CD cupboard. However, **phenobarbitone** does not need to be stored in a CD cupboard.

Recording: All Schedule 2 CD must be fully recorded in a CD Record Book (receipts and administration). Schedule 3 CDs do not legally require recording in a record book, but within this Trust, receipts and administration of **buprenorphine** and **midazolam** must be fully recorded in a CD Record Book.

Disposal: All Schedule 2 CDs, plus buprenorphine and midazolam, must be denatured by an approved person and booked out of the CD Record Book prior to disposal.

Drug	Brand Name(s) (generic version available for many)	Schedule
Alfentanil	Rapifen®	2
Amobarbital	Amyta®l (named patient only) Tuinal® (with secobarbital – named patient only)	3
Buprenorphine*	BuTrans®, Subutex®, Temgesic®, Transtec®, Suboxone® (with naloxone)	3
Butobarbital	Soneryl® (named patient only)	3
Cocaine		2
Codeine injection/powder		2
Dexamfetamine		2
Diamorphine		2
Dihydrocodeine injection		2
Dipipanone	Diconal® (with cyclizine)	2
Fentanyl	Abstral®, Effentora®, Actiq®, Instanyl®, PecFent®, Durogesic DTrans®, Sublimaze® Tilofyl®	2
Hydromorphone	Palladone®, Palladone SR®	2
Methadone*	Methadose®, Physeptone®, Synastone®, Metharose®	2
Meprobamate		3
Methylphenidate*	Ritalin®, Concerta XL®, Equasym XL®, Medikinet XL®	2
Midazolam	Hypnoval®	3
Morphine	Filnarine®, Oramorph®, MST Continus®, Sevredol®, Morphgesic SR®, Zomorph®, MXL®, Morcap® Cyclimorph® (with cyclizine)	2
Oxycodone	OxyNorm®, OxyContin®, Targinact® (with naloxone)	2
Papaveretum	Omnopon®	2
Pentazocine	Fortral®	3

Drug	Brand Name(s) (generic version available for many)	Schedule
Pethadine	Pamergan P100® (with promethazine)	2
Phenobartibal		3
Remifentanil	Ultiva®	2
Secobarbital	Seconal® (named patient only) Tuinal® (with amobarbital – named patient only)	2
Sodium Amytal		3
Tapentadol	Palexia®	2
Temazepam*		3

List of Controlled Drugs in Schedule 4 part 1

(brand names in brackets)

Alprazolam (Xanax) Chlordiazepoxide (Librium) Clonazepam (Rivotril) Diazepam (Valium)	Flurazepam (Dalmane) Loprazolam Lorazepam (Ativan) Lormetazepam	Nitrazepam (Mogadon) Oxazepam

Further information can be found at:
www.homeoffice.gov.uk/publications/drugs/drug-licences/controlled-drugs-list?view=Binary.

Annex 3

Providing Partnership Services in Bedfordshire, Essex and Luton

RECORD OF THE DENATURING AND DISPOSAL OF CONTROLLED DRUGS and / or REPORTING OF CONTROLLED DRUG DISCREPANCIES

Ward / Unit:	**Tel.:**
Registered Nurse in Charge:	**Date:**
Name: Authorised person for denaturing and disposal of Controlled Drugs:	**Signature:**
Name: Nurse witnessing denaturing and disposal:	**Signature:**

Drugs to be denatured:

Name of drug	Form and strength	Quantity denatured	Balance remaining	Stock or patient's own drugs (if POD, state name of patient)	Reason for disposal

Comments:

Discrepancies:

Period over which discrepancy may have occurred:
From (date/time): **To (date/time):**

Adverse Incident Report no:
NOTE: All details must be written on the form

Nurse in Charge notified on (date/time):

Name of authorised pharmacist for follow-up:

Comments:

- Completed copies of this form must be retained on the ward/unit with other Controlled Drug records for 7 YEARS from the date on which the drugs were disposed of.
- A copy should also be sent or faxed to the Accountable Officer as soon as possible after the denaturing/disposal of Controlled Drugs

Annex 4

OPERATIONAL PROCEDURE FOR THE DISPOSAL OF UNWANTED CONTROLLED DRUGS ON WARDS/UNITS (for use only by authorised destruction witnesses - see section 15.4)

1. On arrival at the ward/unit, identify the nurse in charge who has responsibility for the Controlled Drug cupboard keys, and explain that you have come to dispose of their unwanted CDs (show ID).

2. The nurse will need to be present as the witness throughout the booking-out and disposal process.

3. **What to take with you**

   - Copy of Appendix 3 of the procedural guidelines for the safe and secure handling of medicines (this document)
   - CD denaturing kits (the number will depend on the quantity of drugs to be disposed of)
   - Pestle and mortar
   - Measuring cylinder (if ward has liquids to be disposed of)[2]
   - Cat litter (if ward has a large quantity of liquid to be disposed of)
   - Blank forms for consent to disposal and record of disposal (see Annex 3 within Appendix 11 of CLPG13 and Annex 3 of this document)

4. **Preparing the drugs for disposal**

   4.1. Confirm with the member of staff which Controlled Drug(s) require disposal. This may include out of date 'stock' drugs and unwanted 'patient's own' drugs.

   4.2. Deal with one drug at a time. Remove all stock of the drug requiring disposal from the CD cupboard and place it on a clear work bench. In some cases, only part of the stock may need to be disposed of, with the remainder being retained on the ward. However, the entire stock of the drug should be removed from the cupboard so that it can be counted.

   4.3. Check that the content of each pack matches the details on the outer carton, i.e. check that what is printed on a foil/blister strip of tablets is the same drug and strength as stated on the carton.

   4.4. Remove the CD Record Book from the CD cupboard and identify the current page in the record book corresponding to the drug being disposed of. Confirm with the nurse witness that you have identified the correct page – remember that different strengths of a drug will each have separate pages in the Record Book. Note that 'patient's own' supplies of CD medication are recorded on pages at the back of the Record Book.

   4.5. Count the total stock of the drug (number of tablets, capsules, etc). In the case of liquids, measure the volume using a measuring cylinder (full bottles do not need to be measured – accept the volume stated on the container).

[2] Wards are advised to purchase measuring cylinders, so this may not be necessary

4.6. Confirm that the quantity in stock agrees with the quantity stated in the CD Record Book. If so, proceed with booking-out. If there is a discrepancy, refer to section 7.

4.7. Confirm whether the entire stock of the drug is to be disposed of, or whether part of the stock is to be retained, e.g. because it is still in date. If part of the stock is to be retained, separate this from the stock requiring disposal and place it to one side until the entry has been made in the Record Book. Count the number of tablets, capsules, etc. requiring disposal.

Note: Very occasionally a ward may be holding both 'stock' and 'patients own' supplies of the same drug, only one of which requires disposal. In this case there should be separate pages in the CD Register for the two supplies. (The 'patient's own' medication should have been recorded on a page at the back of the CD Record Book, and the container will carry a community pharmacy label with the patient's name and dosage instructions).

In this situation, both pages of the CD Record Book will need to be checked. The supply that does *not require disposal* should be counted and checked against the record book, and then returned to the CD cupboard.

4.8. If the drugs to be disposed of are a patient's own, check that the patient has signed a consent form for their disposal (see Annex 3 within Appendix 11 of CLPG13).

NB – *If not present confirm with the nurse that the patient who the drugs belonged to has been discharged from the ward; if so, the drugs can be disposed of. If the patient is still present on the ward but no longer requires the drug, ask the nurse to get a consent form completed immediately.*

5. Booking the drugs out of the Controlled Drug Record Book

5.1. Having identified the items requiring disposal and having established the quantity to be disposed of, double-check that you have the correct page in the CD Record Book for the product in question. Then make an entry on the next blank line in the book. This entry should include the following information:

- The date and time of denaturing
- The quantity of drug denatured, e.g. '*Ten(10) tablets'*, '*thirty-five (35) ml'*
- The reason for denaturing, e.g. '*out of date'*, '*no longer required*'
- In the case of a patient's own CDs, '*patient's consent obtained*'
- The signatures of the authorised nurse and the authorised witness
- The remaining balance in stock, or NIL if the entire stock has been denatured. In the case of a patient's own CDs that have been denatured, the running balance should be zeroed and a line put through the remainder of the page.
- If part of the stock was retained for future use, check that the remaining quantity agrees with the new running balance in the Record Book and return it to the CD cupboard.

5.2. The style of the disposal entries in the CD Record Book should be similar to these examples:

NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate tablets MR 10mg (MST Continus 10)*										13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			01/01/11	19:15	Balance transferred from page 12				15 ✓*initial*	
			12/07/11	10:45	Seventeen (17) tablets destroyed (out of date stock)		*Signature & name*	*Signature & name*	*NIL ✓initial*	

NAME, FORM OF PREPARATION AND STRENGTH *Methadone Liquid 1mg/ml (Physeptone)* – James SMITH										98
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			19/08/10	*12:30*	*Twenty ml (20ml) destroyed (patient's own, no longer required – consent obtained*		*Signature & name*	*Signature & name*	*NIL ✓initial*	

If the ward has more than one CD requiring disposal, repeat the above preparation and booking-out processes for each drug in turn before proceeding to the denaturing stage.

6. Denaturing the unwanted items

6.1. Wear rubber gloves during the disposal process – these should be available on the ward.

6.2. With the exception of very large quantities of liquids (see section 6.6), all items should be disposed of using a CD denaturing kit. See sections 6.5 to 6.8 for how to prepare items prior to placing them in the kit.

6.3. The CD denaturing kit carries instructions for its use. It should be shaken well before use, and must not be filled beyond half-full (use a second kit if necessary). When all the drugs have been added, the kit should be filled with water and the lid replaced securely. It should then be shaken well – the contents will set to a gel within 5 minutes.

6.4. The entire kit should then be placed in the 'pharmaceutical waste' bin. If the ward does not have such a bin, the kit should be stored securely until a bin is available (contact Estates Dept).

6.5. Solid dose formulations – tablets, capsules

6.5.1. Put a small amount of water in a mortar. Add the tablets and grind/crush with the pestle to make a loose slurry – add more water if necessary. If there are capsules to be disposed of, pull them apart and let the powder and shell fall into the mortar before grinding. If the capsules cannot be pulled apart, crush them so that the shell is split.

6.5.2. Pour the slurry from the mortar into the kit, then rinse the mortar with a little more water to transfer any remaining debris.

6.6. Liquid formulations

6.6.1. Small volumes of liquid (up to 100ml) can be poured directly into the denaturing kit and mixed with any other items being disposed of at the same time. If necessary, a second kit can be used.

6.6.2. If the quantity of liquid to be disposed of is very large (>300ml), an alternative is to carefully mix it with an appropriate amount of cat litter in a bowl. The litter can then be disposed of in the 'pharmaceutical waste' bin.

6.6.3. Minor volume discrepancies are common with liquid preparations. If the quantity of liquid in stock *exceeds* the balance stated in the Record Book, the excess can be disposed of – in this case the entry should state the amount of the excess, e.g. *'Forty-five ml (45ml) plus twenty ml (20ml) excess destroyed'*

6.6.4. If the quantity of liquid in stock is *less than* the amount stated in the CD Record Book, the Lead Clinical Pharmacist for Bedfordshire and Luton should be contacted to investigate. Disposal should not proceed until this investigation has been completed. If there is a very large shortfall, the Accountable Officer should also be notified.

6.7. **Injections**

6.7.1. Ampoules containing liquids should be opened and the liquid tipped into the kit. The remains of the ampoule should be placed in a 'sharps' bin suitable for sharps contaminated with pharmaceutical waste.

6.7.2. Ampoules containing powder should be opened and water added to dissolve the powder. They should then be treated as above.

6.8. **Patches**

6.8.1. The backing paper should be removed from the patch, and the patch folded over on itself. It can then be placed into the kit. It is essential that gloves are worn whilst carrying out this process.

7. Completing the denaturing/disposal record / Discrepancies

7.1. Once the denaturing process has been completed, the authorised person and the witness should complete a record sheet which lists the items that have been disposed of (see Annex 3). Any patient consent forms should be attached to the record sheet.

7.2. The original of the completed record sheet must be retained on the ward for 7 years. A copy should be retained by the authorised destruction witness and a second copy should be sent or faxed to the Accountable Officer for CDs.

7.3. If a discrepancy is found between the content of the CD cupboard and the CD Record Book, this should be detailed on the denaturing/disposal form. Disposal of the drug in question must not proceed, although other drugs may be disposed of. The discrepancy must be reported and investigated as explained in sections 10.3.8 - 10.3.10 of this document.

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

THE USE OF UNLICENSED MEDICINES

1. INTRODUCTION

1.1. In order to minimise the risk to patients and the legal liability of healthcare professionals, the use of unlicensed medicines, and licensed medicines for unlicensed indications should only occur in line with procedures set out in this document.

1.2. In the UK, no medicine can be marketed for human use without a 'marketing authorisation' (formerly called a product licence) issued by the MHRA (Medicines and Healthcare products Regulatory Agency) or by the EMA (European Medicines Agency) if it has been authorised via the EU-wide procedure. The marketing authorisation (MA) is intended to guarantee the quality, safety and efficacy of the medicine, and states the clinical indication(s), recommended dose, and route of administration by which the medicine may be used; contraindications, special warnings and other particulars for the safe use of the drug will also be included, such as the age group to which it can be given.

1.3. Provided a medicine is used within the terms of its MA, the manufacturer will usually carry full liability for any unforeseen adverse consequences that are directly attributable to the medicine.

1.4. When a drug does not have a MA, the drug is said to be 'unlicensed'. When a drug does have a MA, but is used in a way or for an indication which is not set out within the MA, the drug is said to be used 'off-label'. Although the terms are clearly defined, in reality, 'unlicensed' is often used to describe both situations.

1.5. For a variety of good clinical reasons, the use of unlicensed medicines and licensed medicines for unlicensed indications or in unlicensed doses is widespread in secondary care and in community based palliative care. In such circumstances, it is judged by the prescriber to be in the best interests of the patient based on the available evidence. Were this practice to be curtailed the treatment of many patients would be impeded. It is therefore important that prescribers and pharmacists are aware of the associated medico-legal implications. Such prescribing may carry an increased level of risk for the patient, and may expose the prescriber and the Trust to liability for any adverse consequences that arise from the treatment.

1.6. Whilst licensed medicines are subject to stringent control by the MHRA, neither prescriber nor pharmacist can make the same assumptions of quality, safety and efficacy about unlicensed medicines.

1.7. The purpose of this procedure is to provide a framework within which the Trust can assess the use of unlicensed medicines and off-label indications or doses, thereby safeguarding patients against the risk of injury and minimising the likelihood of claims against individual practitioners or the Trust.

2. OFF-LABEL USE OF MEDICINES

2.1. The use of licensed medicines for indications, or at doses, that are outside the terms of the MA is widespread, a good example being the use in children of medicines that are only licensed for use in adults.

2.2. Clinicians are often unaware that a medicine is not licensed for a particular indication or at a particular dose, especially if the drug is widely used in this way. Nevertheless, the manufacturer is unlikely to be found liable for any harm resulting from prescribing for an unlicensed indication unless the product itself can be shown to have been defective.

2.3. It is often not apparent from the prescription that a medicine is being used for an unlicensed indication, and the Trust cannot maintain a fully comprehensive system for monitoring such prescribing.

2.4. However, as far as is possible, the Medicines Management Committee will attempt to identify the well-established unlicensed uses for which licensed medicines are being used within the Trust as part of its formulary development role. Provided there is a reasonable body of evidence supporting the unlicensed indication, they will be listed within the Trust Formulary and Prescribing Guidelines.

2.5. Prescribers wishing to use licensed medicines for unlicensed indications not covered by the Formulary and Prescribing Guidelines are required to seek approval from the Medicines Management Committee, particularly if the dosage exceeds that recommended for licensed indications. This should be done using the Unlicensed Medicine Request Form in Annex 1.

3. UNLICENSED MEDICINES

3.1. The Medicines Act permits clinicians to prescribe unlicensed medicines (i.e. ones that do not have a MA) provided they:

- act responsibly and with reasonable skill and care, consistent with a reasonable body of their peers of similar professional standing.
- do so knowingly.
- obtain patient consent where possible, ensuring that the patient is aware of the unlicensed status of the drug and that its effects may be less well understood than those of a licensed product.

3.2. Unlicensed medicines will usually fall into one of the following broad categories:

- Medicines purchased on a named patient/named doctor basis. These include medicines without a UK license but which are licensed abroad and can be imported.
- Medicines for which the UK license has been suspended, revoked or not renewed, but which the manufacturer continues to make available for certain categories of patient.

- Medicines for which a MA has not been applied, or for which the MA has not yet been approved.
- Clinical trial medicines; these will usually be covered by a clinical trials exemption certificate.
- Admixtures of licensed medicines, for example in a syringe driver.

3.3. Responsibility for the use of an unlicensed medicine rests with the prescriber, and the Trust is required to have a system in place to ensure that a prescriber knows that a medicine is unlicensed and that he is aware of his responsibilities .

3.4. Provided the unlicensed medicine has been approved by the Medicines Management Committee (see section 6), the pharmacy department will obtain a supply, taking the necessary steps to ensure the quality of the product.

4. RESPONSIBILITIES OF PRESCRIBERS

4.1. Prescribers should be aware of the licence status of medicines that they use, and before prescribing an unlicensed medicine be satisfied that an alternative licensed medicine would not meet the patient's needs.

4.2. Additionally, before prescribing a medicine off-label the prescriber should be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative.

4.3. Prescribers should remember that whenever an unlicensed medicine is prescribed, or a licensed medicine is prescribed outside the terms of its licence, the prescriber is professionally accountable and may be called upon to justify their actions.

4.4. The prescriber should be satisfied that there is a sufficient evidence base to show its safety and efficacy, and take responsibility for monitoring and follow-up. MHRA guidelines recommend that:

- the reason(s) for prescribing are recorded and that the content of the requisite conversation, regarding an unlicensed medicine, with the patient and/or carers is also recorded. This conversation should give sufficient information to allow patients (and/or their carers) to make an informed decision about the proposed treatment.
- as for licensed medicines, health care professionals should report suspected adverse drug reactions to an unlicensed medicine to the MHRA via the Yellow Card Scheme.

4.5. Prescribers shall complete an 'Unlicensed Medicines Request Form' for submission to the Medicines Management Committee for unlicensed medicines not previously used in the Trust.

4.6. Where a consultant requests an unlicensed medicine, he should confirm whether junior medical staff will be permitted to prescribe it.

4.7. Prescribers must liaise with the relevant hospital Pharmacy to ensure continuity of supply for outpatients receiving unlicensed medicines. General Practitioners should not be asked to assume prescribing responsibility for unlicensed medicines.

4.8. Prescribers must consult fully with general practitioners before asking them to take on the responsibility for the prescribing of a licensed medicine outside the terms of its product licence. A general practitioner is not obliged to prescribe in such circumstances.

5. RESPONSIBILITIES OF PHARMACISTS

5.1. Pharmacists must ensure that the prescriber is aware whenever a requested medicine is only available as an unlicensed product.

5.2. Where an unlicensed medicine is to be ordered for the first time pharmacy must ask the requesting consultant to complete an 'Unlicensed Medicines Request Form'.

5.3. The pharmacy department will ensure that if a licensed medicine is available it is purchased in preference to an unlicensed product, wherever possible.

5.4. As purchaser, the pharmacy department will take responsibility for the quality of medicines obtained from manufacturers with a Specials Manufacturing Licence. Items purchased should be produced in accordance with a product specification provided by the local Pharmacy Quality Assurance Service.

5.5. Incoming unlicensed medicines should be quarantined and segregated from storage of licensed medicines. Certificates of Analysis of Conformity must be forwarded to the Pharmacy Quality Assurance Service who may request that further testing be carried out before the medicine can be released from quarantine.

5.6. Pharmacy will maintain appropriate records of receipts and issues of unlicensed medicines and a list of unlicensed medicines, currently being purchased and used within the Trust.

5.7. As purchaser, pharmacy will ensure that there are no breaches in patient confidentiality, when providing information to external suppliers of unlicensed medicines.

6. RESPONSIBILITIES OF THE MEDICINES MANAGEMENT COMMITTEE

6.1. It is the responsibility of the Trust's Medicines Management Committee (MMC) to manage the unlicensed use of medicines within the Trust.

6.2. Where a consultant wishes to initiate treatment with an unlicensed medicine the committee will receive and assess a completed 'Unlicensed Medicine Request Form'. In some situations this will be retrospective to the commencement of prescribing.

6.3. The minutes of the MMC meeting will record approval for use. Decisions by the MMC to monitor use will be communicated to the requesting consultant. Reports on outcomes may be required.

7. REQUESTING AN UNLICENSED MEDICINE / OFF-LABEL USE

7.1. Verbal requests to obtain an unlicensed medicine not previously used in the Trust should be made to the relevant pharmacy department in the first instance, who will advise on alternative options as appropriate.

7.2. The Trust requires that all unlicensed medicines prescribed within the organisation have been approved by the Medicines Management Committee. In order to achieve this, clinicians wishing to use an unlicensed medicine are required to complete an 'Unlicensed Medicine Request Form', (see Annex 1). Copies of the form can be downloaded from the Medicines Management web pages of the SEPT intranet.

7.3. The clinician should complete Section 1 of the request form and liaise with the appropriate pharmacy department to enable completion of Section 2. The completed form should then be signed and sent to the Chief Pharmacist who will ensure that the request is discussed at the next available meeting of the Medicines Management Committee.

