London Ambulance Service NHS
NHS Trust

Policy and Procedure for the Use of Medicines by LAS Staff

DOCUMENT PROFILE and CONTROL.

Purpose of the document: To ensure that all LAS staff are aware of their responsibilities regarding the storage and security of drugs.

Sponsor Department: Medical Directorate

Author/Reviewer: Medicines Safety Officer. To be reviewed by June 2018

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15/03/18	5.3	Trust Pharmacist	Reviewed – no changes
22/11/16	5.2	Chair – Medicines Management Committee	Amendment to Appendix 6 detailing actions to be taken by operational staff on discovering a CD discrepancy, as agreed by Director of Operations and Medical Director
10/05/16	5.1	IG Manager	Document Profile & Control update and formatting.
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Links to Related documents or references providing additional information		
		Version
Legislation	• Human Medicines Regulations 2012 • Health Act 2012 • Misuse of Drugs Act 1971 • The Controlled Drugs (Supervision of Management and Use) Regulations 2013 • The Misuse of Drugs Regulations 1985 • The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2012 (SI 2012 No. 973) • The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798) • The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 • The Misuse of Drugs Regulations 2001 (SI 2001 No. 3998)	

	• The Misuse of Drugs Regulations 2001: Group Authority for National Health Service (NHS) Ambulance Paramedics and Employing NHS Ambulance Trusts, July 2008 • Human Medicines Regulations 2012	
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1. Introduction

1.1 The London Ambulance Service NHS Trust ("the Trust") is committed to the safe and secure management of medicines. The principles which govern the management of medicines must be applied to all the activities in which medicines are involved. The key principles are:

- compliance with current legislation;
- adherence to guidance issued by the Department of Health and other national guidance;
- management of the risks to patients and staff arising from the use of medicines.

1.2 The policy should be read in conjunction with the legislation and regulations outlined below, and their subsequent amendments:

- Human Medicines Regulations 2012
- Health Act 2012
- Misuse of Drugs Act 1971
- The Controlled Drugs (Supervision of Management and Use) Regulations 2013
- The Misuse of Drugs Regulations 1985
- The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2012 (SI 2012 No. 973)
- The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798)
- The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007
- The Misuse of Drugs Regulations 2001 (SI 2001 No. 3998)
- The Misuse of Drugs Regulations 2001: Group Authority for National Health Service (NHS) Ambulance Paramedics and Employing NHS Ambulance Trusts, July 2008

1.3 Staff registered with any of the UK Healthcare Regulatory Bodies are reminded that they also need to comply with any guidance given by their respective Regulatory Body, including:

- Standards of Conduct, performance and Ethics (2016)
  Health and Care Professions Council
- Standards of Proficiency – Paramedics (2014)
- Good Medical Practice (2013)
  General Medical Council
- The Code of Conduct (2015)
  Nursing and Midwifery Council
- Guidance on Conduct and Ethics for Students (2012)
  Health and Care Professions Council

NHS Codes of Practice / other guidance

- Confidentiality, NHS Code of Practice, Department of Health, November 2003
- Records Management, NHS Code of Practice (Part 1), Department of Health, May 2006
- Records Management, NHS Code of Practice (Part 2), Department of Health, January 2009
- Security standards and guidance for the management and control of controlled drugs in the ambulance sector 2013
- Guidance on the Security and Storage of Medical Gas Cylinders NHS Protect

1.4 The term “medicine” is used in the title of the policy and procedure as an overarching term in the Scope and Objectives sections. Thereafter the terms “drug”, “fluid” and “medicine” will be used as appropriate.

Ambulance staff are permitted to carry and administer a range of medicines as dictated by their scope of practice and that this is facilitated via a range of laws and regulations. It is ultimately the responsibility of the individual clinician administering a medicine to ensure that it is given appropriately. Every clinician is issued with the current pocket book version of the UK Ambulance Service Clinical Practice Guidelines (JRCALC Guidelines). All front line clinical staff are required to carry it at all times whilst on duty. This pocket book details the presentation, indications, contra-indications, actions, cautions, side effects, dosage and route of administration for each drug.
The Trust may issue additional guidance including Patient Group Directions (PGDs), and staff should ensure that they are able to refer to this as required.