7.4. When there is no urgency to obtain a supply of the unlicensed medicine the request will be considered at the next meeting of the Medicines Management Committee. If the committee gives approval for use pharmacy will then order a supply.

7.5. When an unlicensed medicine is urgently required the Chief Pharmacist may arrange for a supply to be obtained, if its need has been authorised by the MMC Chair. However, approval for continued use must still be sought by submitting a completed request form.

7.6. Where there is disagreement between a requesting consultant and pharmacy on either the need for an unlicensed medicine or the urgency of the request, the matter should be discussed with the Medical Director.

8. INDEMNITY

8.1. NHS bodies owe a duty of care to patients receiving treatment or undergoing tests. NHS indemnity covers negligent harm caused to these patients in the following circumstances:

- Whenever they are receiving an established treatment, whether or not in accordance with an agreed guideline or protocol.
- Whenever they are receiving a novel or unusual treatment which in the clinical judgement of the health professional is appropriate for the particular patient.
- Whenever they are subjects of clinical research, whether as patients hoping to derive therapeutic benefit or as healthy volunteers. (Research

projects must have the approval of the Trust's Research Governance Group.

- NHS indemnity will normally cover the use of unlicensed medicines and the use of licensed medicines outside the terms of their product licence.

8.2. In such instances the Trust will normally carry full legal liability for any claims of negligence arising from harm to patients from the unlicensed use of medicines providing the requirements set out in this procedure have been followed.

9. FURTHER INFORMATION

9.1. Further information on the off-label or unlicensed use of medicines can be obtained from the MHRA website (Drug Safety Update April 2009) http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

UNLICENSED MEDICINE REQUEST FORM

Section 1 DRUG DETAILS (to be completed by the consultant)

Product (name, form, strength):	
Manufacturer / Supplier (if known):	
Clinical indication for use:	
Dose and frequency:	
What treatment (medicine or other) would previously have been prescribed for this indication?:	
Give reason(s) for preferred use of the requested product:	
If a patient information sheet is to be used, please attach a copy (NB – most unlicensed products do not have English-language package inserts). If an information sheet is not being used, please give reason(s).	

Section 2 PRODUCT AVAILABILITY DETAILS (to be completed jointly by consultant and pharmacist)

Does this product have a product license or marketing authorisation in another country?	YES / NO

If YES:

Manufacturer and country of origin:	
Licensed indication(s) for the product in that country:	
Is the product licensed in the country for the intended indication given in Section 1?	YES / NO
Obtain a Summary of Product Characteristics and attach a copy	

If NO

Is there a product manufactured in the UK?	YES / NO
If yes, state manufacturer:	
Is the manufacturer a pharmaceutical company?	YES / NO
Is the product intended for HUMAN use?	YES / NO

Patient's status (informal/compulsorily detained) …… (2nd opinion required if compulsorily detained)

Consultant Name:	**Signature:**	**Date:**

By signing above you confirm that you have investigated the benefits and risks associated with the use of the unlicensed medicine specified in Section 1. Attach a copy of the patient consent form. If not, please give reason(s) below

Pharmacist Name:	**Signature:**	**Date:**

Notes:

This product is not covered by a UK medicinal Marketing Authorisation (MA). Unlicensed medicines have not usually been subjected to the rigorous independent assessment of efficacy and safety that applies to licensed medicines and their use may carry a higher level of risk to patients.

In the event of harm to a patient, the manufacturer of an unlicensed medicine is only likely to be found liable if the harm results from a defect in the product. The manufacturer carries no legal responsibility for unlicensed use, putting greater liability on the prescriber and the Trust. A clinician directing the supply of an unlicensed product retains liability for any adverse consequences arising from use of the product; this applies even for products licensed within other EU countries.

When proposing the use of an unlicensed medicine it is the responsibility of the consultant to:

- Take special care to investigate and assess the risks and benefits. If necessary, the proposed use of the product should be discussed with a specialist to ensure that there is a reasonable body of medical opinion supporting the use of the medicine as proposed.
- Obtain informed consent from the patient whenever practical.
- Be appropriately insured.
- Complete an 'Unlicensed Medicine Request Form' and supply information supporting the use of the product to the Medicines Management Committee (MMC), for each patient requiring the unlicensed medicine, unless exempted from this requirement by the MMC.
- Write the first prescription for each patient. Thereafter, another doctor working under that consultant can continue to prescribe the unlicensed medicine, unless the MMC requires 'consultant-only' prescribing.
- Report any serious adverse drug reactions using the 'Yellow Card' system.
- Inform the patient's GP in writing of any unlicensed prescribing that will be continued on discharge from hospital. Prescribing of unlicensed medicines should usually be continued by the hospital.

Consultants wishing to use an unlicensed drug for the first time should complete an 'Unlicensed Medicine Request Form', which will require information from the supplying pharmacy. Completed forms and supporting information should be sent to the Chief Pharmacist to be added to the MMC agenda.

MMC approval will normally be required before the pharmacy will be authorised to purchase an unlicensed medicine, and the consultant will be notified of the date of the MMC meeting at which their request is to be considered. In exceptional circumstances the MMC Chair can authorise purchase prior to MMC approval; in this event, all prescriptions must be written by the consultant.

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

NEW DRUGS

1. INTRODUCTION

1.1. When new drugs are introduced, there is usually only limited clinical experience and data on efficacy and adverse effects. New drugs also tend to be considerably more expensive than existing alternatives. All licensed drugs have been considered by the licensing authority to be safe and to be more effective than placebo for the licensed indication(s). However comparison with other drugs and relative cost-effectiveness are not considered during the licensing process.

1.2. The Formulary and Prescribing Guidelines list medicines that have been approved for use within the Trust. These can usually be prescribed without restriction unless specifically indicated otherwise within the Formulary (for example consultant-only use).

1.3. Newly-introduced drugs that are not listed in the Formulary may not be prescribed unless they have been approved by the Medicines Management Committee (MMC). Before approving the use of a new product, the Committee has a responsibility to consider whether the drug is:

- More effective and/or safer than existing drugs
- Equally as effective and safe as existing drugs, but less expensive
- Equally as effective and safe as existing drugs. but more expensive

1.4. The introduction of many new drugs into clinical practice is associated with additional cost. It is therefore important that the MMC can make an assessment of the likely cost implications of approving a new drug for inclusion within the Formulary and Prescribing Guidelines in terms of both drug acquisition costs and any associated non-drug costs (i.e., staff resources, training, biochemical tests etc). If GPs are expected to provide on-going treatment, the Committee will also need to consider the likely impact on primary care prescribing costs.

1.5. For drugs with a cost implication of over £5,000 per year to the Trust, a final decision regarding inclusion in the formulary will be made by the Clinical Governance Committee, based on the recommendation of the MMC.

1.6. The Medicines Management Committee will consider what advantages the drug demonstrates in comparison with alternatives as demonstrated in peer-reviewed clinical trials. Criteria considers may include:

- reduction in mortality / morbidity or improved quality of life
- improved safety or tolerability (i.e. proven lower incidence of major adverse effects)
- improvement in surrogate markers (e.g. biochemical parameters)

- more convenient administration
- savings in drug or non-drug costs

2. REQUESTING A NEW DRUG

2.1. Clinicians wishing to use a new medicine that is not listed in the Trust Formulary are required to complete a 'New Drug Request Form' (see Annex 1), which should be countersigned by the appropriate Clinical Director.

2.2. Requests for new drugs to be made available for prescribing within the Trust will be considered by the Medicines Management Committee at the next available meeting, as long as there is sufficient information available for an informed discussion to take place. Evidence supporting the effectiveness of the drug, rationale for its use, anticipated place in therapy, and likely cost implications should also be provided. Where necessary, an evidence-based product evaluation will be sought from the local Medicines Information Service. Where this is necessary it may take longer for the request to be considered.

2.3. The requesting consultant must be prepared to attend the Medicines Management Committee at which the request will be considered.

2.4. Research projects must have the approval of the Trust's Research Governance Group.

2.5. If it is considered necessary to obtain a new drug as a matter of clinical urgency, this can be authorised by the MMC Chair. However, approval for continued use must still be sought by submitting a completed request form.

2.6. In circumstances where a consultant wishes to try a drug for an individual patient before requesting inclusion in the Formulary and Prescribing Guidelines a Non-Formulary Request Form should be used (see Annex 2).

2.7. Where a new drug has general relevance to the Trust, a new drug submission may be added to the MMC agenda by the Chief Pharmacist or MMC Chair, without a specific consultant request being received.

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

NEW DRUG REQUEST FORM

(To be completed by Consultants only)

Approved name of drug:	
Brand name:	
Requested by:	
Clinical Directorate / Specialty:	

		YES	NO
1.	Is this a new drug? (i.e. one not listed in the Formulary and Prescribing Guidelines)		
2.	Is it a new clinical indication for a drug already listed in the Formulary and Prescribing Guidelines?		
3.	Is it a new formulation of a drug already listed in the Formulary and Prescribing Guidelines?		
4.	Is it an unlicensed use of a drug?		
5.	Could this drug replace a drug that is already listed in the Formulary and Prescribing Guidelines? If YES, which drug it could replace?		
6.	Estimate YOUR annual usage for this drug (no of patients):		
7.	Are you aware that other clinicians may also wish to prescribe this drug? If yes, please give names:		
8.	Has this request been discussed within your directorate?		
9.	Are there any non-drug resource implications associated with the product (e.g. training, staffing, biochemical tests)? If YES please specify:		
10.	Should prescribing be restricted to specialists?		
	If NO, is it appropriate for GPs to take on clinical responsibility for the patient and for prescribing on-going treatment		
	If GPs will be requested to prescribe the drug, are there significant cost implications for primary care?		

Main advantages in terms of indication(s), benefits and cost compared to existing treatments:
Manufacturer:
Formulations available:
Indications:
Dosage:
Pharmacology:
Pharmacokinetics:
Efficacy:
Adverse effects:
Interactions:
Contraindications / Precautions:

Existing alternative treatments:
Advantages over existing treatments:
Disadvantages compared to existing treatments:
Consequences of not using drug:
Other comments:

Please enclose published evidence (e.g. clinical trials) to support your request.

Declaration

	YES	NO
Have you received any funding or other benefits from, or have any interest in, the manufacturer of the drug requested? If YES, please provide details		

Consultant Name:	Signature:
Telephone No:	E-mail:
Date:	
Clinical Director Name:	Signature:

Annex 2

Providing Partnership Services in Bedfordshire, Essex and Luton

NON FORMULARY DRUG REQUEST FORM

Name and formulation of drug:	

Patient's name:		Date of Birth:	
Consultant:		Ward:	

TREATMENT WITH NON-FORMULARY DRUGS SHOULD BE REVIEWED AT REGULAR INTERVALS AND DISCONTINUED IF NO ADDITIONAL CLINICAL BENEFIT IS OBSERVED

Current Medication

Drug name and formulation	Dose

Current diagnosis and reason for prescribing non-formulary drug

Medication previously prescribed for this indication

Drug name	Total daily dose	Reason for stopping

Consultant Name:	**Signature:**	**Date:**
Pharmacist Name:	**Signature:**	**Date:**

This form to be completed and sent to pharmacy prior to commencing treatment. A copy will be returned to the ward to be filed in the patient's healthcare record

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PRESCRIBING ANTIPSYCHOTIC MEDICATION ABOVE RECOMMENDED MAXIMUM DAILY DOSES

1. INTRODUCTION

1.1. The prescribing of antipsychotic medications occurs in two ways:

- A single antipsychotic prescribed at a dose in excess of the maximum BNF* recommended dose
- The combined use of 2 or more antipsychotics where the total of the individual doses, expressed as a percentage of the BNF maximum recommended dose, exceeds 100%

1.2. There is no evidence to support the routine use of high dose antipsychotic therapy (HDT), either as a single agent or as a combination of antipsychotics. Thus, the use of such therapy should only be after evidence-based strategies have failed and where:

- diagnosis has been re-confirmed
- adherence to medication has been verified
- adjuvant medication has been optimised (for example, antidepressants and mood stabilisers)
- akathisia has been dismissed
- substance misuse has been eliminated

1.3. POMH-UK has produced an 'antipsychotic dosage ready reckoner' to aid the calculation of total daily prescribed antipsychotic dose as a percentage of the BNF maximum. This can be downloaded from the Medicines Management pages of the Trust intranet or printed copies obtained from Pharmacy.

2. PRESCRIBING HIGH DOSE THERAPY

1.4. The decision to commence a patient on an elective trial of antipsychotic medication at a dose higher than the maximum BNF recommended dose is the responsibility of the patient's consultant. Non-medical prescribers should not make the decision to proceed to the use of high dose antipsychotics.

1.5. The reason for the treatment, should be documented using a high dose therapy (HDT) form (see Annex 1), and the patient be given an explanation why they are receiving a trial of high dose medication. Forms are available on wards and in the pharmacy departments. If an individual patient is not informed then an explanation as to why that was not done should be documented in the patient's healthcare record.

* British National Formulary

1.6. Pharmacists will place a “high dose sticker” on treatment cards where they notice HDT is being prescribed. This will act as a reminder to prescribers to review therapy.

1.7. In those circumstances where higher than BNF limits might be prescribed for quite some time, the consultant will ask for a second opinion from a senior colleague not involved in the day to day care of the patient.

1.8. The clinical indications should be documented in the patient's healthcare records, and the outcome reviewed every three months.

1.9. Consideration before initiating therapy should be given to baseline tests for renal and/or hepatic insufficiency i.e. urine electrolytes and liver function tests and also an ECG to exclude significant cardiac disease. If these investigations are not carried out an explanation for not doing so should be documented in the healthcare records. Repeat investigations of renal and hepatic function should be considered at each regular review of the patient and any change in the patient's physical health documented. (See also CLP55, *Physical Healthcare Policy for Inpatients* and CLPG55 *Physical Healthcare for Inpatients*).

1.10. A trainee reviewing follow-up patients must confirm with the consultant any repeat prescription for antipsychotics above BNF limits.

1.11. If the dose of antipsychotic medication is changed, the reason should be documented i.e. whether due to lack of response, intolerance of side-effects or the patient's improving mental state.

1.12. If there is no clear response to high dose medication, a reduction in the dose to the level of the maximum recommended BNF dose should be made after defining an adequate trial period.

1.13. It would be expected that the consultant would reduce the dosage to within BNF limits as soon as clinical indications make this possible.

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

HIGH DOSE AND COMBINATION ANTIPSYCHOTIC TREATMENT MONITORING FORM

Patient's name:		Date of Birth:	
Consultant:		Ward:	

This form is to be completed **prior** to commencing antipsychotic drugs that either exceed 100% of the BNF maximum recommended dose (including PRN) OR involve more than one antipsychotic drug prescribed on a regular basis

HIGH DOSE OR COMBINATION ANTIPSYCHOTIC TREATMENT SHOULD BE REVIEWED AT INTERVALS OF TWO WEEKS OR LESS AND DISCONTINUED IF NO ADDITIONAL CLINICAL BENEFIT IS OBSERVED.

Current Medication		
Drug name and formulation	Current total daily dose	Planned maximum daily dose

Previous Antipsychotic Medication		
Drug name and formulation	Total daily dose	Reason for stopping

Reasons for High Dose / Combination Antipsychotics

	YES	NO
1. Has this patient been prescribed clozapine? If NO, please state reason(s) for not prescribing If YES, please state reason(s) for discontinuation		
2. Has the patient shown signs of adverse effects to antipsychotic drugs or is there evidence of drug interactions? If YES, please give details		
3. Is the patient subject to Section 58 (consent to treatment) requirements?		
If YES, has the patient either given informed consent to high dose treatment and T2 been amended accordingly, or SOAD consent has been obtained on Form T3? (Answer must be YES)		

Monitoring required prior to commencing high dose treatment								
	ECG	FBC	U&Es	LFTs	TFTs	Glucose	Lipids	
Date								
Normal / Abnormal								

Monitoring required after commencing high dose treatment (repeated at a minimum of every three months)								
Date	ECG (Norm/Abn)	FBC (Norm/Abn)	U&Es (Norm/Abn)	LFTs (Norm/Abn)	TFTs (Norm/Abn)	Glucose (Norm/Abn)	Lipids (Norm/Abn)	

Consultant Name:	Signature:
Date of commencing High Dose Treatment:	

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURES FOR THE SECURITY AND SAFE HANDLING OF FP10 PRESCRIPTION FORMS

1. INTRODUCTION

1.1. FP10 prescription forms are valuable documents, which if lost or stolen may be fraudulently used to obtain medicines from community pharmacies. In this sense, they resemble 'blank cheques', and should be treated as such.

1.2. The security of these prescription forms is the responsibility of the organisation and the individual prescribers who use them. These guidelines are based on guidance on the security of prescription forms issued by the NHS Security Management Service in March 2011.

1.3. Due to the differing arrangements for the provision of pharmacy services within Bedfordshire, Essex and Luton, different arrangements for the handling of FP10s apply in each area:

1.3.1. **In Essex**: The ordering, receipt and distribution of FP10s is managed by the in-house pharmacy service, overseen by the Pharmacy Services Manager. FP10s are supplied to prescribers in line with pharmacy standard operating procedure PHARM-E09 *Ordering and Issuing Controlled Stationery*.

Separate arrangements apply to FP10s used by the Community Drug and Alcohol Teams, which obtain FP10s from Essex Contractor Services at Carnarvon House, Clacton in the same manner as GP surgeries.

1.3.2. **In Bedfordshire and Luton**: The ordering, receipt and distribution of FP10s is managed by the lead clinical pharmacist, based at Charter House. Arrangements will be reviewed if pharmacy services are brought in-house.

1.4. **Note: All the records for receipts and issues of prescriptions referred to in this document must be retained for at least 3 years**

2. RESPONSIBILITIES

2.1. **Chief Pharmacist:** The Chief Pharmacist is responsible for:

- authorising new FP10 cost centres and liaison with the Prescription Pricing Division
- monitoring FP10 prescribing data and investigating unusual expenditure and/or usage patterns
- auditing compliance with the record-keeping requirements set out within this document

- advising administrators and prescribers on all matters related to record-keeping and the use of FP10 prescription forms
- the initial Trust response to incidents involving missing, lost or stolen prescriptions, and involvement in subsequent investigations

2.2. **FP10 Co-ordinators**: named individuals responsible for:

- purchasing FP10 prescription pads on behalf of the organisation
- storing them securely until they are required
- issuing prescription pads to Trust sites in response to written orders from administrators
- arranging secure transport for the delivery of prescription pads to Trust sites (Bedfordshire & Luton only)

<table>
<tr><td colspan="2">Essex</td></tr>
<tr><td>For Teams in South East Essex

Pharmacy Services Manager
Pharmacy Department
Rochford Hospital
Union Lane
Rochford SS4 2RB

Tel: 01702 538098 (8098)
Fax: 01702 538226 (8226)</td><td>For Teams in South West Essex

Senior Clinical Pharmacist
Pharmacy Office, Level A
Basildon Mental Health Unit
Nethermayne
Basildon SS16 5NL

Tel: 01268 243577 (7577)
Fax: 01268 243560 (7560)</td></tr>
<tr><td colspan="2">Bedfordshire & Luton</td></tr>
<tr><td colspan="2">Lead Clinical Pharmacist
Floor 8
Charter House
Alma Street
Luton. LU1 2PJ

Tel: 01582 528814 (8814)
Fax. 01582 708958</td></tr>
</table>

2.3. **Local Security Management Specialist:** The responsibilities of the LSMS include co-ordination of the physical aspects of security management. This includes the security of prescription forms whilst in storage at Trust sites, the safe and secure transport of prescriptions between sites, and the investigation of incidents involving missing, lost or stolen prescriptions.

2.4. **Bedfordshire and Luton**

2.4.1. **Administrators**: At each site where FP10 forms are used, a named Medical Secretary must have responsibility for all aspects of security and record-keeping, as detailed in this procedure. Arrangements must be made for another member of staff to deputise for the secretary in their absence. If the secretary leaves, responsibility for FP10 security must be transferred to another named individual, whose details must be notified to the

FP10 co-ordinator prior to the departure of the current administrator.

2.4.2. **Couriers (in Bedfordshire and Luton only):** The Trust transport service is responsible for the collection of prescription pad orders from the FP10 co-ordinator's office and for securely transporting and delivering them to the administrator at the intended destination. Packages containing prescription pads must be locked in a secure box whilst in transit

2.5. **Essex**

2.5.1. **Prescribers**: FP10 prescription pads are issued to individual prescribers who are responsible for all aspects of security and record-keeping, as detailed in this procedure.

3. ORDERING, RECEIPT AND STORAGE OF PRESCRIPTIONS BY FP10 CO-ORDINATORS

3.1. The Chief Pharmacist and the FP10 co-ordinators (via Ascribe or eProc) are the only people within the Trust who are authorised to purchase FP10 prescriptions from the contracted secure printer for the NHSBSA. When supplies of FP10 prescriptions are required, the co-ordinator should raise orders for forms to be printed on behalf of approved cost centres, ordering a sufficient quantity to maintain a buffer stock to meet the anticipated demand from each cost centre.

3.2. Prescription orders will be delivered to the co-ordinator's base by secure courier. On receipt, the co-ordinator (or Charter House receptionist in Bedfordshire and Luton) should check the number of sealed packages against the driver's delivery note and confirm that they are all intact. Any discrepancies or insecure packages should be noted on the driver's delivery note.

In Bedfordshire and Luton, the receptionist should then contact the co-ordinator to arrange for the packages to be collected immediately. If the co-ordinator is not available, the receptionist should immediately transfer the packages to a locked office or safe, where they should remain until collected by the co-ordinator.

3.3. Provided the delivery appears to be in order, the co-ordinator should open the packages and check that the contents (numbers of pads and serial numbers) correspond with the details on the delivery note. If so, the co-ordinator should record the details of the prescriptions received.

3.3.1. For **green FP10HNC pads**, the first and last serial number of each pad of 50 forms should be recorded against the appropriate cost centre.

3.3.2. **Blue FP10MDA** prescriptions are not pre-printed with cost centre details and must be recorded separately, using the serial numbers of the first and last forms in each box.

3.4. The delivery note must be retained for future reference.

3.5. After logging the serial number details, all the prescriptions must be transferred to secure storage with access limited to those who are responsible for the distribution of prescription forms. This may be a lockable cupboard or filing cabinet, provided that it cannot readily be removed, within a room which must be kept locked outside normal working hours or when unattended. Keys must also be kept securely with access limited to those who are responsible for prescription forms.

3.6. If a discrepancy was noted at the time of delivery, if a package appears to have been tampered with in transit, or if pads/forms are found to be missing when a package is opened, the co-ordinator should immediately contact the supplier. A written record of the contact with the supplier, and any subsequent actions or investigations, must be retained by the co-ordinator. The Chief Pharmacist and the Local Security Management Specialist should also be notified immediately whenever it has been necessary to contact the supplier about a problem with a delivery of prescriptions.

4. ORDERING PRESCRIPTION FORMS

4.1. In Bedfordshire and Luton administrators are responsible for ordering supplies of FP10 prescriptions for each site from the FP10 co-ordinator. In Essex consultants order their own prescription pads from the pharmacy department.

4.2. The quantity ordered should reflect local usage patterns – it is advisable to hold minimal stocks of prescription forms in order to reduce the number lost in the event of theft.

4.3. Orders can be placed either by email or in writing on Trust headed paper. The order should be addressed to the relevant FP10 co-ordinator (see section 2.2) and should include the following information:

- The number prescription pads required (each pad contains 50 forms)
- The service/address they are required for, and the internal post code
- The service code (RWNxx) as printed on the prescription forms
- The name of the person placing the order
- Contact details (i.e. telephone number) in case of any query

4.4. Two types of FP10 are available:

- **Green FP10 HNC Forms**: These are available as pads of 50 forms.

- **Blue FP10 MDA Forms**: These single-sheet forms are used only in substance misuse services, for instalment prescribing. The forms come in boxes of 500, and the order should specify the number of boxes required (part boxes will not be supplied).

5. Transport of prescription forms (Bedfordshire & Luton only)

5.1. The process for transporting FP10 prescription forms between Charter House and Trust sites is shown diagrammatically in Annex 1. Packages containing prescription pads will be collected by the internal courier service and transported in a locked safe deposit box within the courier van. Prior arrangements must be make with a named recipient (usually the named administrator) at the delivery site to ensure that the package can be received and dealt with on the same day.

5.2. A Delivery/Receipt Form (Annex 2) must accompany the package in transit; this is signed by the courier on receipt of the package from the FP10 co-ordinator and by the named recipient when it is delivered. On receipt this must be faxed back to the FP10 co-ordinator to confirm that the package has arrived at its destination and that its contents are intact.

5.3. If the FP10 co-ordinator does not receive the faxed confirmation of delivery within the expected time-frame, the location of the package must be investigated immediately by contacting the named recipient and, if necessary, the courier service.

5.4. A small number of Trust sites may collect their FP10 pads in person from Charter House. In these cases, the person responsible for transporting the package to their base will be asked to complete a different version of the Delivery/Receipt Form (Annex 3) and to fax back a copy to the co-ordinator when the prescriptions have been delivered.

5.5. The co-ordinator will take a photocopy of the Delivery/Receipt Form before packages of prescription forms are released to the courier. This copy will be retained until the signed version is faxed back confirming safe delivery.

6. Receipt of prescription forms (Bedfordshire & Luton only)

6.1. When packages containing FP10 prescriptions are delivered by the courier service, the administrator must immediately open the package and check that the contents (number of pads and serial numbers) correspond to the details on the Delivery/Receipt Form. This form must then be signed in the presence of the courier and immediately faxed back to the FP10 co-ordinator to confirm receipt.

6.2. If there are any discrepancies, or if the package appears to have been tampered with, the FP10 co-ordinator must be contacted immediately by telephone while the courier is present and before signing the Delivery/Receipt Form.

6.3. The administrator must then file the Delivery/Receipt Form for future reference and enter the details of the pads received on a 'Prescription Receipts Log' (Annex 4). The receipts log must list the serial numbers of all pads received and the date of receipt. This log may be kept electronically or in hard copy.

6.4. When completing the receipts log, each pad of forms must be given a consecutive number. This number must be clearly marked on the front cover of the pad as 'Pad no. xx'. Note: this does not apply to the loose FP10MDA forms used in substance misuse services

6.5. Once the log has been completed, the prescription pads should be transferred to secure storage (see section 7).

7. Storage of prescription forms

7.1. FP10 pads/forms that are not in use should be stored in a locked cupboard (e.g. stationery cupboard, filing cabinet, wall safe) at all times.

7.2. **Bedfordshire & Luton**

7.2.1. Access to this should be restricted to the administrator and their authorised deputy. Medical staff should not have access, except via the administrator or their deputy.

7.3. In **Essex** prescribers are responsible for the safe storage of the prescription forms which have been issued to them

8. Prescription record sheets

8.1. The Trust requires that every FP10 prescription issued be traceable to the patient it was issued to, and to the prescriber who wrote the prescription.

8.2. In order to achieve this, an 'Individual Prescription Record' sheet must be prepared for every prescription pad before it is used for the first time. A template for the Individual Prescription Record is shown at Annex 5.

8.3. The following details should be entered on the record sheet:

- The RWN code that is printed on the forms
- The serial numbers of the first and last forms in the pad
- The Pad number (see 6.4)
- The serial numbers of each form in the pad – these should be entered in the left hand column*

8.4. In Bedfordshire and Luton an Individual Prescription Record will be prepared for each prescription pad held by the administrator who holds the FP10 pads

* Each pad contains 50 forms, and the template contains 50 lines. If the last digit of each serial number is placed in brackets, it will be seen that the remaining 10 numbers run in numerical sequence.

for the clinic. In Essex the record sheet will be issued to the prescriber by pharmacy when the prescription pad is collected.

8.5. Once the Individual Record Sheet has been prepared, it should be attached to the pad and should remain with it until all the forms have been issued. It is the responsibility of the prescriber to enter the patient and medication details on the record sheet each time a form is issued.

8.6. **Bedfordshire & Luton**: When all the forms in the pad have been issued, the administrator must file the completed record sheet in a secure place for future reference/audit purposes.

8.7. **Essex**: the completed record sheet must be returned to pharmacy when a new pad is requested.

Note: These requirements do not apply to 'batch-printed' prescriptions within substance misuse services

9. Issue of FP10 prescription pads to prescribers (Bedfordshire & Luton only)

9.1. When FP10 forms need to be used in a clinic, a prescription pad should be issued to the doctor/nurse prescriber at the start of the clinic, and returned to secure storage at the end of the clinic. The administrator who issues the pad must ensure that the appropriate prescription record sheet is given to the doctor/nurse at the same time as the pad, and that this sheet is also returned at the end of the clinic (see section 8).

9.2. If a prescriber finds that the serial number of the first blank prescription in the pad does not match the first unissued serial number on the record sheet, this must be reported immediately to the administrator as a suspected missing or stolen prescription form incident. The administrator must immediately report such incidents to the Lead Clinical Pharmacist at Charter House (internal ext. 4814), or in his absence, to the Local Security Management Specialist (LSMS), who is based in the Risk Management Department.

9.3. In order to maintain an audit trail, the doctor/nurse prescriber should be asked to sign for the pad when it is issued to them, using the issues/returns form shown at Annex 6. The administrator should sign this form at the end of the clinic to confirm the return of the pad to safe storage.

9.4. In the event of a late-running clinic, it may not be possible for the prescriber to return the prescription pad to the administrator. In this situation, the prescriber is responsible for safe keeping of the pad until such a time as it can be returned to the administrator, ideally the following morning.

9.5. Prescribers should not be issued with pads to hold on a personal basis. A pad may be issued to a clinician who is seeing a patient in the community who might need to be given a prescription, but this pad should be returned to the administrator on their return to base.

10. Recording individual prescription issues

10.1. All FP10 prescriptions carry a unique 11-digit serial number printed in the bottom left-hand corner. The forms in a pad are numbered sequentially, but for security reasons, **the final digit does not form part of the sequence**. When recording serial numbers, the last digit should be put in brackets, as this makes it easier to follow the sequence, e.g. 4107157126(4), 4107157127(3), etc.

10.2. Whenever a prescription form is issued, the name of the patient and the medication(s) prescribed must be entered against the appropriate serial number on the Individual Prescription Record sheet (Annex 5). This provides the final step in the prescription audit trail, and when all the forms in a pad have been issued, the record sheet must be retained by the administrator (Bedfordshire & Luton)/pharmacy (Essex) for future reference/audit purposes.

10.3. Spoiled prescription forms and those that have been written but not issued to be patient should be destroyed by shredding in the presence of a witness.

10.3.1. **Bedfordshire & Luton**: The form should be returned to the administrator for destruction. The administrator should ensure that the prescriber has written “form not issued” against the appropriate serial number on the record sheet. The administrator should then write “form destroyed” on the record sheet and destroy the form by shredding it in the presence of a witness. The administrator and witness should, then both sign and date the record sheet to confirm disposal of the form.

10.3.2. **Essex**: The prescriber should ensure that “form not issued” is written against the appropriate serial number on the record sheet. The FP10 form should be crossed through and retained with the pad. Such forms should be returned to the pharmacy for destruction along with the Individual Prescription Record Sheet when a new pad is collected. In pharmacy two members of staff will destroy the spoiled form by shredding, then both sign and date the record sheet to confirm disposal of the form.

11. Prescription security - good practice

11.1. Blank prescription forms must **NEVER** be pre-signed.

11.2. In clinics, pads should be kept in a lockable drawer and only produced when required – they should not be left on desks or in unattended rooms. It is not uncommon for a few forms to be stolen from within a pad when the prescriber is not looking; this is likely to go undetected for some time, whereas the theft of a whole pad would usually be noticed immediately.

11.3. Prescribers who need to carry a prescription pad off Trust premises are personally responsible for its safe keeping. Pads should be kept on the person and not be left in unattended bags, cars, etc.

12. Closure of units / re-organisation of teams

12.1. If internal re-organisation results in a site/team/prescriber no longer requiring FP10 prescriptions the relevant FP10 co-ordinator must be contacted to make arrangement for the return of any unused prescriptions, together will receipts/issues records and Individual Prescription Record sheets. FP10 pads must not be sent through the internal mail or by courier unless prior arrangement has been made with the recipient to expect delivery at a specified time.

12.2. The FP10 co-ordinator will retain the records and arrange for the disposal of any unwanted forms in the presence of a witness.

13. Missing, lost or stolen prescriptions

13.1. If FP10 prescription forms go missing, or are lost or stolen, this must be reported immediately to the relevant FP10 co-ordinator. In their absence, the loss must be reported to the Local Security Management Specialist (LSMS), who is based in the Risk Management Department.

13.2. The FP10 co-ordinator (or in his absence, the LSMS) will notify the Chief Pharmacist of the incident, and respond to it in accordance with the guidance issued by the NHS Business Services Authority. The action taken in response to the loss will depend on the nature of the incident (see Annex 7 for further details).

13.3. Following the immediate response to the incident, particular individuals have key responsibilities in relation to the investigation of the incident. These individuals are:

- The Trust Chief Pharmacist
- The Local Security Management Specialist
- The Local Counter Fraud Specialist

13.4. The responsibilities of these individuals are documented in Annex 8

14. Audit

15.1. Audits of prescription security, transport and record-keeping will be conducted periodically as part of the Trust's Medicines Management audit programme and reported to the Medicines Management Committee.

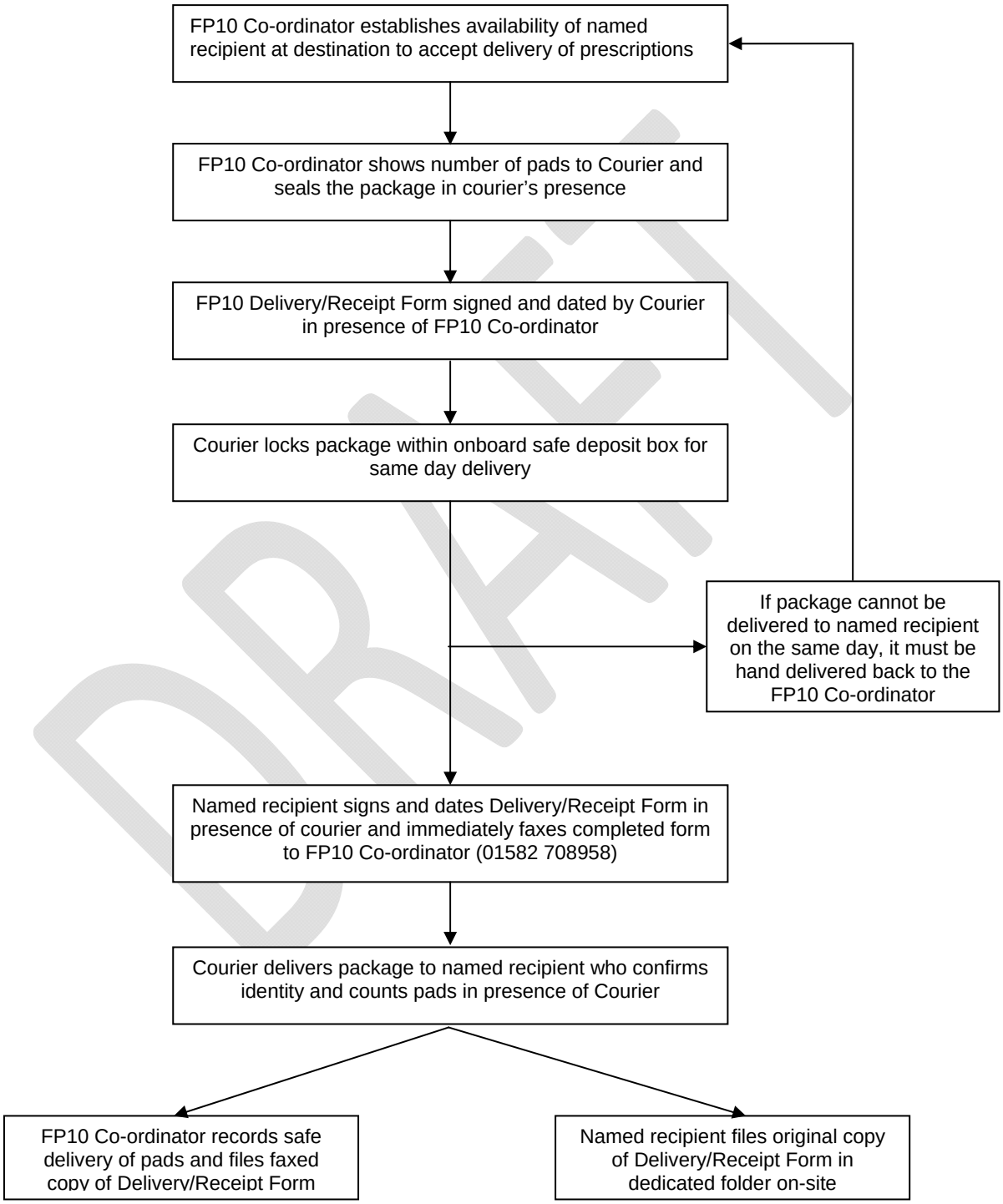
15. Training

15.2. **Administrators**: Newly-appointed administrators in Bedfordshire and Luton will be given written and verbal advice on their responsibilities by the relevant FP10 co-ordinator. If necessary, a site visit will be conducted in order give further one-to-one instruction to administrators and/or local managers.

15.3. **Prescribers**: The Pharmacy Team provides instruction on FP10 prescription security and record-keeping as part of the induction programme for new medical staff. Similar training for any non-medical prescribers who need to use FP10 forms will be provided at the regular fora that NMPs are required to attend. Additional one-to-one training will be provided on an as-required basis.

Annex 1

FLOWCHART FOR THE TRANSPORT OF FP10 PRESCRIPTION FORMS FROM CHARTER HOUSE TO CLINICS (BEDFORDSHIRE & LUTON ONLY)



Annex 2

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

FP10 PRESCRIPTION FORMS DELIVERY/RECEIPT FORM (COURIER) (BEDFORDSHIRE & LUTON ONLY)

To:	Name and Address of Team Administrator:	Date:

This parcel contains the following pads:

FP10 type	RWN Code	Serial Number of first form in pad (last digit in brackets)	Serial Number of last form in pad (last digit in brackets)	No of forms

I acknowledge collection of the above from Charter House, Luton which has been packaged/ sealed in my presence by: _____

Signed (Courier) _____ Date _____ Time_____

I acknowledge receipt of the above prescriptions via internal courier, which I confirm I have checked in the presence of the courier.

Signed (Team Administrator) _____ Date _____ Time_____

A copy of this form must be faxed immediately following receipt of the prescription to the FP10 Co-ordinator 01582 708958.

Annex 3

Providing Partnership Services in Bedfordshire, Essex and Luton

FP10 PRESCRIPTION FORMS DELIVERY/RECEIPT FORM (STAFF MEMBER) (BEDFORDSHIRE & LUTON ONLY)

Name and Address of Team Administrator:	**Date:**

This parcel contains the following pads:

FP10 type	**RWN Code**	**Serial Number of first form in pad** (last digit in brackets)	**Serial Number of last form in pad** (last digit in brackets)	**No of forms**

I acknowledge collection of the above from Charter House, Luton which has been packaged/ sealed in my presence by: _____

Signed (Staff Member) _____ Date _____ Time_____

I acknowledge receipt of the above prescriptions, which I confirm I have checked in the presence of the staff member transporting them.

Signed (Team Administrator) _____ Date _____ Time_____

Original of this form must be held securely by the team administrator responsible for prescriptions at the site

.

Annex 4

Providing Partnership Services in Bedfordshire, Essex and Luton

FP10 PRESCRIPTION RECEIPTS LOG (BEDFORDSHIRE & LUTON ONLY)

FP10 Prescription pads for use at _____ **Code RWN** _____

The details of each pad received should be entered on a separate line.
Each pad should be numbered consecutively on receipt (see last column), and this number should be written on the front cover of the pad.

Date Received	**Received by** (signature)	**Serial Number of first form in pad** (last digit in brackets)	**Serial Number of last form in pad** (last digit in brackets)	**Pad No** (give each pad a consecutive number)

Annex 5

Providing Partnership Services in Bedfordshire, Essex and Luton

INDIVIDUAL PRESCRIPTION RECORD

Serial Number of first form in pad: (last digit in brackets)	**Serial Number of last form in pad:** (last digit in brackets)	**Pad No:**

Serial Number (last digit in brackets)	**Issued by** (print name)	**Name of Patient**	**Date of Issue**	**Medication prescribed** (drug names only)

Serial Number of first form in pad: (last digit in brackets)	**Serial Number of last form in pad:** (last digit in brackets)	**Pad No:**

Serial Number (last digit in brackets)	**Issued by** (print name)	**Name of Patient**	**Date of Issue**	**Medication prescribed** (drug names only)

Serial Number of first form in pad: (last digit in brackets)	**Serial Number of last form in pad:** (last digit in brackets)	**Pad No:**

Serial Number (last digit in brackets)	**Issued by** (print name)	**Name of Patient**	**Date of Issue**	**Medication prescribed** (drug names only)

Annex 6

Providing Partnership Services in Bedfordshire, Essex and Luton

RECORD OF FP10 PRESCRIPTION ISSUES AND RETURNS (BEDFORDSHIRE & LUTON ONLY)

ISSUES					RECEIPTS			
Date	**Pad No.**	**Serial no of first prescription in pad when issued** (last digit in brackets)	**Pad issued to** (name of prescriber)	**Signature of prescriber**	**Date**	**Pad No.**	**Serial no of first prescription in pad when returned** (last digit in brackets)	**Pad received by** (administrator signature)

Annex 7

INCIDENT RESPONSE

Source: NHS Security Management Service. *Security of prescription form guidance* (Annex C). March 2011

NATURE OF INCIDENT	WHO SHOULD BE CONTACTED?
Discrepancy in prescription forms ordered and received.	**Contact supplier** Ask the driver to remain on-site while the supplier is contacted.
Following enquiries with the supplier, if discrepancy in prescription forms ordered and received cannot be accounted for, and forms are still missing.	**Notify the designated person with overall responsibility for prescription forms at the health body, accountable officer, LSMS and police as required. Report the matter using the health body's incident reporting system.** The matter must be reported as a security incident and an alert/warning circulated locally and/or nationally. Serial numbers of the missing forms must be submitted to the NHS CFSMS database using the appropriate notification form.
If prescription forms are lost through negligence or by accident.	**Notify the designated person with overall responsibility for prescription forms at the health body, the accountable officer, LSMS and police as required. Report the matter using the health body's incident reporting system** The matter must be reported as a security incident and an alert/warning circulated locally and/or nationally. Serial numbers of the missing forms must be submitted to the NHS CFSMS database using the appropriate notification form.
If prescription forms are stolen.	**Contact the police and report the matter using the health body's incident reporting system. Notify the accountable officer and LSMS.** The matter must be reported as a security incident and an alert/warning circulated locally and/or nationally. Serial numbers of the missing forms must be submitted to the NHS CFSMS database using the appropriate notification form.
If it is suspected that a presented prescription form is forged.	**Notify the accountable officer, police, LCFS and contact the NHS Counter Fraud Service on 0800 068 6161.**
If it is suspected that prescription forms are being misused.	**Contact the police, LCFS and accountable officer** LCFS submits report to NHS CFS Pharmaceutical Fraud Team.