Any drug that is administered to a patient must be documented in accordance with the Patient Report Form User Guide and OP014 (Managing the Conveyance of Patients).

1.5 This policy and procedure **does not** cover the use of any medicine whether it is a controlled drug or otherwise used by Voluntary Aid Society staff, i.e., St. John Ambulance, British Red Cross, BASICS or private organisations subcontracted by the LAS.

This policy and procedure **does** cover staff employed by other UK NHS Ambulance Services working on behalf of the LAS under pre-planned or mutual aid arrangements.

- A registered paramedic is defined as a person whose name appears on the Paramedic Register maintained by the Health and Care Professions Council under the Health Professions Order 2001.

- A registered nurse or midwife is defined as a person whose name appears on the Register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001.

- A registered doctor is defined as a person whose name appears on the List of Registered Medical Practitioners maintained by the General Medical Council under the Medical Act 1983

1.6 LAS Staff are forbidden from using any LAS equipment or drugs whilst working for a private medical / ambulance service, any of the voluntary aid societies, charities or voluntary organisations.

1.7 Staff must not take medicines from stock for personal use.

2. Scope

2.1 This policy and procedure covers **all** medicines issued by the London Ambulance Service NHS Trust (LAS) for use by **all** clinical staff including Patient Transport Service staff and Non Emergency Transport staff. The policy and procedure is split into the following parts:

- Part A deals with Controlled Drugs.
- Part B with all other medicines.
- Part C gives guidance on the use of medicines administered under a Patient Group Direction (PGD).
- Part D gives guidance on the administration of a patient's own medication, including Patient Specific Directions.
- Part E deals with guidance related to medical gases.

2.2 This policy provides information and guidance on how medicines are to be requisitioned, issued and disposed of. It also covers auditing of these procedures. The policy **does not** seek to cover the detailed administration of specific drugs that can be administered to a patient. That information is contained in the current UK Ambulance Service Clinical Practice Guidelines (JRCALC Guidelines), and also in any PGD Issued by the London Ambulance Service.

3. Objectives

3.1 To ensure that all LAS Managers and staff are aware of their responsibilities as detailed in policies and procedures relating to procurement, storage, security and handling for all medicines and medical gases ordered, stored, administered and disposed of by LAS staff, and;

3.2 To ensure that all ambulance staff are aware of their responsibilities regarding the storage and security of medicines within their possession or held on a vehicle or other designated location during their shift period.

3.3 Give guidance to staff on their responsibilities in relation to all aspects of controlled drugs.

3.4 Give specific guidance on the actions to take if any controlled drug is lost / stolen or misplaced.

3.5 Detail the method by which unused controlled drugs are to be disposed of.

3.6 Detail the procedure to be applied for destroying all out of date controlled drugs.

3.7 To ensure that the Logistics Department makes adequate provision for exchange of sealed drug packs and sealed Paediatric Advanced Life Support packs on every LAS ambulance station and maintains the provision of station based drugs.

4. Responsibilities

4.1 The responsibilities of individual LAS staff regardless of rank or clinical grade in relation to drugs are as follows:

- Receiving, checking, recording and storage of stock as appropriate;
- The safe and legal possession of any drug legitimately in their possession as part of their duties;
- Returning unused units to stock following shift completion and completing all paperwork accordingly;
- Recording accurately in the patient's clinical record the amount of drug administered, route and time of administration, relevant drug pack codes and details of any controlled drug wasted.;
- Reporting adverse incidents involving medicines, as soon as is possible to LAS management, and via the LA52 Incident reporting system.

4.2 **All staff** who are involved in the ordering, storage, carriage, use and administration of drugs held by the LAS are under an obligation to report any discrepancy or loss, no matter how minor, as soon as possible to an appropriate manager. Further specific advice regarding the management of an incidence of the loss of a controlled drug is given in Part A.

If the discrepancy involves a controlled drug the GSM must also inform the Drug Licensing and Compliance Unit of the Home Office using the

"Theft / Loss" form reproduced at Appendix 2, via the following e-mail link:- licensing_enquiry.aadu@homeoffice.gsi.gov.uk . The Accountable Officer and the LAS Medicines Management Group must also be informed medicinesmanagement@lond-amb.nhs.uk

The Medical Director has the overall responsibility for the implementation, review, and thus revision where required, of this policy and procedure. Such review and revision(s) will be carried out on behalf of the Medical Director by the Medicines Management Group (see below).