Annex 8

KEY RESPONSIBILITIES IN INCIDENT INVESTIGATION

Source: NHS Security Management Service. *Security of prescription form guidance* (Annex D). March 2011

Individual identifying loss of forms (e.g. Prescriber, manager, person taking receipt of delivery) responsibilities:	• Follow local procedures and guidance for the immediate reporting of incident • Provide details of the numbers of prescription forms stolen, their serial numbers, and where and when they were stolen. Prescribers should follow local instructions following the loss or theft of prescription forms – this may include writing and signing prescription forms in a particular colour for a period of two months.
Health Body responsibilities: (C)	• Ensure matter is reported immediately to the supplier/police/accountable officer/LSMS/LCFS/Health Body as appropriate. • Ensure a Missing/lost/stolen NHS prescription form(s) notification form is completed and submitted to the LSMS (see annex B of national guidance). • Ensure incident form has been completed. • Following the reported loss of a prescription form, the Health Body will normally inform a prescriber to write and sign all prescriptions in a particular colour (normally red) for a period of two months. • The Health Body will inform all pharmacies in their area and adjacent Health Bodies of the name and address of the prescriber concerned, the approximate number of prescription forms stolen and the period within which the prescriber will write in a specific colour. This will normally be put in writing within 24 hours with the exception of weekends. • In consultation with the LSMS/LCFS, the Health Body should take necessary action to minimise the abuse of the forms taken.
The **Local Security Management Specialist**'s responsibilities include:	**THEFT OF PRESCRIPTION FORMS (or lost or missing)** • Ensure matter has been reported to the police and accountable officer and determine action taken/required. Ensure incident form has been completed on health body's incident reporting system. • Liaise with and inform relevant staff such as the chief pharmacist, medicines management team, director of clinical services and the nurse prescribing lead. This list is not exhaustive and the LSMS should inform all the appropriate staff.

	Investigate cases of **THEFT** by: • **Taking a report of what has been stolen and where from, undertaking an audit trail, determining the value of the item, impact on healthcare, whether the incident was witnessed and, if so, taking witness statements where appropriate, co-ordinating the facts and concluding as applicable**. • Reporting investigations to the security management director. • Ensure a completed Missing/lost/stolen NHS prescription form(s) notification form is submitted to the NHS CFSMS national database. • Liaising with/notifying the LCFS as required. • If legal advice is required, contact the NHS CFSMS Legal Protection Unit. • The relevant NHS SMS Area Security Management Specialist can also provide support and advice.
The **Local Counter Fraud Specialist**'s responsibilities include:	**FRAUD/CORRUPTION** **FORGERY OR MISUSE OF PRESCRIPTION FORMS** • Ensure matter has been reported to the police and determine action taken/required. Ensure incident form has been completed on health body's incident reporting system. • Liaise with and inform relevant staff such as the chief pharmacist, medicines management team, director of clinical services and the nurse prescribing lead. This list is not exhaustive and the LCFS should inform all the appropriate staff. • Investigate cases of specific **FRAUD/CORRUPTION**. • Report investigations to the director of finance. • Refer to NHS CFSMS all cases of **FRAUD/ CORRUPTION** appropriate to them. • Inform NHS CFSMS of all cases of suspected **FRAUD/ CORRUPTION** being investigated. • Send full reports of all cases where the director of finance believes **FRAUD/CORRUPTION** to be present to the NHS CFSMS, audit committee, internal and external audit. • Liaise/notify the LSMS as required.

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT GROUP DIRECTION (PGD) FOR

Drug Name:	**CLASS:** ***e.g. POM***

Controls Assurance Statement
The aim of this Patient Group Direction is to ensure that the supply and administration of medicines under a Patient Group Direction complies with the legal requirements and guidance set out in *HSC2000/026: Patient Group Directions (England Only)*. Failure to comply with the law could result in criminal prosecution under the Medicines Act.

Patient Group Direction Prepared by

Name	Position	Base

This patient group direction must be agreed to and signed by all health care professionals involved in its use. The NHS Trust should hold the original signed copy. The PGD must be easily accessible in the clinical setting

Authorisation

Lead Doctor	Name: Position: Signature:	Date:
Lead Nurse / Allied Health Professional *(depending on who will be using PGD)*	Name: Position: Signature:	Date:
Lead Pharmacist	Name: Position: Signature:	Date:
Clinical Governance Lead	Name: Position: Signature:	Date:
Organisational Authorisation by:	Name: Position: Signature:	Date:
Responsibility for ensuring this PGD is reviewed	Position:	

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT GROUP DIRECTION (PGD) FOR

Drug Name:	**CLASS: *e.g. POM***

Clinical Condition

Indication	*Need to be specific on the clinical condition to be treated.* *Is it a licensed indication - check SPC, BNF.*
Inclusion criteria	*Follow any clinical guidelines or policies that are available either locally or nationally e.g. SIGN, NICE, Prodigy* *Check SPC.* *Consult clinicians working in that area.*
Exclusion criteria	*Check SPC/published guidelines such as SIGN, NICE, Prodigy* *Decide if there are limitations for service i.e. to age or patient groups (e.g. immunocompromised patients).* *Explain reason for exclusion if necessary e.g.* • *Patients on methotrexate – reduced excretion, increasing risk of toxicity* • *Provide cut off points for exclusion e.g. not just "children" but for example "children under two years old"* • *Include interactions here that may give rise to toxicity or need for an increased dose e.g. salbutamol PGD would exclude patients taking beta blockers.* *Explain action to take if patient is to be excluded e.g.* • *Should a doctor wish to exclude a particular patient from these directions this must be recorded in the patient's notes and on the prescription and administration record.*
Cautions/Need for further advice	• *Check SPC / published guidelines such as SIGN, NICE, Prodigy* • *Pregnancy and breast feeding – explain reason for inclusion, exclusion or caution wherever possible.* • *Interactions – list ones that are clinically significant and relevant to this PGD and provide advice if possible e.g.:* o *Anticoagulants – effects may be enhanced (prolonging the prothrombin time). Advise patient that INR may change whilst taking drug X and to monitor more closely if appropriate*
Action if patient declines or is excluded	*Enter details of action to be taken according to local policy e.g.* • Excluded patients will have their treatment managed by the appropriate medical team
Referral arrangements for medical advice	*Enter details of local arrangements e.g. contact appropriate doctor (GP, ward doctor, team doctor, or duty doctor through SEPT switchboard).*
Evaluation of treatment and follow up action which may be required	*To be decided locally*

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT GROUP DIRECTION (PGD) FOR

Drug Name:	**CLASS: *e.g. POM***

Drug Details

Name, form & strength of medicine	*References include: BNF/SPC/ Medicines for Children* *Use clear format to express strength and form e.g. BNF style: Amoxicillin Capsules 250 mg; Amoxicillin Suspension 250mg in 5mL*
Route/Method	*References: BNF/SPC /Medicines for Children* *To avoid errors, state in full and do not use abbreviations e.g. oral not p.o.*
Dosage	*References: BNF/SPC/Medicines for Children* *Are dosages licensed – need to add reference / note to support use in unlicensed / off-label circumstances.* *Decide on format to express dosage, especially in children – will it be on weight-adjusted basis or would doses be rounded up to the nearest spoonful etc. Liaise with pharmacy on practical issues relating to dosage and quantity to supply.* *State in full and do not use abbreviations e.g. Take one capsule three times a day not 1 tds.*
Frequency	*References: BNF/SPC/ local and guidelines/ Medicines for Children*
Duration of treatment	*Decide with service provider and pharmacy.*
Maximum or minimum treatment period	*To be decided locally.*
Quantity to supply/administer	*Depends on above i.e. dosage, frequency and duration.*
Side effects	*Useful references: SPC/BNF/Meyler/Medicines for Children.* *List common side effects and may need to refer to other sources for full details. Advisable to warn about potential adverse effects e.g. any CSM advice.*
Advice to patient/carer	• Manufacturer's Patient Information Leaflet • Any further instructions to aid compliance • Storage or expiry details • Practical advice on self-care if appropriate • Advice on recognising side effects and what to do • Advice on where to seek help if treatment fails or condition worsens
Follow up	*Enter details of local policy.*

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT GROUP DIRECTION (PGD) FOR

Drug Name:	**CLASS: *e.g. POM***

Referral Arrangements and Audit Trail

Referral arrangements	*As per local arrangements/national guidelines.*
Records/audit trail	• *Patient's name, hospital unit number, date of birth* • *Diagnosis* • *Dose and form administered* • *Batch and expiry details* • *Advice given to patient (including side effects)* • *Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment* • *Details of any adverse drug reaction and actions taken including documentation in the patient's medical record* • *Referral arrangements (including self-care)* *Think about what you would want to find out from an audit so you can make sure you have covered the important points to record for the audit but do not exclude any of the above.*
Record of Medication Supplied	*Think about what records need to be completed when medication is supplied. eg* • *A record of all supplies must be made in the patient's medical records. A record sheet detailing all packs of medication supplied under this direction must be completed and retained. This must include the patient's name, the quantities and details of medication supplied, and the date on which the supply was made.* • *The signature / identification of the person making the supply must be recorded.*
References/Resources and comments	

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT GROUP DIRECTION (PGD) FOR

Drug Name:	**CLASS: *e.g. POM***

Staff Characteristics

Qualifications	Registered professional *[appropriate qualification to be listed]* with a current *[professional]* registration e.g. • *Registered nurse who holds a valid current NMC registration.* • *The Nurse will be in the employ of SEPT*
Specialist competencies or qualifications	*Refer to guidelines relating to this drug e.g. nurses must be trained in anaphylaxis if administering vaccines e.g.* • *Nurse to have undertaken an education programme in the management of relevant conditions recognised by SEPT.* • *Training to demonstrate competence in understanding diagnosis and management of relevant conditions, performing competent and safe assessment interviews with patients and managing ongoing monitoring*
Continuing training & education	*The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.* *Include training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support, if relevant for the medicine listed.*

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT GROUP DIRECTION (PGD) FOR

Drug Name:	**CLASS:** ***e.g. POM***

Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Date

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURE FOR THE DISPOSAL OF WASTE MEDICINES

1. INTRODUCTION

1.1. This procedure must be read in conjunction with the Trust's policy RM13 *Waste Management Policy* and RMPG13a *Procedural Guidelines for the Handling, Segregation and Disposal of Waste*.

1.2. The legislation and regulation relating to the transport and disposal of waste, do not allow unwanted medicines to be transferred to another organisation for disposal. Due to the differing arrangements for the provision of pharmacy services within Bedfordshire, Essex and Luton, pharmaceutical waste must be handled differently in each area.

1.3. **Essex:** only spoiled doses and patient's own drugs which should be disposed of on the ward in line with this document. All other medicines that are no longer required (including controlled drugs) must be returned to the hospital pharmacy as soon as possible. The.

1.4. **Bedfordshire and Luton:** Unwanted medicines **MUST NOT** be sent back to the hospital pharmacy for disposal. All Trust sites where medicines are handled must keep suitable pharmaceutical waste bins which must be used in accordance with this procedure.

1.5. This document relates only to the disposal of pharmaceutical waste, i.e. licensed medicines classified as 'General Sales List' (GSL), 'Pharmacy Medicines' (P) or 'Prescription Only Medicines' (POM), including Controlled Drugs (CDs). It does not deal with the disposal of radioactive pharmaceutical waste or chemical waste.

2. PHARMACEUTICAL WASTE

2.1. Pharmaceutical waste is likely to consist of patients own medicines that are no longer required, out of date stock and medicines dispensed for individual patients, leave/discharge medicines that have not been issued or which have been brought back unused, and Controlled Drugs that have been denatured (see section 3).

2.2. It is not permissible to use 'patients own' medicines for other patients, even if they are in date and appear to be in good condition. Unwanted 'patients own' medicines must be disposed of (with the patient's consent) in accordance with these procedures (see also Appendix 11 of CLPG13).

2.3. Stock medicines that are still within their expiry date but which are no longer required should be notified to the supplying pharmacy department. It may be possible for the pharmacy to collect and re-issue them to another SEPT ward in Bedfordshire and Luton.

2.4. Pharmaceutical waste may include:

- Tablets and capsules
- Liquid medicines
- Eye, ear and nasal drops
- Transdermal patches
- Medicated dressings
- Inhalers
- Respirator solutions
- Creams and ointments
- Sachets of powder
- Vials and ampoules
- Suppositories

2.5. With the exception of cytotoxic/cytostatic drugs and sharps contaminated with pharmaceuticals, waste medicines should be stored in a 'pharmaceutical waste' bin, which is a yellow plastic container with a blue lid (see section 3.1).

3. WASTE CONTAINERS

3.1. **Non-hazardous pharmaceutical waste** (yellow bin with BLUE lid)

3.1.1. These bins should be used for the majority of waste medicines, apart from sharps contaminated with pharmaceuticals (see section 3.2) and cytotoxic or cytostatic drugs (see section 3.3). Annex 1 contains a list of the drugs classed as cytotoxic or cytostatic.

3.1.2. Medicines should be separated from any outer packaging and leaflets prior to disposal. Outer packaging and patient information leaflets should be disposed of as general domestic waste. **Any labels identifying a patient's name must be disposed of in confidential waste**. Empty blister packs do not need to be disposed of in the pharmaceutical waste container.

3.1.3. Annex 2 gives advice on how different types of product should be handled before placing them in the pharmaceutical waste container.

3.2. **Sharps contaminated with pharmaceuticals** (yellow bin with YELLOW lid)

3.2.1. Sharps contaminated with pharmaceuticals, e.g. unused or partially-used syringe/needle combinations and used or broken ampoules/vials should be placed in the container for sharps contaminated with pharmaceuticals.

3.2.2. Sharps not contaminated with pharmaceuticals, may be placed in the standard 'sharps bin' (yellow bin with ORANGE lid).

3.2.3. Sharps contaminated with cytotoxic or cytostatic drugs (see section 3.3), should be disposed of in the container for hazardous pharmaceutical waste (yellow bin with PURPLE lid).

3.3. **Hazardous pharmaceutical waste** (yellow bin with PURPLE lid)

3.3.1. Products containing cytotoxic or cytostatic drugs are regarded as hazardous waste, and must be segregated from non-hazardous pharmaceutical waste prior to disposal. A separate container (yellow with a PURPLE lid) must therefore be used for all cytotoxic/cytostatic waste.

3.3.2. Annex 1 contains a list of the drugs that are regarded as cytotoxic or cytostatic. Although the majority of these drugs will not be encountered in a mental health setting, the list includes some commonly-used products, including chloramphenicol and hormones found in oral contraceptives and hormone-replacement therapy).

3.3.3. When disposing of unwanted medicines, Annex 1 should be referred to in order to ensure that the appropriate containers are used. Any unidentifiable medicines should be regarded as hazardous pharmaceutical waste.

3.4. All bins for storing pharmaceutical waste must be kept in a secure place prior to their collection by the waste contractor; the bins must not be accessible to patients, visitors or non-nursing staff. This will usually mean that the bins should be kept in a locked cupboard within a room such as a clinical room.

3.5. Once full the lid must be firmly secured, all paperwork correctly filled in and the waste consigned to the appropriate codes (see RMPG13a). Further advice on the arrangements for the collection of waste from wards/units can be obtained from the Facilities Department.

4. DISPOSAL OF CONTROLLED DRUGS

4.1. Controlled Drugs (CDs) must be denatured prior to disposal, and the denaturing process must be carried out by an authorised person in the presence of an authorised nurse who works on the ward/unit where the CDs are being held.

4.2. This process is described in detail in section 15 of Appendix 1 to CLPG13. Once CDs have been denatured and booked out of the CD Record Book, the destruction kit can be placed in the container for non-hazardous pharmaceutical waste (yellow bin with BLUE lid).

Annex 1

List of "Hazardous" medicines ("Cytotoxic/Cytostatic") adapted from Table 2 HTM 07-06 to include BANs where appropriate (taken from Principles on the Disposal of Pharmaceuticals used within Community Health Services)

Aldesleukin	Imatinib mesilate
Alemtuzumub	Interferon alfa-2a
Alitretinoin	Iinterferon alfa-2b
Altretamine	Interferon alfa-n1
Amsacrine	Interferon alfa-n3
Anastrozole	Irinotecan HCl
Arsenic trioxide	Leflunomide
Asparaginase	Letrozole
Azacitidine	Leuprorelin acetate
Azathioprine	Lomustine
Bacillus Calmette-Guêrin Vaccine (BCG)	Megestrol
Bexarotene	Melphalan
Bicalutamide	Menotropins
Bleomycin	Mercaptopurine
Busulfan	Methotrexate
Capecitabine	Methyltestosterone
Carboplatin	Mifepristone
Carmustine	Mitomycin
Cetrorelix acetate	Mitotane
Clorambucil	Mitoxantrone HCl
Chloramphenicol	Mycophenolate mofetil
Choriogonadotropin alfa	Nafarelin
Chlomethine hydrochloride	Nilutamide
Cidofovir	Oxaliplatin
Cisplatin	Oxytocin
Cladribine	Paclitaxel
Colchicine	Pegaspargase
Cyclophosphamide	Pentamidine isethionate
Cytarabine	Pentostatin
Ciclosporin	Perphosphamide
Dacarbazine	Pipobroman
Dactinomycin	Pinitrexim isethionate
Daunorubicin HCl	Picamycin
Denileukin	Podofilox
Dienostrol	Podophyllum resin
Diethylstibestrol	Prednimustine
Dinoprostone	Procarbazine
Docetaxel	Progesterone
Doxorubicin	Progestins
Dutasteride	Raloxifene
Epirubicin	Raltitrexed
Ergometrine/methylergometrine	Ribavirin
Estradiol	Streptozocin
Etramustine phosphate sodium	Tacrolimus
Estrogen-progestin combinations	Tamoxifen
Estrogens, conjugated	Temozolomide
Estrogens, esterified	Teniposide
Estrone	Testolactone
Estropipate	Testosterone
Etoposide	Thalidomide
Exemestane	Thioguanine
Finasteride	Thiotepa
Floxuridine	Topotecan
Fludarabine	Toremifene citrate
Flurouracil	Tositumomab
Fluoxymesterone	Tretinoin
Flutamide	Trifluridine
Fulvestrant	Trimetrexate glucuronate
Ganciclovir	Triptorelin
Ganirelix acetate	Uramustine
Gemcitabine	Valganciclovir
Gemtuzumab ozogamicin	Valrubicin

continued...

Choriogonadotropin alfa	Vidarabine
Goserelin (Zoladex)	Vinblastine sulfate
Hydroxycarbamide	Vincristine sulfate
Ibritumomab tiuxetan	Vindesine
Idarubicin	Vinorelbine tartrate
Ifosfamide	Zidovudine

Annex 2

DISPOSAL ADVICE

Product type	Disposal advice
Aerosol inhalers and other pressurised devices	Remove product from inert packaging. Aerosols should be placed in the waste container intact.
Capsules	See under Tablets.
Creams, ointments and shampoos	Remove product from inert packaging then place in waste container.
Eye, ear and nasal drops and ointments	Remove product from inert packaging then place in waste container. Products containing **chloramphenicol** must be disposed of as cytotoxic/cytostatic waste (yellow bin with purple lid).
Flammable liquids	Small quantities of flammable liquids remaining in a bottle, e.g. alcohol hand rubs, may be placed in the waste container. Large quantities of flammable liquids must not be placed in the container – contact Estates for advice on collection and disposal.
Inhalers (non-aerosol)	Remove product from inert packaging then place in waste container.
Injections (intact vials or ampoules)	Remove from inert packaging then place ampoules/vials in waste container.
Injections (broken or part-used vials or ampoules)	Place in waste container for sharps (yellow bin with yellow lid).
Injections (unused or part-used syringes with needles)	Place in waste container for sharps (yellow bin with yellow lid). Do not discharge the syringe contents.
Liquids (external and internal, in bottles)	The liquid should remain in the bottle and the bottle itself should be placed in the waste container. Under no circumstance should a liquid be poured directly into the waste container. Liquid Controlled Drugs will require denaturing prior to disposal.
Liquids (oral doses that have been measured but not administered)	Small quantities may be disposed of by washing down a sink or toilet.
Nebules	Treat as injections (intact).
Patches (removed from the patient's skin)	Fold the patch over on itself, then place in the waste container.
Patches (unused - sealed in individual pouches)	Remove pouches from inert packaging and then place unopened pouches in waste container
Powders (in tins/sachets)	Place in waste container intact. Do not open sachets.
Suppositories and vaginal preparations	Remove product from inert packaging then place in waste container. Do not remove suppositories/pessaries from individual foil/plastic wrapping.
Sprays e.g. nasal sprays	Remove product from inert packaging then place in waste container.
Tablets and capsules (in blister strips)	Remove blister strips from inert packaging and place in waste container (do not pop tablets/capsules out of their blisters).
Tablets and capsules (loose in a bottle or pot)	Tablets/capsules must remain in the bottle. Place bottle containing tablets/capsules directly in the waste container.

Product type	Disposal advice
Tablets and capsules (in a monitored dose system, e.g. blister packs in a plastic frame)	The disposable packaging containing the unwanted medicines should be removed from any re-usable equipment and placed intact into the waste medicines container*. The re-usable equipment can be returned to the pharmacy that dispensed the system. If any of the medicines are on the cytotoxic/cytostatic list (see Annex 1), the whole pack must be placed in the container for hazardous pharmaceutical waste (yellow bin with purple lid).
Tablets and capsules (in a personal compliance box, e.g. Dosett)	If the compliance aid does not contain medicines sealed in disposable packaging, there is no alternative but to empty the contents directly into the waste medicines container. However, before doing so, there is a duty of care to determine whether the container includes any medicines on the cytotoxic/cytostatic list (see Annex 1). If so, the entire contents should be emptied into the container for hazardous pharmaceutical waste (yellow bin with purple lid).
Tablets and capsules (prepared but not administered)	Place directly in pharmaceutical waste container. However, if 'contaminated' e.g. as a result of the patient spitting out, place in the container for sharps (yellow bin with yellow lid).
Unidentifiable medication of any sort	Place in the container for hazardous pharmaceutical waste (yellow bin with purple lid)

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

USE OF PATIENT'S OWN MEDICINES

1. INTRODUCTION

1.1. It is permissible to use a patient's own medicines brought with them on admission, provided these have been assessed as suitable for continued use. This document includes an algorithm (see Annex 1) which should be used by nursing or pharmacy staff to assess whether a patient's own medicines are suitable for use.

1.2. This algorithm can be used for assessing a patient's own controlled drugs, but additional record-keeping requirements apply. Refer to Appendix 3 of CLPG13.

1.3. If a patient's own medicines have been assessed as suitable for continued use, written consent to do so must be obtained using the consent form contained in Annex 2. The completed consent form should be filed in the patient's healthcare record.

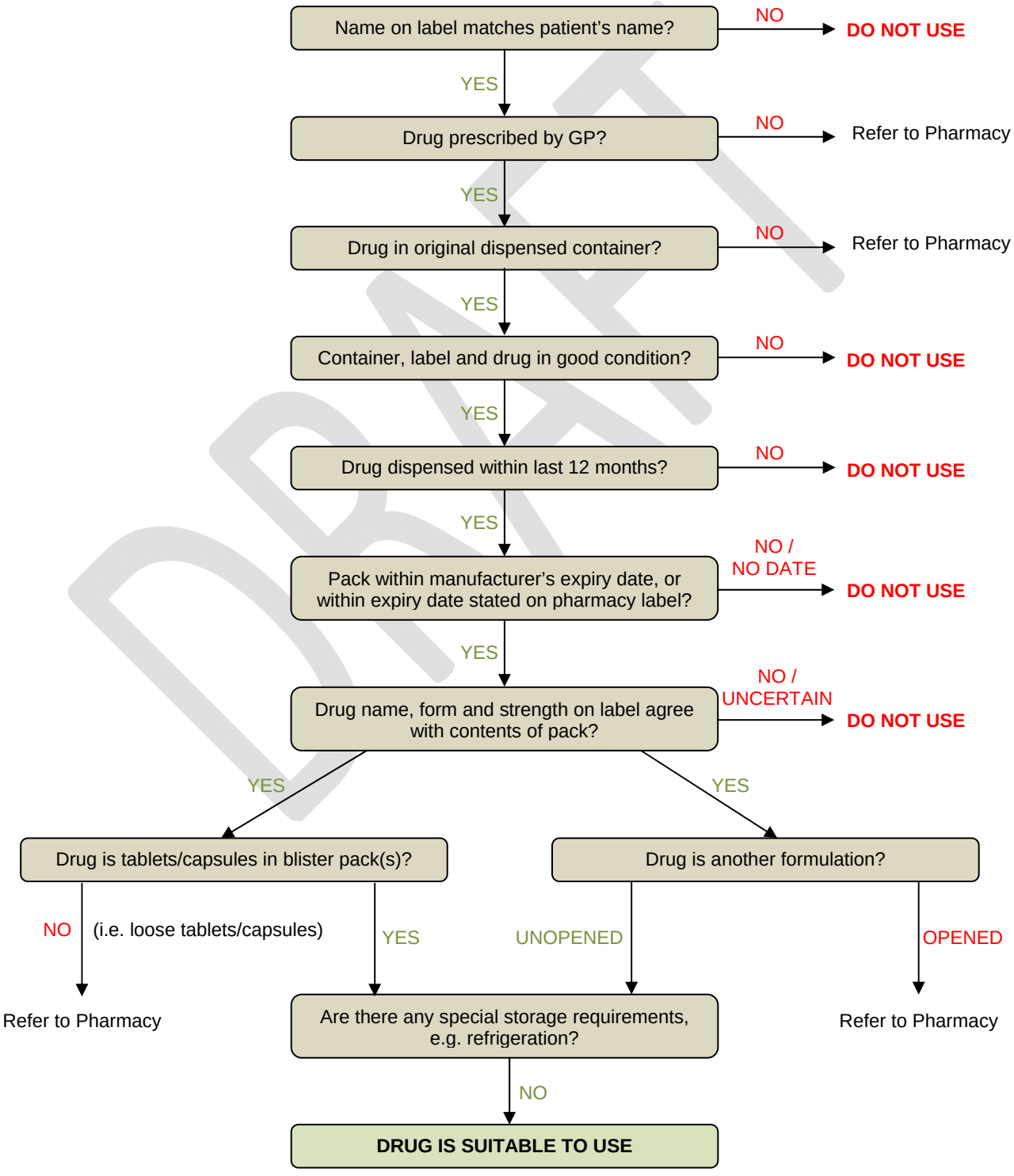
1.4. If a patient's own medicines are not required because the admitting doctor decides to discontinue the treatment, or they are assessed as unfit for use, permission should be sought for the medicines to be disposed of as pharmaceutical waste on the ward. Consent for disposal must be obtained using the consent form contained in Annex 3.

1.5. If permission to destroy a patient's own medicines is not granted, they should be sent home in the same way as any other property not required by the patient.

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

ALGORITHM FOR ASSESSING WHETHER A PATIENT'S OWN MEDICINE IS SUITABLE FOR CONTINUED USE WHILST AN INPATIENT



Annex 2

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT CONSENT TO USE THEIR OWN MEDICINES

Patient's name:		NHS Number:	
Ward:		Date of Admission:	

1. I agree to the continued use of my own medicines (listed below), whilst I am an inpatient.

2. I understand that any remaining supply of my medicines will be returned to me on my discharge. If my own supply of any of these medicines runs out whilst I am an inpatient, I understand that an additional supply will be provided for me.

3. Any of my medicines that are discontinued by a doctor whilst I am an inpatient may be disposed of.

4. I understand that my medicines will be stored in a locked cupboard, and given to me by a member of the nursing staff at the appropriate times.

Drug name and formulation	Strength	Directions	Quantity

Signature:	**Date:**

This form should be filed in the patient's healthcare record

Annex 3

Providing Partnership Services in Bedfordshire, Essex and Luton

PATIENT CONSENT TO THE SAFE DISPOSAL OF UNWANTED MEDICINES INCLUDING CONTROLLED DRUGS

Dear Patient

Thank you for bringing your medicines in with you when you were admitted.

The following medicine(s) are no longer required for your treatment, or are not suitable for use. We would like to ask your permission to dispose of them safely on the ward, in line with environmental guidelines and regulations. If you consent to these medicines being disposed of, please sign the box below.

Thank you

Name of patient			NHS No:
Ward/unit	Date		Time
Qualified nurse			
Medicines to be disposed of:			
Name	Strength	Form	Quantity
Patient signature for consent to destruction			

If you do not consent to these medicines being destroyed on the ward, they will be stored safely until you are ready to be discharged. You will then have the opportunity to consent to their destruction on the ward, or to take them home with you. If you decide to take them home, even though you no longer require them for your treatment, you are advised to take them to a community pharmacy for safe disposal.

Nursing staff: If the medicines listed above include a Controlled Drug, and the patient consents to disposal, this form should be placed inside the CD Record Book pending transfer to the pharmacy (Essex only) or denaturing of the item by an approved person (Bedfordshire and Luton only).

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURE FOR MONITORING THE TEMPERATURE OF DRUG STORAGE AREAS

1. INTRODUCTION

1.1. Medicines must be stored according to the manufacturer's requirements and away from direct sunlight, heat source or moisture. For most medicines this is below 25°C, although some specify storage in a "cool dry place" or below 15°C, and others require refrigeration between 2° and 8°C.

1.2. Where items are stored outside the required conditions the stability and/or efficacy of the product will be affected and the product may no longer be fit for use.

1.3. In order to provide the necessary level of assurance, the temperature of areas used to store drugs, including refrigerators, should be monitored and recorded on a **daily** basis.

2. STORAGE AT ROOM TEMPERATURE

2.1. Rooms used for the storage of medicines must be maintained below 25°C. In order to ensure that this is the case, the temperature needs to be monitored on a daily basis.

2.2. Items requiring storage in a "cool dry place" or below 15°C must be stored under these conditions or otherwise in a fridge.

3. REFRIGERATED STORAGE

3.1. Medicines that require refrigeration usually need to be stored at a temperature between +2° and +8° C and this will be clearly marked on the outer carton or bottle. In order to ensure that the refrigerator is operating correctly, the temperature needs to be monitored on a daily basis, and the purpose of this paper is to explain how this monitoring should be carried out.

3.2. Most of the drug products requiring fridge storage will not deteriorate significantly if they are kept out of a fridge for short periods, e.g. during transport between the pharmacy and the ward. This includes items such as insulin, lorazepam injection and some antibiotic syrups and eye drops. If an item is left out of the fridge for any period or the fridge is found to be outside the range of +2° and +8° C advice must be sought from the pharmacy department.

3.3. Certain products must be maintained at fridge temperature at all times or their efficacy cannot be guaranteed. For such products, a 'cold chain' must be maintained whenever the products are in transit, by using cool bags and cool packs. This includes Risperdal Consta® injection and most vaccines.

Risperdal Consta®, commonly used in mental health, is both temperature-sensitive and very expensive.

4. MONITORING AND RECORDING TEMPERATURES

4.1. Managers must ensure that named members of staff are responsible for carrying out this monitoring, and that these staff fully understand how to make the measurements and record them. Staff should also be trained to ensure that they know what action to take if a temperature reading falls outside the permitted range, and in respect of refrigerators of the need to defrost the drug fridge on a regular basis.

4.2. Readings should be made on a daily basis using a **digital maximum-minimum thermometer**. Some modern drug fridges come with an integral digital maximum-minimum thermometer, but most have a simple dial thermometer built into the door. This type of thermometer is not suitable for temperature monitoring, and sites with this type of fridge will need to purchase a separate digital maximum-minimum thermometer.

4.3. The maximum-minimum thermometer has a probe which can be inserted into the body of the fridge by passing the cable through the seal on the hinged side of the door. The thermometer unit can then be placed on top of the fridge so that readings can be taken without needing to open the door.

4.4. Most digital maximum-minimum thermometers measure both the ambient (room) temperature and the temperature of the probe. This type is preferred as one thermometer can be used for both sets of reading.

4.5. The probe (remote) temperature reading needs to be recorded for the refrigerator. The thermometer shows the maximum and minimum temperatures reached within the fridge since it was last reset, and these are the readings that need to be recorded – they must remain within the range **+2° to +8°C**. It is essential that the thermometer is reset after each daily reading is taken.

4.6. A monthly temperature monitoring sheet is available at Annex 1. Completed sheets should be retained for 2 years.

Top Tips

- Ensure the probe is in a suitable position – it should not be touching the interior walls of the fridge, the ice compartment or any of the contents.
- Ensure that the body of the thermometer is in a suitable position – it should not be close to a radiator or other heat source, or in a draught from a window or air-conditioning unit.
- Make sure that the staff who are responsible for monitoring the fridge and room temperatures know how to take the daily readings and reset the thermometer.

Top Tips (continued)

- The 'reset' button must be pressed after recording the daily maximum and minimum temperatures, in order to obtain a new baseline.
- If the readings are the same every day, it suggests that the thermometer is not being reset on a daily basis – small day-to-day variations in maximum and minimum temperatures are normal, provided they remain within the range +2° to +8° C for the refrigerator and below 25°C for the room temperature.
- Investigate any readings that fall outside the permitted ranges. If investigation confirms that the readings were taken correctly, contact a pharmacist for advice about whether the refrigerator or drug cupboard contents can still be used. Check that the refrigerator is working correctly – if not, transfer the contents to another fridge until it can be repaired or replaced.
- Ensure that the fridge is defrosted and cleaned regularly, e.g. monthly, and that the contents are stored in a suitable place during defrosting.
- If the fridge is not likely to be required for storing any medications for an extended period, it should be turned off rather than run empty. It should be defrosted and cleaned in the usual way, and then stored with the door held ajar rather than closed.

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

TEMPERATURE MONITORING FORM

Ward: Unit	Month:	Year:

If the fridge temperature reading falls outside the +2° to +8° C range or the room rises above 25°C:

- report this to the ward/unit manager, check the points overleaf and contact the pharmacy department for advice
- report as a medicines incident via DATIX

		FRIDGE		ROOM			
Date	Time	Max. Reading (Must be below +8°)	Min. Reading (Must be above +2°C)	Max. Reading (Must be below +25°C)	Thermo-meter(s) Reset (tick)	Checked by (initials)	Action taken if outside range
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
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16							
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DAILY READINGS MUST BE TAKEN (UNLESS NOT A WORKING DAY)

CHECK THE FOLLOWING IF FRIDGE TEMPERATURE FALLS OUTSIDE +2° - +8° C

- Has the fridge been disconnected / turned off or has there been a power cut? If the power supply to the fridge is broken report this immediately to ward/unit manager
- Has the fridge door been left open?
- Has the fridge been opened frequently in the last few hours?
- Is the thermostat set too high or too low (if applicable)?
- Was the thermometer reset correctly after the last reading?
- If used, is the thermometer probe correctly placed inside the fridge?
- Is the fridge more than half full?
- Does the fridge need defrosting (if applicable)?
- Has the thermometer been accidentally damaged, e.g. fallen off the fridge?
- Does the fridge need servicing?

If in doubt remove the affected stock and place it in bags labelled 'DO NOT USE' and store in a properly working refrigerator. Seek advice from pharmacy about whether the stock can be used.

END OF MONTH REVIEW

	Yes	No
Has the room temperature been checked every day? *		
Has the fridge temperature been checked every day? *		
Has any action been necessary due to the temperature being out of range		
If yes, give details		

Reviewed by (Manager)	Date:

RECORD TO BE RETAINED ON THE WARD FOR 2 YEARS

* excluding weekend and public holidays if the site is closed

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURE FOR THE ADMINISTRATION OF MEDICINES

ACTION	RATIONALE
ENVIRONMENTAL FACTORS	
1. Free from distraction and interruptions	It is generally accepted that when undertaking an activity that requires a high degree of concentration people should do so with the least interruptions and distractions.
2. Well lit area	Ensuring adequate light and space will enable the nurse to view the medication and prescriptions properly and reduce the opportunity for error.
3. Clean and tidy	Quality begins by having things in the right place and of the correct quantity. Putting something back incorrectly leads to wasted time for another nurse in looking for the item and poses a risk to future administration.
4. Alarm system in place (Pinpoint etc)	
PREPARATION PRIOR TO ADMINISTRATION	
5. Identify which drug charts are required. Identify service users prescribed controlled drugs, checking prescription and identify a second nurse to check medication and complete controlled drug stationary appropriately	On a purely practical basis it is worth selecting out those service users medicine cards that are definitely on prescribed medications at that time, those who may ask for PRN 'as required' medicines and those who are not on the ward. The administration of all controlled drugs (CD's) must be witnessed by a second practitioner in order to check accurate administration.
6. Check drug chart for: • Patient's name • Consent to treatment (Form T2 / T3) • Signatures • Legibility • Written correctly • Dates / time of administration • Name of drug to be administered • Dosage • Route of administration	The Medicine Act (1968) and the Mental Health Act make specified requirements about medicines. The nurse should not administer medicines if she finds the prescription illegible, incorrect or unsigned.
7. Omit service users on leave and mark drug charts with leave code	This makes sure when evaluating the drug regimen that staff have a clear impression of compliance to medications.
8. Check ward diary and care plans for medication to be withheld for any reason**.**	Source of communication in wards often extend out of the service user's notes, and prompts in the form of a ward management book or diary are often used to record, for example, due dates of depot antipsychotic medication

ACTION	RATIONALE
9. Prepare medicine dispensing containers	Making sure there are enough medicine containers can greatly improve the flow of medicine administration. Having to stop to wash containers not only wastes time but is a cue for distractions to creep into the procedure.
10. Jug of water	It is recommended that people take a full cup of water with their medicines as this improves the absorption of the medicine.
11. Container to collect used items	To keep used items and clean items separate.
12. Check cupboard/trolley is well stocked and tidy	To ensure a consistent supply. If a medicine is low on stock this should be ordered at the earliest convenience or alert the relevant pharmacy staff.
13. Identify member of staff to ask service users to attend individually.	To maintain concentration on task and avoid queues. To maintain privacy for service users
14. Wash hands with bactericidal soap and water or alcohol handrub	(a) To prevent cross infection. (b) Personal hygiene is necessary when handling drugs, to comply with health and safety legislation
ADMINISTERING THE MEDICATION	
15. Allow only one service user at a time into clinic room.	Evidence shows that if service users have some regular and quality contact time at their medicine administration they are more likely to ask questions about their medicines. Information about effects must be given at all stages of recovery. This also provides confidentiality for the service user
16. Greet each service user and confirm identification checking their name, DOB and consult other member of staff if necessary to cross reference with medicine card.	In order to confirm correct service user identification. Nurses must not dispense any medication unless absolutely certain of identity of service user.
20. Select medication to be given	It is helpful to verbally confirm the medications e.g. Olanzapine 10mg, six o' clock, Joe Bloggs' this both confirms the drug and person with the second practitioner and involves the service user actively in the checking of their medications.
21. Check the expiry date for all medication given.	To protect the service user from harm. Treatment with medication that is outside the expiry date is dangerous. Drugs deteriorate with storage. The expiry date indicates when a particular drug is no longer pharmacologically efficacious.
22. Re-check the dose on the drug chart and check that it is due and has not already been administered	To protect service user from harm.
23. Place the required dose into a medicine container without touching the preparation	To prevent cross infection (non-touch technique). To prevent harm to the nurse.
24. Repeat steps 16 – 20 for each item of medication to be given	Having a standard helps staff to see the effectiveness of care. Frequent repetition and behavioural modelling are important as part of the learning process.

ACTION	RATIONALE
25. Engage the service user in conversation about their treatment, checking knowledge of the medication offer information and advice about the medication and any side effects. Hand the service user the medication to be administered	Service users have the right to information about treatment. Nurses need to link the interaction regarding medication to the service user's overall plan of care including discharge. Patient's have a right to information about their treatment.
26. Offer water to the service user to facilitate swallowing the medication	A full glass of water should be taken with medications to help with absorption
28. If any medications are not given mark with appropriate code state reason why, make entry in healthcare record and hand-over to next shift.	Doses are often omitted with little thought to the overall management of medication.
29. If PRN medication is given, this must also be documented in nursing notes. PRN administration should be part of the overall care plan	Use of PRN can increase risk of side effects as dosage and side effects are related due to high doses and polypharmacy issues. There is evidence of nurses giving PRN wrong medication: e.g. for agitated restlessness when calm, for insomnia when observed to be asleep
30. Tidy medicine cabinet/trolley Check medicine trolley/cupboard is stocked, locked and secured (to a fixed point if a trolley is used)	Quality begins with everything in its correct place. Preparing for the next medication administration is good practice. The Medicines Act indicates that medicines should be stored in a locked cupboard or trolley secured to a fixed place.
32. Wash and dry medicine administration containers.	Hygiene is an essential part of nursing practice. Washing and drying containers reduces the risk of mixing medication residue and cross infection. It also facilitates the next medication administration.
33. Replace drug charts	Medication cards should be kept locked in the clinic room.
34. Re-order medication from pharmacy where appropriate and remove all discontinued medication from trolley.	Stocks should be checked at regular intervals and re-ordering as part of the medication administration. A reduction in the therapeutic dose of a treatment programme could occur if administrations are missed due to lack of stock.

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURE FOR THE PREPARATION AND ADMINISTRATION OF INJECTIONS

1. INTRODUCTION

1.1. Drugs given via the parenteral route are usually absorbed faster than when administered orally or are altered by ingestion. Available options include intradermal, intramuscular, subcutaneous, and intravenous injections. Depot injections, which deposit medication deep into muscle tissue, are given to facilitate the slow-release of the drug. This route of administration provides absorption of relatively large volume (up to 4mls in appropriate sites).

1.2. Within this Trust, nurses may be required to administer drugs by subcutaneous (SC) or intramuscular (IM) injection, but should not administer drugs intravenously or by any other parenteral route.