The Medical Director will report any concerns arising from this policy and procedure direct to the Trust Board for their consideration and action.

The Medicines Management Group will interpret law, regulations, introduce new drugs, and develop policy to guide the management of all medicines within the Trust.
The group does not deal with supply of drugs or operationalisation of policy.

The Medicines Safety Officer will act under the direction of the Medical Director and the Chair of the Medicines Management Group. The MSO will be a member of the National Medication Safety Network, support local medication error reporting and learning and act as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).

Assistant Directors of Operations are responsible implementing the operational aspects of this policy within their sector. They will also be responsible for ensuring that regular and unannounced audits of all aspects of the storage and recording of drug use are performed and areas for improvement are addressed.

Group Station Managers are responsible for ensuring:

- Drugs lockers and medical gas storage lockers remain secure and serviceable;

- Regular review of drug stocks held on station

- Requisition and movement of drugs (including controlled drugs) between stations is managed in accordance with policy and procedure.

- Adverse incidents and near misses involving medicines are reported appropriately

- Incident Response Officers and Station Administration Staff who are not registered paramedics understand their role in assisting the GSM to ensure this policy is adhered to by all members of staff.

The LAS Corporate Logistics Manager In consultation with the Medical Director, Medicines Management Group and the supplying pharmacy will be responsible for maintaining an on-going review of the supply arrangements to ensure that they meet LAS needs and comply with current legislation.

5. Incident Reporting and Near Misses

5.1 Clinicians of all grades are encouraged to report adverse incidents, errors and 'near misses' promptly so the risk of recurrence of the same or similar incidents are minimised.

5.2 Any adverse reaction to a drug, or any untoward event/ near miss that occurs as a result of drug administration is to be reported as soon as possible using the Trust incident reporting system. Serious incidents should be escalated through EOC.

5.3 Quality Assurance
All aspects of the procurement, storage, distribution and administration of medicines will be subject to routine quality assurance audit.

6. Sample Audit

6.1 Sample audits of packed paramedic and general drugs packs will be carried out at the Logistics Support Units.

6.2 A daily sample of 5% of packs will be audited by the Logistics Manager (Supply & Materiel), or a designated member of staff. The sample audit must not be carried out by the person who has packed or checked the packs. 6.3 The result of the audit should be recorded on the Stores Drug Sampling Form LA283. Any defective bags should be returned to the packing store.

6.3 A further 5% sample audit of packs held at the Logistics Support Unit will be carried out on a quarterly basis, by an outside agency appointed by the LAS. The results of these audits will also be recorded on the Stores Drug Sampling Form (LA283). Any defective packs will be returned to the packing store.

7. Security of Medicines and medical gases

7.1 Any drug or fluid must be stored in a locked cupboard in a room/area to which access is denied to persons not having reasonable cause to enter that room/area. This means that it is acceptable for the drug / fluid store

to be in the Station Office or garage area, provided that it is capable of being locked or secured. When formulating individual Station policies the need for staff to have reasonable access to drugs outside office hours must be considered. It therefore follows that medicines should not be stored in communal areas such as rests rooms, kitchens etc.

7.2 All medical gases stored on stations must be held in secure, locked cabinets specifically designed and approved to hold medical gases, to which access is denied to persons not having reasonable cause to have access to medical gases. Specific arrangements should be made by relevant operational managers to enable deliveries of medical gases and to facilitate locking of medical gas cabinets following delivery.

7.3 It is the responsibility of all LAS Staff to ensure that drugs/ fluids are securely stored on any ambulance vehicle or in any designated area of work they are responsible for during their tour of duty. Where vehicles are left unattended the doors should be shut and no drugs left in view wherever possible.

8. Traceability

8.1 All drugs must be traceable by batch number to allow:

- Recall of medicines and / or identification of patients potentially affected by a recall notice issued by a manufacturer or the MHRA.
- Reporting of adverse drug reactions to the MHRA and / or the manufacturer.