1.3. There is little need for drugs to be administered intravenously within mental health settings, and Trust doctors should not normally prescribe drugs by this route. One exception to this is flumazenil, which may need to be given urgently by IV injection to reverse the respiratory depressant effect of benzodiazepines such as lorazepam or midazolam.

The other main exception is within ECT departments, where the administration of drugs intravenously by an anaesthetist from a local acute trust is standard clinical practice. If information is required on the administration of drugs by the intravenous route, please refer to the Royal Marsden Manual (see 1.4 below).

Patients requiring the intravenous administration of medication on a regular basis should be transferred to a general hospital. Certain patients may need to be accompanied by a member of Trust staff.

1.4. This procedure contains step-by-step operational techniques to be followed when preparing and administering drugs by subcutaneous and intramuscular injection. It is closely based on the Royal Marsden Manual of Clinical Nursing Procedures, the full version of which is available on the Trust intranet.

2. PROFESSIONAL RESPONSIBILITIES

2.1. Prescribers are responsible for ensuring that the prescription indicates the correct route of administration in accordance with the licence of that medication (i.e. deep intra-muscular).

2.2. The safe preparation and administration of drugs by subcutaneous or intramuscular injection require that healthcare staff have achieved a series of competences relating to: (a) the prescription of the injection; (b) preparing the injection for administration; (c) the administration of the injection; and, (d) monitoring the administration of injections (for further guidance: www.npsa.nhs.uk/health/).

It is expected that these competences will normally be achieved as part of an educational programme leading to registration as a healthcare practitioner (mental health nurse or doctor). Team Managers must ensure that only those practitioners who have achieved the required competences are involved in preparing and administering drugs by injection.

If these competences have not been achieved, then the healthcare practitioner must make their manager aware, in accordance with their code of professional conduct (for example*:* NMC), and complete a short programme of training before preparing or administering drugs by injection. The Trust's Infection Control & Physical Health Care Lead should be contacted in confirming the arrangements for required training and a period of supervised practice.

The short programme of training and supervised practice to support the acquisition and demonstration of competences must include:

- the prescription, preparation and administration of injections
- the ordering and storage of injectable medicines
- knowledge of the licensed indications for the injectable medicines
- knowledge of and monitoring of side-effects associated with the injectable medicines
- knowledge of the procedure for reporting near misses and errors relating to the preparation and administration of drugs by injection

If the practice of a healthcare professional raises cause for concern, then the Team Manager is required to arrange for a re-appraisal of the practitioner's skills in the preparation and administration of drugs by injection before being permitted to continue this aspect of their practice. In some cases, this may form a component of a professional development plan within a competence or capability framework.

2.3. It is the responsibility of the person who administers the medication to ensure that they have the required information and skills to do so safely and effectively in line with current evidence based practice, and their professional code of conduct.

2.4. It is the responsibility of the Trust to ensure that staff are provided with the opportunity to update their skills and knowledge base as required.

3. INJECTION ROUTES

3.1. Injection can be described as the act of giving medication by use of a syringe and needle. Injections are sterile solutions, emulsions or suspensions. They are prepared by dissolving, emulsifying or suspending the active ingredient and any added substances in water for injections, in a suitable non-aqueous liquid or in a mixture of these vehicles.

3.2. **Single-dose preparations:** The volume of the injection in a single-dose container is sufficient to permit the withdrawal and administration of the nominal dose using a normal technique (see also **Annex 1**, sections (c) and (d)).

3.3. **Multi-dose preparations:** Multi-dose aqueous injections contain a suitable antimicrobial preservative at an appropriate concentration except when the preparation itself has adequate antimicrobial properties. When it is necessary to present a preparation for injection in a multi-dose container, the precautions to be taken for its administration and, more particularly, for its storage between successive withdrawals, are given in the product literature (see also **Annex 1**, section (e)).

3.4. There are a number of possible routes for injection, including intra-arterial, intra-articular, intrathecal and intra-lesional. However, this procedure is only concerned with administration by the subcutaneous or intramuscular routes.

4. Intramuscular Injections

4.1. Intramuscular injections deliver medication into well perfused muscle, and many drugs may be administered by this route provided they are not irritant to soft tissues and are sufficiently soluble.

4.2. Absorption is usually rapid, and can produce blood levels comparable to those achieved by intravenous bolus injection, although depot antipsychotic injections are formulated to release the drug slowly over a period of several weeks.

4.3. Relatively large doses, from 1 ml in the deltoid site to 5 ml elsewhere in adults can be given. These values should be halved in children because muscle mass is less. Intramuscular injections should, where possible, be avoided in thrombocytopenic patients.

4.4. The choice of site should take into consideration the patient's general physical status and age, and the amount of drug to be given. The proposed site for injection should be inspected for signs of inflammation, swelling, and infection, and any skin lesions should be avoided. The patient's preference as to site should be considered where appropriate.

4.5. Five sites are recommended for intramuscular injections (see **Annex 2**):

- **Mid-deltoid:** Used for the injection of drugs such as narcotics, sedatives, vaccines and vitamin B12. It has the advantage of being easily accessible whether the patient is standing, sitting or lying down. It is also a better site than the gluteal muscles for small-volume (less than 2 ml) rapid-onset injections because the deltoid has the greatest blood flow of any muscle routinely used for intramuscular injections. However, as the area is small, it limits the number and size of the injections that can be given at this site.
- **Gluteus medius:** Used for deep intramuscular and Z-track injections. The gluteus muscle has the lowest drug absorption rate. The muscle mass is also likely to have atrophied in elderly, non-ambulant and

emaciated patients. This site carries with it the danger of the needle hitting the sciatic nerve and the superior gluteal arteries. In even mildly obese patients, injections into the dorsogluteal area are more likely to be into adipose tissue than muscle, with consequently slower absorption of the drug.

The Z-track method involves pulling the underlying skin downwards or to one side of the injection site, inserting the needle at a right angle to the skin, which moves the cutaneous and subcutaneous tissues by approximately 1–2cm. The injection is given and the needle withdrawn, while releasing the retracted skin at the same time. This manoeuvre seals off the puncture tract (see diagrams in **Annex 3**).

- **Ventrogluteal:** Used for antibiotics, antiemetics, deep intramuscular and Z-track injections in oil, narcotics and sedatives; typical volume is 1–4 ml. It is best used when large-volume intramuscular injections are required and for injections in the elderly, non-ambulant and emaciated patient as it provides the safer option to accessing the gluteus medius muscle.

  This is because the site is away from major nerves and vascular structures and there have been no reported complications. Additionally, the ventrogluteal site has a relatively consistent thickness of adipose tissue over it, thus ensuring that a standard size 21-guage (green) needle will usually penetrate the gluteus medius muscle area.

- **Rectus femoris:** Used for antiemetics, narcotics, sedatives, injections in oil, deep intramuscular and Z-track injections. It is rarely used in adults but is the preferred site for infants and for self-administration of injections.

- **Vastus lateralis:** Used for deep intramuscular and Z-track injections. This site is free from major nerves and blood vessels. It is a large muscle and can accommodate repeated injections. This is the site used for children up to 7 months since the muscle mass will be greater in this area, but the ventrogluteal site is the optimum choice.

4.6. Although traditionally the dorsogluteal site has been most frequently used for depot injections, current evidence indicates that the ventrogluteal site is safer. This site consists of the gluteus medius lying on top of the gluteus minimus muscle, and should be the primary site for anyone more than 7 months of age, unless contra indicated by muscle contraction or damage to the area such as inflammation, oedema or irritation. See **Annex 4** for more information on locating anatomical sites for intramuscular injections.

4.7. Insert the needle at an angle of 90 degrees to the skin surface, leaving approximately a third of the needle above the skin. Pull back slowly on the plunger to aspirate for blood, if blood is present discard all equipment and re-start the procedure. If no blood is present, slowly and steadily inject the medication into the muscle (a slow, steady injection rate allows the muscle of distend gradually and accept the medication under minimal pressure).

4.8. Needle gauge and length

4.8.1. Needles should be long enough to penetrate the muscle and still allow a quarter of the needle to remain external to the skin. The most commonly-used needles for IM injections are 21g or 23g and 2.5-5cm (1”-2”) in length (the higher the gauge number the finer the bore).

4.8.2. Oily depot injections should given through needles with a bore of at least 21g (green); finer bore needles (higher number) are not recommended. The ampoule should be warmed to room temperature prior to drawing-up and administration, as this makes the oil less viscous.

4.8.3. When choosing the correct needle length for intramuscular injections it is important to assess the muscle mass of the injection site, the amount of subcutaneous fat and the weight of the patient. Without such an assessment, most injections intended for gluteal muscle are deposited in the gluteal fat. The following are suggested as ways of determining the most suitable size of needle to use:

- *Deltoid and vastus lateralis muscles*
  The muscle to be used should be grasped between the thumb and forefinger to determine the depth of the muscle mass or the amount of subcutaneous fat at the injection site.
- *Gluteal muscles*
  The layer of fat and skin above the muscle should be gently lifted with the thumb and forefinger for the same reasons as before.

4.8.4. The position of the patient (lying, standing) will also affect the amount of subcutaneous fat which the needle has to pass through, and should also be taken into consideration.

4.8.5. The Royal Marsden Manual recommends that the patient's weight should be used to to calculate the needle length required to penetrate the muscle, using the following guide:

- 31.5 - 40kg 2.5cm (1”) needle
- 40.5 - 90kg 5cm - 7.5cm (2”-3”) needle
- >90kg 10cm - 15cm (4”-6”) needle

4.8.6. The most appropriate Vanishpoint safety needle and syringe device should be selected to ensure that the length and gauge of needle are appropriate for the site of administration.

5. Subcutaneous Injections

5.1. The subcutaneous route is used for a slow, sustained absorption of medication up to 1-2ml being injected into the subcutaneous tissue. It is ideal for drugs such as insulin, which require a slow and steady release, and as it is relatively pain free, it is suitable for frequent injections.

5.2. These are given beneath the epidermis into the fat and connective tissue underlying the dermis. Injections are usually given using a 25 g needle, at a 45° angle. However, following the introduction of shorter needles the recommendation for insulin injections is at an angle of 90°.

5.3. The skin should be gently pinched into a fold to elevate the subcutaneous tissue which lifts the adipose tissue away from the underlying muscle. It is no longer necessary to aspirate after the needle has been inserted, as it has been shown that piercing a blood vessel during a subcutaneous injection is rare. It has also been noted that aspiration of heparin increases the risk of haematoma formation. The maximum volume tolerable using the subcutaneous route is 2ml, and drugs should be highly soluble to prevent irritation.

5.4. Recommended sites are the lateral aspects of the upper arms and thighs, the abdomen in the umbilical region, the back and lower loins. Absorption from these sites through the capillary network is slower than that of the intramuscular route. Rotation of these sites decreases the likelihood of irritation and ensures improved absorption. Subcutaneous injections given in the upper arm are thought to be less painful since there are fewer large blood vessels and less painful sensations in those areas. See **Annex 5** for more information on locating subcutaneous injections.

5.5. Insulin injections should be systematically rotated within an anatomical site – for example, using the upper arms or abdomen for several months, before there is a planned move elsewhere in the body.

5.6. It is no longer necessary to aspirate after needle insertion before injecting subcutaneously. It has also been noted that aspiration before administration of heparin increases the risk of haematoma.

6. SKIN PREPARATION

6.1. Studies have suggested that cleansing with an alcohol swab is not always necessary prior to SC and IM injections. This practice may predispose the skin to hardening, and there is no experimental evidence that skin bacteria are introduced into the deeper tissues by injection, thereby causing infection. Also, the antiseptics in current use cannot produce complete sterility in the time allowed in practice (5 seconds on average), and if an alcohol swab is used and the injection is given before the skin is completely dry, it is likely to be more painful for the patient.

6.2. Provided the patient's skin is physically clean and a high standard of hand hygiene and asepsis is maintained during the procedure, skin disinfection with an alcohol swab is not recommended prior to SC and IM injections.

6.3. However, the use of an alcohol swab is still recommended prior to taking blood samples and giving IV injections, and before giving any injection to an immunocompromised patient. The recommendation is to clean the skin with an alcohol swab for 30 seconds using a circular motion with friction from the centre of the chosen site and progress outwards. The skin should then be allowed to dry for 30 seconds, otherwise skin cleansing is ineffective and results in the patient feeling a stinging pain on needle entry.

7. OTHER CONSIDERATIONS

7.1. Strict hand hygiene and strict aseptic technique should be used during preparation and administration in line with ICPG1 Section 2 (Standard Universal Precautions in Infection Control), and Section 5 (Infection Control in Clinical Practice). It is essential that gloves are worn throughout the administration procedure.

7.2. Ensure privacy is maintained prior to administer the inject and position the patient for easy access to the chosen injection site.

7.3. An older patient will probably bleed or ooze serous fluid from the site after the injection, because of decreased tissue elasticity, applying a small bandage may be helpful.

7.4. If the patient has experienced pain or emotional trauma from repeated injections, consider numbing the area before cleaning it by holding ice on it for several seconds.

7.5. Keep a record that lists all available injection sites for patients who require repeated injections. Failure to rotate sites in patients who require repeated injections can lead to deposits of unabsorbed medications. Such deposits can reduce the desired pharmacological effects and may lead to abscess formation of tissue fibrosis. (Lippincott et al 2000).

7.6. **Monitoring**

7.6.1. Check with the patient whether they are experiencing any discomfort after the injection. Where circumstances permit, it is good practice to check the injection site 2 – 4 hours after administration, to ensure there are no complications.

7.6.2. In the community, it is advisable to check at subsequent visits that the patient has not had any adverse effects to the medication.

7.7. Potential problems

Issue:	Remedy:
Immediately after the injection, the patient has a reaction.	Contact the medical staff, monitor the patient and assess the need to giving an adrenaline injection (see CLPG27 - Anaphylaxis Procedures)
On giving the injection, you hit what you think may be a bone.	Withdraw the syringe without removing the needle from the patient. Observe the area and if it appears OK, give the injection causing less prolonged trauma to the area.
When giving an injection you suspect you may have hit a nerve – the patient has an uncontrolled movement either in the immediate area or a nerve related area.	Withdraw the needle completely, get the medical staff to examine the patient. Give the injection in another area on the advice of the medical staff.
After administering the injection, the patient says it was the worst injection they have ever had.	Discuss with the patient why they felt that, try to assure them through effective communication, document what was said in the nursing records.

8. TRAINING

7.8. Face to face theory and practical injection technique training must be attended by all qualified clinical staff including student associate practitioners and associate practitioners. A 3-yearly e-learning update must then be completed thereafter. It is the responsibility of the individual to obtain practical training sooner if necessary. [DN. is this correct and applicable Trust-wide?]

Annex 1

RECOMMENDED OPERATIONAL PROCEDURES FOR THE PREPARATION AND ADMINISTRATION OF SUBCUTANEOUS AND INTRAMUSCULAR INJECTIONS (based on Royal Marsden Manual: Chapter 11)

a) Equipment and documentation to be assembled prior to injection

1 Clean tray or receiver in which to place drug and equipment.

2 21 g needle(s) to ease reconstitution and drawing up, 23 g if from a glass ampoule.

3 21, 23 or 25 g needle, size dependent on route of administration

4 Syringe(s) of appropriate size for amount of drug to be given. Trust-approved safety-devices (i.e. Vanishpoint) should be used unit drug is ready supplied in a syringe for administration

5 Swabs saturated with isopropyl alcohol 70% (if required - see section 6).

6 Sterile topical swab, if drug is presented in ampoule form.

7 Drug(s) to be administered.

8 Patient's prescription chart, patient group direction or other written direction to administer, in order to check dose, route, etc., and to record administration.

9 Recording sheet or book as required by law or local policy.

10 Ensure that appropriate equipment is available for the disposal of sharps at the point of use.

b) Preparation of the injection

Action	**Rationale**
1. Collect and check all equipment.	To prevent delays and enable full concentration on the procedure.
2. Check that the packaging of all equipment is intact.	To ensure sterility. If the seal is damaged, discard.
3. Wash hands with soap and water or bactericidal alcohol hand rub.	To prevent contamination of medication and equipment.
4. Prepare needle(s), syringe(s), etc. on a tray or receiver.	To contain all items in a clean area
5. Inspect all equipment.	To check that none is damaged; if so, discard.
6. Consult the patient's prescription sheet, and ascertain the following: a. Drug b. Dose c. Date and time of administration d. Route and method of administration e. Diluent as appropriate f. Validity of prescription g. Signature of prescriber	To ensure that the patient is given the correct drug in the prescribed dose using the appropriate diluent and by the correct route.

Action	Rationale
7. Check all details with another nurse if required by local policy.	To minimize any risk of error.
8. Select the drug in the appropriate volume, dilution or dosage and check the expiry date.	To reduce wastage. Treatment with medication that is outside the expiry date is dangerous. Drugs deteriorate with storage. The expiry date indicates when a particular drug is no longer pharmacologically efficacious.
9. Put on non-sterile gloves. Proceed with the preparation of the drug. See (c), (d) and (e) for further information on preparing and drawing-up drugs from ampoules and multi-dose vials.	Risk of coming into contact with body fluids and protect practitioner during preparation.
10. Take the prepared dose to the patient, whose identity is checked	To prevent error and confirm patient's identity.
11. Evaluate the patient's knowledge of the medication being offered. If this knowledge appears to be faulty or incorrect, offer an explanation of the use, action, dose and potential side-effects of the drug or drugs involved.	A patient has a right to information about treatment.
12. Close room door or curtains if appropriate.	To ensure patient privacy and dignity
12. Administer the drug as prescribed. See (f) and (g) for further information on SC and IM administration	To ensure patient received treatment
13. Record the administration on appropriate sheets.	To maintain accurate records, provide a point of reference in the event of any queries and prevent any duplication of treatment.

c) Preparing/drawing-up drugs from single-dose ampoules (liquids)

Action	Rationale
1. Inspect the solution for cloudiness or particulate matter. If this is present, discard and follow hospital guidelines on what action to take, e.g. return drug to pharmacy.	To prevent the patient from receiving an unstable or contaminated drug.
2. Tap the neck of the ampoule gently.	To ensure that all the solution is in the bottom of the ampoule.
3. Cover the neck of the ampoule with a sterile topical swab and snap it open. If there is any difficulty a file may be required.	To aid asepsis. To prevent aerosol formation or contact with the drug which could lead to a sensitivity reaction. To reduce the risk of injury to practitioner.
4. Inspect the solution for glass fragments; if present, discard.	To minimize the risk of injection of foreign matter into the patient.
5. Withdraw the required amount of solution, tilting the ampoule if necessary.	To avoid drawing in any air.
6. Tap the syringe to dislodge any air bubbles. Expel air and/or excess solution back into the ampoule.	To prevent aerosol formation. To ensure that the correct amount of drug is in the syringe.
7. Discard used needle into appropriate sharps container – do not attempt to re-sheath. Fit new needle using no-touch technique.	To reduce the risk of infection. To avoid tracking medications through superficial tissues. To ensure that the correct size of needle is used for the injection. To reduce the risk of injury.

d) Preparing/drawing-up drugs from single-dose ampoules (powders)

Action	Rationale
1. Tap the neck of the ampoule gently.	To ensure that any powder lodged here falls to the bottom of the ampoule.
2. Cover the neck of the ampoule with a sterile topical swab and snap it open. If there is any difficulty a file may be required.	To aid asepsis. To prevent contact with the drug which could cause a sensitivity reaction. To prevent injury.
3. Add the correct diluent carefully down the wall of the ampoule.	To ensure that the powder is thoroughly wet before agitation and is not released into the atmosphere.
4. Agitate the ampoule according to the manufacturer's instructions	To dissolve the drug.
5. Inspect the contents.	To detect any glass fragments or any other particulate matter. If present, continue agitation or discard as appropriate.
6. When the solution is clear withdraw the prescribed amount, tilting the ampoule if necessary.	To ensure the powder is dissolved and has formed a solution with the diluent. To avoid drawing in air.
7. Tap the syringe to dislodge any air bubbles. Expel air and/or excess solution back into the ampoule.	To prevent aerosol formation. To ensure that the correct amount of drug is in the syringe.
8. Discard used needle into appropriate sharps container – do not attempt to re-sheath. Fit new needle using no-touch technique.	To reduce the risk of infection. To avoid tracking medications though superficial tissues. To ensure that the correct size of needle is used for the injection. To reduce the risk of injury to the nurse.

e) Preparing/drawing-up drugs from multi-dose vials (powders)

Action	Rationale
1. Clean the rubber cap with the chosen antiseptic and let it dry.	To prevent bacterial contamination of the drug.
2. Insert a 21 g needle into the cap to vent the bottle (see Fig. 1a).	To prevent pressure differentials, which can cause separation of needle and syringe.
3. Add the correct diluent carefully down the wall of the vial.	To ensure that the powder is thoroughly wet before it is shaken and is not released into the atmosphere.
4. Remove the needle and the syringe.	
5. Place a sterile topical swab over the venting needle (see Fig. 1b) and shake to dissolve the powder. *Note*: Other presentations of drugs for injection may be encountered, e.g. vials with a transfer needle. The manufacturer's instructions should be followed in these instances.	To prevent contamination of the drug or the atmosphere. To mix the diluent with the powder and dissolve the drug.
6. Inspect the solution for cloudiness or particulate matter. If this is present, discard.	To prevent patient from receiving an unstable or contaminated drug.
7. Clean the rubber cap with an appropriate antiseptic and let it dry.	To prevent bacterial contamination of the drug.

Action	Rationale
8. Withdraw the prescribed amount of solution, and inspect for pieces of rubber which may have 'cored out' of the cap (see Fig. 1c). *Note*: coring can be minimized by inserting the needle into the cap, bevel up, at an angle of 45° to 60°. Before complete insertion of the needle tip, lift the needle to 90° and proceed (see Fig. 2).	To prevent the injection of foreign matter into the patient.
9. Tap syringe to dislodge any air bubbles. Remove air and/or excess solution from syringe by injecting back into the vial (see Fig. 1d).	To reduce risk of contamination of practitioner. To prevent aerosol formation. To ensure that the correct amount of drug is in the syringe.
10. Remove syringe and needle from vial and discard used needle into appropriate sharps container – do not attempt to re-sheath. Fit new needle using no-touch technique.	To reduce the risk of infection. To avoid possible trauma to the patient if the needle has barbed. To avoid tracking medications through superficial tissues. To ensure that the correct size of needle is used for the injection.

Figure 1: Suggested method of vial reconstitution to avoid environmental exposure. (a) When reconstituting vial, insert a second needle to allow air to escape when adding diluent for injection. (b) When shaking the vial to dissolve the powder, push in second needle up to Luer connection and cover with a sterile swab. (c) To remove reconstituted solution, insert syringe needle and then invert vial. Ensuring that tip of second needle is above fluid, withdraw the solution. (d) Remove air from syringe without spraying into the atmosphere by injecting air back into vial.

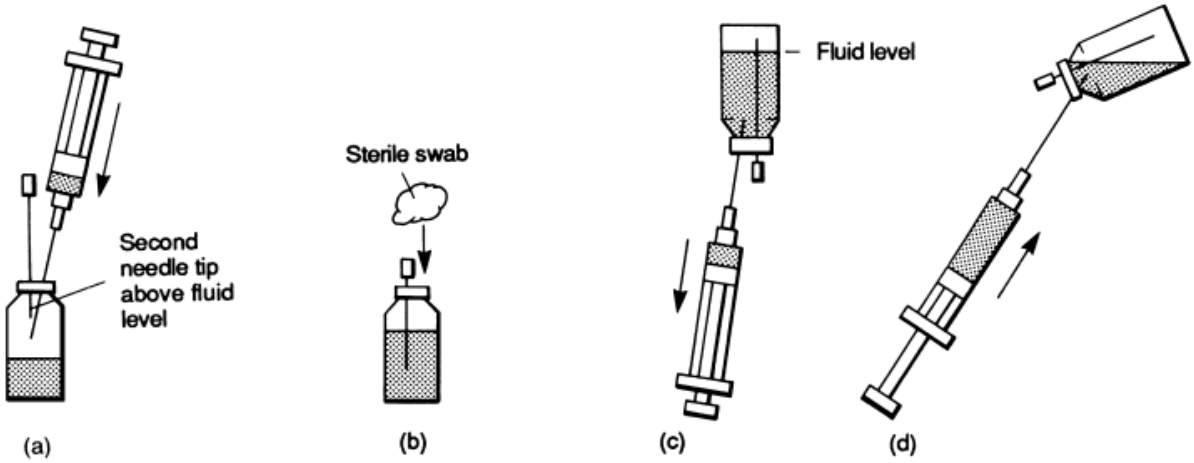
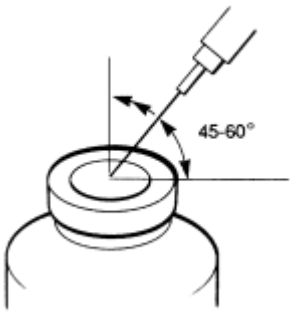


Figure 2: Method to minimize coring.



f) Administration - subcutaneous injections

Action	Rationale
1. Explain and discuss the procedure with the patient.	To ensure that the patient understands the procedure and gives his/her valid consent.
2. Consult the patient's prescription sheet, and ascertain the following: a. Drug b. Dose c. Date and time of administration d. Route and method of administration e. Diluent as appropriate f. Validity of prescription g. Signature of prescriber	To ensure that the patient is given the correct drug in the prescribed dose using the appropriate diluent and by the correct route.
3. Assist the patient into the required position.	To allow access to the chosen site.
4. Remove appropriate garments to expose the chosen site. Assess the injection site for signs of inflammation, oedema, infection and skin lesions	To gain access for injection. To promote effectiveness of administration, reduce risk of infection, avoid skin lesions and avoid possible trauma to the patient.
5. Choose the correct needle size.	To minimize the risk of missing the subcutaneous tissue and any ensuing pain.
6. If appropriate, clean the chosen site with a swab saturated with isopropyl alcohol 70% (not usually necessary for SC and IM injections - see Section 6 for further information).	To reduce the number of pathogens introduced into the skin by the needle at the time of insertion.
7. Gently pinch the skin up into a fold.	To elevate the subcutaneous tissue, and lift the adipose tissue away from the underlying muscle.
8. Insert the needle into the skin at angle of 45° and release the grasped skin (unless administering insulin, when an angle of 90° should be used). Inject the drug slowly.	Injecting medication into compressed tissue irritates nerve fibres and causes the patient discomfort. The introduction of shorter insulin needles makes 90° the more appropriate angle.
9. Withdraw the needle rapidly. Apply pressure to any bleeding point.	To prevent haematoma formation.
10. Record the administration on appropriate sheets.	To maintain accurate records, provide a point of reference in the event of any queries and prevent any duplication of treatment.
11. Dispose of syringe-needle combination by placing directly into a sharps bin, needle down. Do not attempt to re-sheath the needle or separate the needle from the syringe.	To ensure safe disposal and to avoid laceration or other injury to staff.

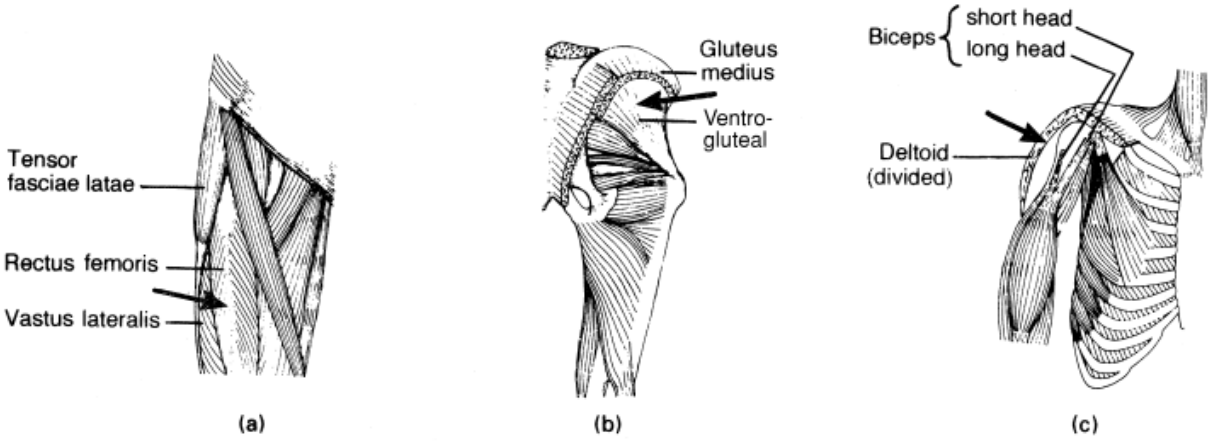
g) Administration - Intramuscular injections

Action	Rationale
1. Explain and discuss the procedure with the patient.	To ensure that the patient understands the procedure and gives his/her valid consent.
2. Consult the patient's prescription sheet, and ascertain the following: a. Drug b. Dose c. Date and time of administration d. Route and method of administration e. Diluent as appropriate f. Validity of prescription g. Signature of prescriber	To ensure that the patient is given the correct drug in the prescribed dose using the appropriate diluent and by the correct route.
3. Assist the patient into the required position.	To allow access to the chosen site and to ensure the designated muscle group is flexed and therefore relaxed.
4. Remove appropriate garments to expose the chosen site. Assess the injection site for signs of inflammation, oedema, infection and skin lesions	To gain access for injection. To promote effectiveness of administration, reduce risk of infection, avoid skin lesions and avoid possible trauma to the patient.
5. If appropriate, clean the chosen site with a swab saturated with isopropyl alcohol 70% (not usually necessary for SC and IM injections - see Section 6 for further information).	To reduce the number of pathogens introduced into the skin by the needle at the time of insertion.
6. Stretch the skin around the chosen site. See Section 5 for details on the Z-track technique.	To facilitate the insertion of the needle and to displace the underlying subcutaneous tissue.
7. Holding the needle at an angle of 90°, quickly plunge it into the skin. Leave a third of the shaft of the needle exposed*. *Note – Risperdal Consta injection is supplied with a special 2” needle that has to be used. It may be necessary to leave more than a third of this needle shaft exposed if the patient is of low weight and has little subcutaneous fat, in order to avoid hitting bone.	To ensure that the needle penetrates the muscle. To facilitate removal of the needle should it break.
8. Pull back the plunger. If no blood is aspirated, depress the plunger at approximately 1 ml every 10 seconds and inject the drug slowly. If blood appears, withdraw the needle completely, replace it and begin again. Explain to the patient what has occurred.	To confirm that the needle is in the correct position. This allows time for the muscle fibres to expand and absorb the solution. To prevent pain and ensure even distribution of the drug.
9. Wait 10 seconds before withdrawing the needle.	To allow the medication to diffuse into the tissue.
10. Withdraw the needle rapidly. Apply pressure to any bleeding point.	To prevent haematoma formation.
11. Record the administration on appropriate sheets.	To maintain accurate records, provide a point of reference in the event of any queries and prevent any duplication of treatment.

Action	Rationale
12. Dispose of syringe-needle combination by placing directly into a sharps bin, needle down. Do not attempt to re-sheath the needle or separate the needle from the syringe.	To ensure safe disposal and to avoid laceration or other injury to staff.

Annex 2

Intramuscular Injection Sites.



(a) Rectus femoris. (b) Gluteus medius and ventrogluteal. (c) Mid-deltoid.

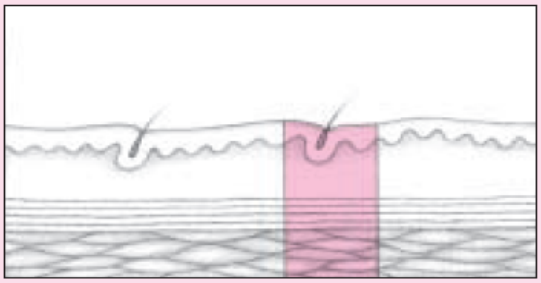
Annex 3

Z-Track Injection Technique

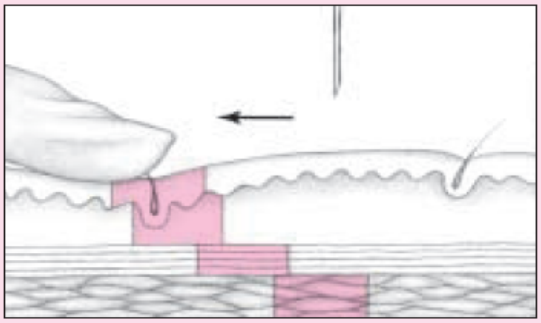
Displacing the skin for Z-track injection

By blocking the needle pathway after an injection, the Z-track technique allows I.M. injection while minimizing the risk of subcutaneous irritation and staining from such drugs as iron dextran. The illustrations below show how to perform a Z-track injection.

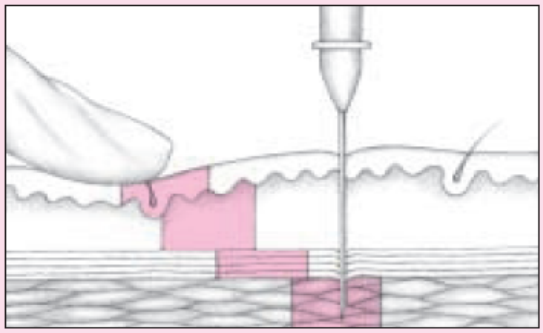
Before the procedure begins, the skin, subcutaneous fat, and muscle lie in their normal positions.



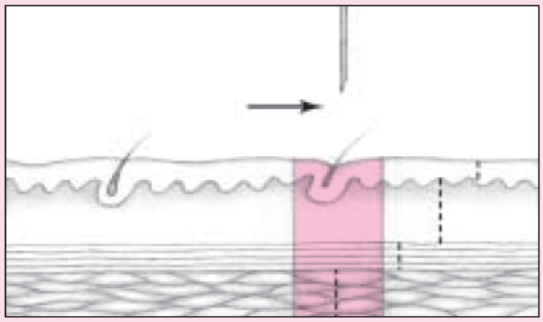
To begin, place your finger on the skin surface, and pull the skin and subcutaneous layers out of alignment with the underlying muscle. You should move the skin about ½" (1 cm).



Insert the needle at a 90-degree angle at the site where you initially placed your finger. Inject the drug and withdraw the needle.

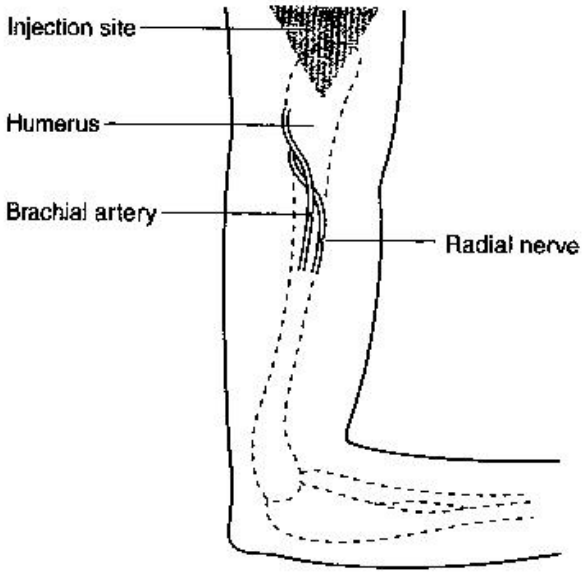


Finally, remove your finger from the skin surface, allowing the layers to return to their normal positions. The needle track (shown by the dotted line) is now broken at the junction of each tissue layer, trapping the drug in the muscle.



Annex 4

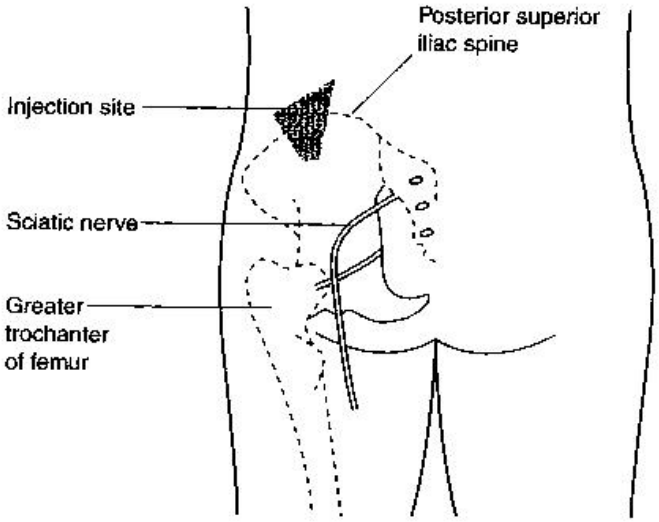
Locating Anatomical Sites for Intramuscular Injections



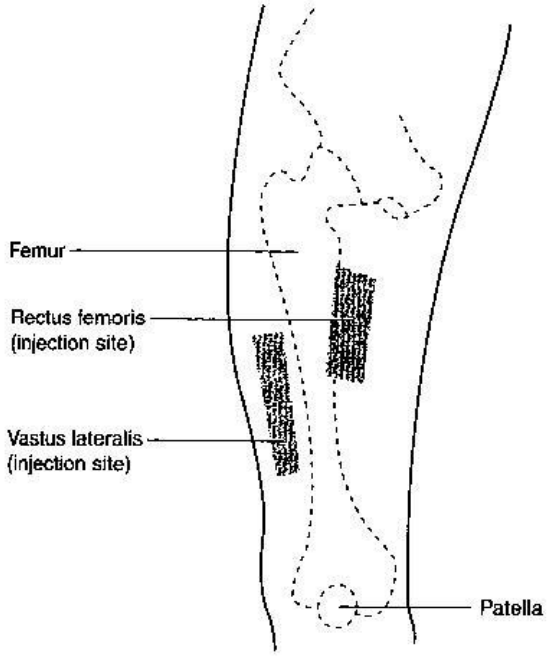
(a) The deltoid site

Deltoid:
Find the lower edge of the acromial process and the point on the lateral arm in line with the axilla. Insert the needle 1" to 2" (2.5 to 5cm) below the acromial process, usually two to three finger-breaths, at 90 degree angle or angled slightly towards the process. Typical injection: 0.5ml (range:0.5 to 2.0ml).

Dorsogluteal:
Inject above and outside a line drawn from the posterior superior iliac spine to the greater trochanter of the femur. Or, divide the buttock into quadrants and inject in the upper outer quadrant, above 2" to 3" (5 to 7.6cm) below the iliac crest. Insert the needle at a 90 degree angle. Typical injection: 1 to 4 ml (range: 1 to 5 ml).



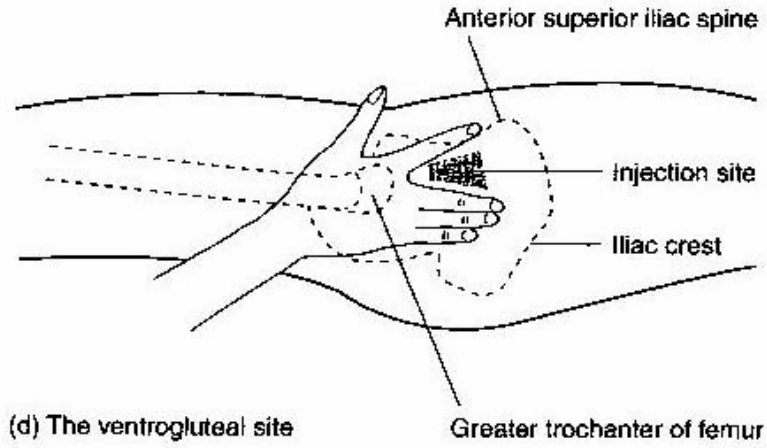
(b) The dorsogluteal site



(c) The rectus femoris and vastus lateralis sites

Vastus lateralis:
Use the lateral muscle of the quadriceps group, from a hand-breath below the greater trochanter to hand-breath above the knee. Insert the needle into the middle third of the muscle parallel to the surface on which the patient is lying. You may have to bunch the muscle before insertion. Typical Injection: 1 to 4 ml (range: 1 to 5 ml; 1 to 3 ml for infants).

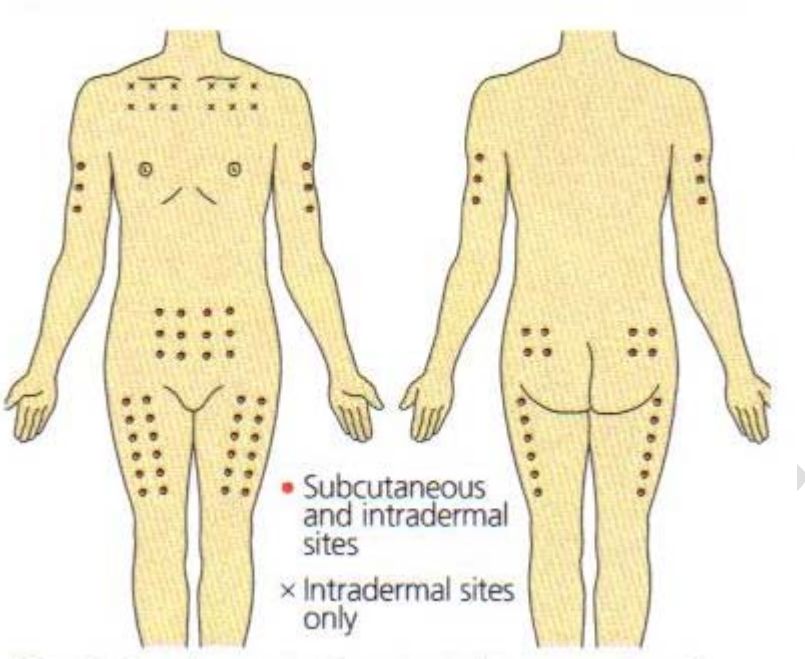
Ventrogluteal:
Locate the greater trochanter of the femur with the heel of your hand so your index finger points towards the anterior superior iliac spine (Use the palm of your right hand on the left greater trochanter or your left hand on the right greater trochanter). Then, spread your index and middle fingers from the anterior superior iliac spine to as far along the iliac crest as you can reach to form a V. The injection site is in the middle of the V Insert the needle between the two fingers at 90 degree angle to the muscle. (Remove your fingers before inserting the needle) Typical injection: 1 to 4 ml (range 1 to 5 ml).



(d) The ventrogluteal site

Annex 5

Anatomical sites for Subcutaneous injections.