8.2 This requires that the Logistics Support Unit are able to identify where individual batches of drugs have been sent, and which pack numbers have been sent to individual stations. Drug pack numbers must be recorded on the PRF.

8.3 Drugs affected by a batch recall notice must be identified and withdrawn as soon as possible.

PART A – CONTROLLED DRUGS

1. General

1.1 The Misuse of Drugs Regulations 2001 defines those persons who are authorised to supply, administer and possess controlled drugs.

1.2 The Medical Director will be the **Accountable Officer**, as required by the Department of Health. In the absence of the Medical Director, an alternative Accountable Officer may be nominated with the approval of the Chief Executive and Medicines Management Group. Individuals undertaking the Accountable Officer role should be of equivalent seniority and have adequate training.

1.3 The **Responsible Manager,** as outlined in the Security Standards and Guidance for the Management and Control of Controlled Drugs in the Ambulance Sector (2012), will be the Group Station Manager supported by Clinical Team Leaders and Incident Response Officers.

1.4 The persons appointed by the Accountable Officer for the witnessing of the destruction of controlled drugs is the Logistics Manager (Supply and Materiel Management) and the Medicines Safety Officer. In addition, members of the Metropolitan Police Controlled Drugs Liaison Team will assist as required with controlled drugs destruction. (See also Appendix 3).

1.5 The majority of Part A of this policy and procedure refers directly to the storage, administration and destruction of morphine sulphate injection for intravenous (IV), intramuscular (IM) or subcutaneous (SC) administration. This will be referred to as “morphine for injection”. The same guidance will apply to other Schedule 2 Controlled Drugs, and drugs of a lower schedule that the LAS chooses to treat in the same way as Schedule 2 Drugs.

1.6 Morphine and Ketamine are Controlled Drugs under Schedule 2 of the Misuse of Drugs Act 1985, and are therefore subject to full controlled drug requirements relating to prescriptions, safe custody and the requirement to keep and register records. Although it is a Schedule 3 CD, Midazolam is treated as though it is a Schedule 2 drug.

1.7 Diazepam IV and PR, and morphine sulphate oral solution, by virtue of their respective places in Schedule 3, 4 & 5 respectively of the Misuse of Drugs Act 1985 are not subject to the same record keeping regulations.

1.8 Clinicians must only draw controlled drugs for the duration of their shift period. Under no circumstances are these drugs to be retained whilst staff are off duty.

1.9 Any controlled drug drawn from a controlled drug safe must be signed out in the controlled drug Register for that safe. Those drugs must then be signed back into that same safe, and the Controlled Drug Register reconciled. Under normal circumstances the practitioner who withdrew the individual drug/s will be responsible for signing these back into the safe.

1.10 If a paramedic, having administered a controlled drug to a patient, needs to hand that patient over to another paramedic or other appropriately qualified healthcare professional (e.g. Prehospital doctor); then the practitioner to whom the patient is handed over must use their own controlled drugs to continue the treatment of the patient. Any unused controlled drugs in the possession of the first paramedic must be destroyed. Controlled drugs must not be transferred between practitioners for any reason including to continue patient care.

2. Storage of Controlled Drugs on LAS premises

2.1 The law requires that there must be suitable and sufficient provision for safe and secure storage of controlled drugs on all LAS premises. Each ambulance station will have a designated controlled drug safe that conforms to Home Office Regulations. Each safe will have a CD Register for morphine sulphate, and additional CD Registers for other CDs as required.

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2.2 The only persons allowed access to controlled drugs safes are;

- Any person authorised by the Medical Director
- Registered Paramedics
- Clinical Team Leaders
- Incident Response Officers
- Group Station Managers – and those persons they have authorised locally so to do
- Logistics Support Unit personnel authorised by the Logistics Manager (Supply and Materiel Management)

2.3 The access number for the Controlled Drugs Safe will be changed as follows:

- The safe entry code is displayed **inside** the safe on the door.
- For one week prior to any change a notice is displayed inside the safe providing the new entry code & date of change.
- The code is to be changed at least once in any three month period.
- The code is to be changed if any incident occurs involving the CD safe, or other drugs lockers on the station group
- The code is to be changed if any member of the station group is

dismissed from the LAS.