Subcutaneous:

Traditionally, Subcutaneous injections are given at 45 degree angle into raised skin fold. However, when giving Insulin due the introduction of shorter needles, (5, 6 or 8mm), the recommendation for Insulin injection is now an angle of 90 degrees. The skin should be pinched up to lift the adipose tissue away from the underlying muscle especially in thin people. This is to prevent the injection being inadvertently absorbed by the muscle, as Insulin is absorbed more rapidly and can lead to glucose instability and potential hypoglycaemia (low blood glucose levels). Insulin Injections should be systematically rotated with anatomical sites.

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

MENTAL CAPACITY AND THE COVERT ADMINISTRATION OF MEDICINES

1. INTRODUCTION

1.1. Covert administration of medication is the administration of any medical treatment in disguised form. This usually involves disguising medication by administering it in food or drink. As a result, the person is unknowingly taking medication. This practice is likely to arise because of the refusal to take medication where it is offered, but where treatment is necessary for the person's physical or mental health or for the safety of others.

1.2. These guidelines should be read in conjunction with current advice from relevant professional bodies such as the Royal College of Psychiatrists and the Nursing & Midwifery Council.

1.3. The Mental Capacity Act 2005 came into force on the 1st October 2007. Staff should refer to the principles of the MCA 2005 when interpreting or applying the principles of this document. In addition, staff should refer to the Trust MCP1 *Mental Capacity Act 2005 Policy* and MCPG1 *Mental Capacity Act 2005 Procedure*.

2. CAPACITY AND CONSENT

2.1. Consent to treatment involves receiving adequate information about the proposed treatment, having the capacity to assess and understand the nature of the treatment (its main benefits, risks and alternatives), and being able to make a free choice without undue pressure or coercion.

2.2. Generally a competent adult has the right to refuse treatment, even if that refusal may adversely affect them. Every adult will be deemed to have capacity to consent or refuse treatment, including medication. An unwise decision must be respected if the patient has capacity.

2.3. A Personal Welfare Lasting Power of Attorney enables appointed attorneys to make decisions about a person's life when they have lost the capacity to make those decisions themself. This may include the power to give or refuse consent to medical treatment including medication administration. A Deputy appointed by the Court of Protection can also make decisions for the incapacitated person.

2.4. No-one else can give consent for an adult, someone over the age of 18 (or 16 in some circumstances).

2.5. For patients detained under the Mental Health Act, see the relevant legislation and code of practice, or seek advice from the Trust's Mental Health Act advisor.

2.6. A Mental Health Act assessment should be considered if appropriate for a person with a mental disorder who requires treatment for that illness but who is refusing treatment.

2.7. Lack of capacity may be enduring, temporary or fluctuating. Lack of capacity means that the person 'has an impairment or disturbance that affects the way their mind or brain works', and this impairment or disturbance means that 'they are unable to make a specific decision at the time it needs to be made'.

2.8. Assessment of capacity should be fully documented in the person's healthcare record and repeated as necessary.

2.9. Under the Mental Capacity Act, which was implemented in 2007, capacity is defined as being able to :

- understand the relevant information
- retain the information
- use or weigh the information as part of a decision making process
- communicate the decision

2.10. Staff must apply the principles contained in Section One of the Act. Anyone, doctor or nurse, can apply the test. It may be necessary to involve a consultant psychiatrist for more complex cases. If someone is found to lack capacity, any decision or action taken must demonstrate that the actions or decisions taken have been in the patient's best interests. In determining what is in a person's best interests the Act sets out a statutory checklist of factors which must always be taken into account when a decision is being made or an action done for a person lacking capacity.

2.11. Although this policy primarily relates to adults the principles are the same for children. Children who have sufficient understanding and intelligence to fully understand a suggested treatment also have the capacity to consent to that treatment (Fraser competence). Children aged 16 or 17 are presumed to have capacity unless shown otherwise. Some children under 16 may not have capacity to consent to or refuse a particular treatment, in which case the right to consent or refuse remains with those with parental responsibility.

3. COVERT ADMINISTRATION OF MEDICINES

3.1. Disguising medication in the absence of informed consent may be regarded as deception. However a clear distinction should always be made between those who have the capacity to refuse medication and whose refusal should be respected, and those who lack this capacity.

3.2. Among those who lack capacity a further distinction should be made between those for whom no disguising is necessary because they are unaware that they are receiving medication and others who would be aware if they were not deceived into thinking otherwise.

3.3. The multidisciplinary team must first make every effort to obtain the person's consent, and to administer medicines openly; such efforts must continue.

3.4. The patient's known wishes, values, religious belief and views must be taken into consideration. The decision to administer covert medication should be based on necessity and capacity.

3.5. The covert administration of medicines may only be considered in the case of patients who actively refuse medication if:

- the person has been shown to lack capacity at the time

  and

- if the covert administration of medication is considered necessary to save the person's life, to prevent deterioration or ensure improvement in the person's mental or physical health, or for the safety of others.

3.6. Medication must not be disguised for the convenience of the healthcare team.

3.7. The ultimate decision to administer medicines covertly must be one that has been informed and agreed by the multidisciplinary team, including the consultant caring for the person, and not by a single practitioner.

3.8. The team should consider the wishes of family and/or carers, and any views previously expressed by the person in the form of an advance statement, advance directive or living will. Where those wishes are known, all staff must respect them provided they are still clearly applicable to the present circumstances and there is no reason to believe the person has changed his/her mind. Family involvement should be positively encouraged.

3.9. All discussions and decisions must be fully documented in the person's healthcare record, and reviewed regularly, initially at least weekly or at a time interval agreed by the multidisciplinary team. It is important to recognise that mental illness might often cause a temporary or fluctuating incapacity and therefore regular assessment of capacity is required.

3.10. All practitioners involved should be fully aware of the purpose and implications of such treatment, and should have the opportunity to contribute to the multidisciplinary discussion. There must be clear expectation that the person will benefit, without significant harm.

3.11. The list of medicines agreed as being essential and therefore to be administered covertly should be documented in the healthcare record (see Annex 1 for checklist). If there is a subsequent need for additional treatment this should be considered and documented separately.

3.12. Medication must be administered by the least restrictive means.

3.13. A patient admitted to hospital should have any previous decisions regarding covert administration of medicines reviewed as their capacity and circumstances may have changed.

3.14. On discharge from hospital the decision to administer medicines covertly should be communicated to the home/carer but it is then their decision to follow local policies for continued covert administration of medicine, as this may no longer be relevant even if the patient still lacks capacity.

3.15. **Disguising medication in food or drink**

3.15.1. The method of disguising the medication must be discussed and agreed with a pharmacist and then documented in the care plan, and on the prescription chart if the person is an inpatient.

3.15.2. Wherever possible, a suitable licensed liquid or soluble or dispersible or "melt" formulation should be used, or treatment changed to a different drug for the same indication that is suitably licensed.

3.15.3. Crushing tablets or opening capsules should be regarded as a last resort, as this renders the product unlicensed and is likely to alter the bioavailability of the medication. This necessitates prior discussion with a pharmacist.

3.15.4. Any method of administration which is outside the product license of that medication is unlicensed, and can only be authorised by a doctor. Healthcare professionals who recommend or who administer a medication by unlicensed methods may be liable if harm ensues.

3.15.5. The prescriber must document any authorisation to administer a medication by an unlicensed method, having first considered the patient's safety, the requirement for that particular medication, and alternative treatments or means of administration.

3.15.6. The checklists included in Annex 1 and Annex 2 should be completed to document the decision to administer covert medication and its review at regular intervals.

4. FURTHER INFORMATION

Nursing & Midwifery Council. *Covert administration of medicines: Disguising medicine in food and drink*. 2007.

Royal Pharmaceutical Society of Great Britain. *Law and Ethics Bulletin on Covert Administration of Medicines*. Pharmaceutical Journal 2003; 270: 32.

Royal College of Psychiatrists. *Statement on Covert Administration of Medicines. The Psychiatrist*. 2004; 28(10): 385.

Nathan, A. *Consent and the New Mental Health Law*. Pharmaceutical Journal 2008; 280: 757

British Medical Association and Law Society. *Assessment of Mental Capacity, Guidance for Doctors and Lawyers*. 1995.

Treloar A al. *Concealing Medication in Patients' Food*. Lancet 2001; 357: 62-4

Griffith R. Tablet Crushing and the Law". Pharmaceutical Journal 2003; 271: 90-1

Mental Welfare Commission for Scotland. *Covert Medication. Legal and Practical Guidance.* 2006

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

COVERT ADMINISTRATION OF MEDICINES CHECKLIST

Name of patient:	NHS No:
Ward/unit:	Date of Birth:

What medicines are being considered for covert administration?	
Why are these medicines necessary? Where appropriate, refer to clinical guidelines	
What alternatives did the team consider? (e.g. other ways to manage the person or other ways to administer treatment) Why were these alternatives rejected?	
Treatment may only be considered for a person who lacks capacity. Outline the assessment of capacity.	Assessed by:
Treatment may only be given if it is likely to benefit the person. What benefit will the person receive?	
Is this the least restrictive way to treat the person? Give reasons.	

Has the person expressed views in the past that are relevant to the present treatment? If so, what were those views?	
Who was involved in the decision? N.B. *A pharmacist must give advice on administration if this involves crushing tablets or combining with food and drink.* N.B. If there is any person with power to consent (i.e. Personal Welfare LPA), then the treatment may only be administered covertly with that person's consent, unless this is impracticable.	Staff involved: Relatives or other carers involved:
Do any of those involved disagree with the proposed use of covert medication? If so they must be informed of their right to challenge the treatment.	Yes/No Date informed:
When will the need for covert treatment be reviewed?	Date of planned review:

Signed:

Name:

Designation:

Date:

Annex 2

Providing Partnership Services in Bedfordshire, Essex and Luton

REVIEW OF COVERT ADMINISTRATION

Name of patient:	NHS No:
Ward/unit:	Date of Birth:

Is treatment still necessary? If so, explain.	
Is covert administration still necessary? If so, explain why.	
Who was consulted as part of the review?	
When will the need for covert treatment be reviewed?	Date of planned review:

Signed:

Name:

Designation:

Date:

SOUTH ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

SELF ADMINISTRATION PROGRAMME

1. INTRODUCTION

1.1. Patients wishing to take responsibility for their own medicines shall be entered on the Trust's self-administration programme. Before any patient is started on the self administration of medicines programme there must be agreement from the multidisciplinary team (MDT) that the patient is suitable for the programme and an entry stating this made in the patient's healthcare records.

1.2. The risk assessment form (Annex 1) must be completed and the stage of the programme that the patient should start on agreed. A record should be made in the healthcare records.

1.3. The patient must complete and sign the consent form (Annex 2). The patient may withdraw consent at any time and the programme stop. A copy of this form should be stored with the prescription and administration card and a copy in the healthcare record.

1.4. The programme may be started at any stage depending on the patient's ability. This must be recorded on the front of the prescription chart and dated.

1.5. Before a patient moves from one stage to the next there should be an assessment of their progress by the MDT and the risk assessment (Annex 1) repeated. If a patient is removed from the self administration programme and subsequently recommenced, a new risk assessment must be completed. Pharmacy must be informed of any changes in the self administration status of each patient.

1.6. Injections (apart from insulin if likely to be used safely), medicines required for one dose, medicines prescribed in variable doses, controlled drugs and some medicines prescribed "as required" (PRN) will continue to be administered by nursing staff.

1.7. The following patients groups should generally be excluded from the self-administration programme unless; after a full assessment as described above it is considered safe and it is the patient's best interests to begin the self-administration programme.

- Patients who do not self-administer when they are not in hospital, e.g. carers administer their medication
- Patients who are confused or disorientated in time and place
- Patients who have a unstable or chaotic mental state
- Patients who continue to abuse alcohol or drugs

- Patients who have a suspected risk of self-harm
- Patients on unstable medication regimes
- Risk factors/circumstances highlighted in the patients' notes which make in unsuitable to enter them into the self-administration programme.

1.8. Medicines must be prescribed by the prescriber on a current prescription chart and administration chart.

1.9. All medicines will be dispensed for the individual patient and labelled with full instructions. Additional instructions should be made available to the patient if necessary in the form best suited to their needs, e.g. printed leaflets, large print, pictures describing administration times etc.

1.10. Stock medicines should never be used for patients who are self administering medicines, except if the prescribed medicines have been changed and a supply is awaited from pharmacy. In this case the nurse must administer the medicines.

1.11. If a patient on Stage 3 goes on leave they may take their supply of medicines with them preventing the need to write up leave prescriptions. If the quantity of the supply is considered too much then a leave prescription must be obtained in the normal way.

1.12. Nurses involved in the supervision of the programme must be registered nurses.

1.13. A lockable medicines locker, or other suitable storage approved by the pharmacist, must be made available to each patient for storing their own medicines for stage 3. The nurse in charge should hold a duplicate key, but this should not be used routinely. The patient's key may be removed if the nurse in charge considers it necessary in the interests of safety.

1.14. Self Administration" should be written in the appropriate section of the prescription and administration card.

1.15. When patients are on stages 1 or 2 of the programme each dose administered must be signed for on the treatment card by the nurse administering/supervising. Monitoring Form 1 should be completed (Annex 3).

1.16. When patients are on stage 3 the nurse need not sign for administration as it may not have been observed, but enter the amount supplied to the patient across the administration boxes on the treatment card and complete Monitoring Form 2 (Annex 4). A suitably trained member of the pharmacy team and/or nursing staff will check at an interval agreed by the MDT that a patient on stage 3 has administered their medicines correctly and complete Monitoring Form 2 (Annex 4).

1.17. Patients on stage 3 may wish to keep a record of their own medicine administration (See Annex 5).

2. Stages of the Programme

2.1. Stage 1

2.1.1. Twenty eight days supply of medication for each patient included in the programme will be dispensed by the pharmacy and kept together in a bag. This should be stored in the medicines trolley.

2.1.2. At the appropriate times the nurse will give the bag containing the entire patient's medication to that patient and supervise the selection and administration of the correct dose(s). Monitoring Form 1 (see Annex 3) should be completed. The nurse should sign the medicines prescription and administration chart.

2.2. Stage 2

2.2.1. As for stage 1 except that the patient will be expected to request their medicines at the correct time. If after 30 minutes (or other time agreed with the MDT) the patient has failed to request their medicines, the nurse should remind them. Monitoring Form 1 (Annex 3) should continue to be used. The nurse should sign the medicines prescription and administration chart.

2.2.2. Patients receiving depot medication will be given an appointment card for their next injection. They will be expected to request their injection from nursing staff at the appropriate time.

2.3. Stage 3

2.3.1. The patient will store their own medicines in their locked medicines cabinet and will be expected to take their medicines correctly with minimum intervention from nursing staff.

2.3.2. The pharmacy will dispense an appropriate quantity of medicines for the individual as determined by the multidisciplinary team. This will usually be seven days, but more able patients may join the scheme storing a larger supply. These medicines may be issued to the patient when they go on leave.

2.3.3. Nursing staff should monitor the patient as agreed with the MDT. At agreed time intervals dose counts should be undertaken to ensure that there is a high level of compliance. Monitoring form 2 (Annex 4) should be completed.

2.3.4. Patients receiving depot medication will be given an appointment card for their next injection. They will be expected to request their injection from nursing staff at the appropriate time.

Annex 1

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

SELF ADMINISTRATION OF MEDICINES
RISK ASSESSMENT FORM

Name of patient:	NHS No:
Ward/unit:	Date of Birth:

RISK	Level of Risk	Comments
Patient's mental state is unstable and/or confused (unaware of time and space)		If yes reassess at future date when stable
Patient has a history/risk of drug/ alcohol abuse		
Patient has a history/risk of self-harm		
Patient has a history/risk of non-compliance		
Patient has a history/risk of concealing medicines		If risk identified only consider stage 1 or 2 initially
Patient is likely to give/sell medicines to others		If risk identified only consider stage 1 or 2 initially
Patient is unlikely to keep medicines locked away at all times (stage 3 only)		If risk identified only consider stage 1 or 2 initially
Patient does not understand how to take their medicines and cannot read labels on the medicine containers.		Larger labels available from pharmacy. If unable to understand instructions start at stage 1
Other risk factors identified (state in comments)		

Risk Levels

High	Unlikely to succeed with self-administration programme
Medium	Likely to be successful with high levels of support, maximum stage 2 until risk reduced
Low	Likely to be successful with support
None	Likely to be successful with programme

	Name	Signature	Date
Consultant:			
Nurse/ Keyworker:			
Pharmacist:			
Stage to enter:	MDT approved: Yes / No		Consent completed: Yes / No

A new risk assessment form needs to be completed before a patient progresses to the next stage of the programme.

Annex 2

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

SELF ADMINISTRATION OF MEDICINES
PATIENT CONSENT FORM

Name of patient:	NHS No:
Ward/unit:	Date of Birth:

Dear Patient

The multidisciplinary team has decided that you have reached a stage in your treatment where it would be beneficial for you to administer your own medicines. If you consent to this, please sign the box below.

Thank you

Consent

The self-administration scheme has been explained to me and I am willing to take part. I understand that I can withdraw my consent at any time.

Patient signature:
Date:
Witnessed by:
Position:

Withdrawal of consent

I do not wish to remain involved in the self-administration system, and therefore withdraw my consent.

Patient signature:
Date:
Witnessed by:

Annex 3

Providing Partnership Services in Bedfordshire, Essex and Luton

SELF ADMINISTRATION OF MEDICINES
MONITORING FORM 1 (Stages 1 and 2)

Name of Patient:	NHS No:	Date of Birth:	Ward/unit:
Agreed frequency of monitoring:			

WEEK COMMENCING:																												
	MONDAY				TUESDAY				WEDNESDAY				THURSDAY				FRIDAY				SATURDAY				SUNDAY			
	B	L	T	N	B	L	T	N	B	L	T	N	B	L	T	N	B	L	T	N	B	L	T	N	B	L	T	N
Requests medication at correct time																												
Reads and instructions on containers																												
Selects correct doses																												
Takes medication as instructed																												
Returns medicines to container/bag																												
Initials																												
Comments:																												

Key: I – Independently performs task P = needed Prompting

Stage 1 patients should be supplied with medication at the appropriate time. Nursing staff are reminded the drug chart needs to be completed for stages 1 & 2
Stage 2 patients should request medication at correct time. If the agreed window elapses the patient should be reminded and this should be documented.

Annex 4

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

SELF ADMINISTRATION OF MEDICINES MONITORING FORM 2 (Stage 3)

Name of Patient:	NHS No:	Date of Birth:	Ward/unit:
Agreed Frequency of Monitoring:			

Drug form and strength	Date & initials			Date & initials			Date & initials		
	Actual	Theoretical	Action	Actual	Theoretical	Action	Actual	Theoretical	Action

Action Key

0 = No action required, medicine reconcile
1 = Dose missed on doctor's instruction
2 = dose missed by patient unintentionally
3 = dose missed by patient intentionally

The reason (if intentional) and further action taken must be fully documented in the healthcare record

Annex 5

Providing Partnership Services in Bedfordshire, Essex and Luton

SELF ADMINISTRATION OF MEDICINES
PATIENT RECORD CHART (Stage 3)

Name:	Ward/ unit:	Date chart Commenced:

Put your initials in the relevant box each time you take your medicines

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
Breakfast time							
Lunch time							
Tea time							
Night time							

If you are not able to take ALL of your medicines as prescribed please speak to a member of the team and state the name and reason for not taking a particular medicine below.

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

COMPLIANCE AID ASSESSMENT FORM

Name of patient:	NHS No:
Ward/unit:	Date of Birth:

Question	Comment
Does the patient normally use a monitored dosage system (MDS) in the community?	If no, what has changed necessitating the need for a MDS now?
Have there been any changes to regular medication?	If no, and the patient already has arrangements for MDS in community, there may be one already prepared. Contact regular community pharmacy
Is the medication regime stable?	Regimes which are likely to change now or in the near future are not suitable for MDS and a medication reminder sheet is more appropriate. Re-assess when medication regime stable if MDS still required, otherwise contact pharmacy for medication reminder sheet/education session
Is the patient being cared for by someone who is willing and able to administer medication?	If yes, has this person agreed/disagreed to undertake this task and are they competent to do so correctly.
Does the patient require a MDS because they have difficulty opening boxes/bottles or splitting tablets?	If yes, tablet cutters, larger bottles, screw caps and/or winged top lids are available from pharmacy and a MDS may not be required
Is a MDS required because the patient has difficulty following printed instructions?	If print too small, pharmacy can print larger labels If difficulty understanding instructions has an education session been attempted with support of a medication reminder sheet/special labelling instructions. Contact pharmacy for further support if necessary
Does the patient require a MDS because he/she is confused?	Has the medication regime been simplified to help concordance (doctor/pharmacist to complete) Has the patient been provided with a medication reminder sheet (available from pharmacy) to support the patient taking the right medicines at the right time?

If after reading through these questions and statements you still feel a patient requires a MDS, please give reasons below:

Date MDS required by: **Duration required:**

Form completed by (PRINT): **Date/time:** **Ext:**

Pharmacy

Date & time request received:

1. Does this patient require a MDS from SEPT pharmacy? If no, what other compliance aid(s) have been provided to support compliance?

2. Are any of the medicines prescribed not suitable for removal from original container for the duration of the MDS supply? If so, what course of action has been taken to maintain efficacy of tablet whilst supporting patient concordance

3. Please detail a community pharmacy (including telephone/contact name) which has been identified (ideally patient's regular pharmacy) to continue providing compliance aid support?

Form Completed by: **Date:**

MDS completed by: **Date:**