3. The Carriage of Morphine Sulphate in the possession of Registered Paramedics once signed out from a controlled drugs safe.

3.1 Morphine sulphate will only be carried in an approved receptacle issued by the LAS.

3.2 Any controlled drug will only be prepared for use once its clinical need has been established. It must not be carried “pre-drawn” in any form.

3.3 If at any time the security of any controlled drug has been or could be compromised, the appropriate line-manager must be advised as soon as possible.

4. System for ordering and recording the storage and use of morphine sulphate for injection in the LAS (General Information).

4.1 There is an absolute requirement in law that each unit of morphine sulphate for injection purchased by the LAS must be accounted for from the point of ordering to the point of administration to a patient, or disposal either as unused or as out of date. The Controlled Drug Order Process flow-charts (Appendix 4) detail the processes to be followed.

5. Station Controlled Drug Register and Procedure for “Booking Out” / “Booking In” Controlled Drugs

See Appendix 1 for an exemplar sheet of a Controlled Drug Register

5.1 All movements in and out of the CD safe must be accounted for, with the name and signature of the person moving the CDs, and the name and signature of the person witnessing the movement clearly recorded.

5.2 The person who signs out any controlled drug, **must** be the same person that signs them back in at the end of a shift, or needs to account for their use in the “usage” column of the CD Register.

5.3 Entries within the controlled drugs register must be made in indelible black biro or ink, and appear consecutively in date order. All entries must be legible and made on the day of the transaction. No cancellation, obliteration or alteration of an entry will be made, and any corrections shall be made only by way of a marginal note.

5.4 Each ampoule of any CD is signed **out** on a separate line in the register.

5.5 If returning more than one ampoule, this can be entered on a single line. The number of ampoules being returned is placed in the ‘IN’ column.

5.6 Controlled drugs registers must be kept for two years from the last date of entry with the exception of the out of date controlled drugs register that must be kept for seven years from the last date of entry.

6. Witnessing Signatures in Controlled Drugs Registers

6.1 When controlled drugs are signed out of a controlled drugs safe by paramedics, every effort must be made to obtain a witness to sign in the "Witnessed by …" column of the Controlled Drug Register.

6.2 On some occasions it is understandable and therefore acceptable that single responders may not be able to obtain a witness signature for the withdrawal or return of morphine. Where this occurs the solo responder should annotate the witness section as 'no witness'.

6.3 It is acceptable for any member of staff such as Incident Response Officers, Emergency Medical Technicians and administration staff to witness to the withdrawal or return of controlled drugs and sign in the appropriate place in the register. They are merely witnessing the signature of the paramedic withdrawing or returning the drug, and confirming the quantities in the CD Safe and the Register tally and are correct.

6.4 Any member of staff who falsifies an entry / signature in any Controlled Drugs paperwork / stationery or book, will be subject to investigation under the LAS Disciplinary Procedure and may also be reported to the Police. If that member of staff is a registered healthcare / medical professional, they will also be reported to their relevant Regulatory Body.

7. Audit and Daily Stock Checks

7.1 A check of controlled drugs shall be carried out in the Storage and Distribution Centre and on all stations once in every 24 hour period.

- The quantity in the safe must be checked against the quantity in the register.
- The result is to be recorded in the Controlled Drugs Daily Audit Check record. Any discrepancy must be reported immediately and investigated by an appropriate manager.

These procedures are detailed in Appendix 5

7.2 Controlled Drugs Daily Audit Check records should be kept for a period of two years from the last date of entry.

8. Procedure for the administration of any Schedule 2 controlled drug to a patient (or CD treated as Schedule 2), including disposal of unused amounts of controlled drugs at scene

8.1 Any amount of drug administered must be recorded on the Patient Report Form.

8.2 Any unused amounts of controlled drugs that were prepared for administration, but not actually given to a patient must be squirted onto a piece of tissue which is then placed into a sharps bin. The amount of drug discarded must be recorded on the PRF and a witness signature obtained.

8.3 On return to station, the PRF and CAD Numbers relating to the patient must be entered in the CD Record Book against the ampoule that was booked out.

9. Reporting incidents involving CDs

9.1 In addition to the normal reporting processes, any incident involving CDs MUST be reported to the Medicines Management Group immediately via medicinesmanagement@lond-amb.nhs.uk

9.2 Any unaccounted loss or possible theft must additionally be reported to the nearest Police station, The Metropolitan Police Controlled Drug Liaison Team and the Home Office. (See Appendix 2)

9.3 The flowcharts at Appendix 6 detail the procedure to be followed if there is any discrepancy in the CD Safe count or ANY member of staff reports a loss / theft od controlled drugs.

10. The role of the Metropolitan Police

10.1 The Controlled Drugs Liaison Officers (CDLO) of the Metropolitan Police will support the Accountable Officer and the Chairman of the Medicines Management Group in ensuring compliance with legislation and investigating discrepancies, loss and theft..

10.2 The CDLOs may also conduct visits, both announced and unannounced, to LAS premises to ensure that the legislation in respect of controlled drugs is being adhered to. Where such visits take place, a formal report will be given to the LAS, and the Accountable Officer or the Chairman of the Medicines Management Group will compile an Action Plan. Both the report and the Action Plan will be submitted formally to the next available Clinical Safety, Development and Effectiveness Committee Meeting, and also detailed within the next scheduled quarterly report to the Controlled Drugs Local Intelligence

Network Meeting.

10.3 The police may ultimately prosecute an individual or organisation where they consider that the regulations have not been complied with.

PART B – ALL DRUGS AND FLUIDS (Other than controlled drugs)

1. Introduction

1.1 Part B deals with the preparation, packing, distribution and usage of the Paramedic and General Drug Bags used by the LAS.

1.2 Under this scheme sealed drug packs will be prepared by the LAS Logistics Support Unit and delivered on a daily basis to all ambulance stations. One pack will be for the use of Paramedics, and one for use by all clinicians.

1.3 A small number of commonly used drugs may be stored on stations, and kept on vehicles.

1.4 Logistics Staff will pack and deliver the drug bags to stations. New packs will be exchanged for used or date expired packs.

1.5 The Logistics Support Unit and Station Management will be required to carry out regular audits of drugs and packs.

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1.6 Any packing errors or missing drugs discovered should be reported to Station Management and an incident report completed. The pack concerned should be isolated, and returned to the Logistics Support Unit with a copy of the incident report which should be submitted by station managers to the Safety and Risk Department.

2. Use of sealed drug packs

2.1 At the start of a shift, a ‘general’ drugs pack and if appropriate a ‘paramedic’ drugs pack are removed from the green locker. The person drawing the drugs pack must check that the pack is sealed and that the pack is in date.

2.2 Where a pack is opened, drugs used, CAD and Date must be recorded on the packing slip.

2.3 A pack may be used on more than one patient.

2.4 At the end of shift, opened packs, and any pack that has reached its expire date are returned to the Red Locker. Sealed, unused packs that are still in date are returned to the Green Locker.

2.5 Drug packs must not be stored in personal lockers or elsewhere on station.

3. Loss of Any Drug Pack

3.1 Should a drug pack be stolen or lost, this must be reported to EOC and a local Police station at the earliest opportunity. Thereafter, the incident must be reported through the incident reporting process. In addition, Logistics must be informed so that they can amend their records accordingly.

4. Station-based drugs

4.1 Frequently used drugs and intravenous fluids are stored on station and drawn by clinicians on an 'as-and-when-required basis'. Drugs must be kept in a locked cupboard, and a stock card maintained for each drug. Station management are responsible for monitoring stock and usage levels and ordering replacement stock from logistics.

4.2 Paramedics may store intravenous fluids and saline flush in personal-issue paramedic bags. They are responsible for ensuring that these remain in date and are not subjected to extremes of temperature.

4.3 Stock Cards must be kept for two years from the date of last entry.

5. Audit in Stores

5.1 The Logistics Manager (Supply and Materials Management) or his / her designated deputy will carry out a weekly audit of all drugs held in the main drugs stock and the packing stock.

5.2 The number of sealed bags held should also be audited on a weekly basis.

5.3 A selection of Drug Packs must be audited on a regular basis to ensure compliance with packing lists.

PART C – PATIENT GROUP DIRECTIONS

1. A PGD is a specifically written instruction for the supply or administration of a named medicine in an identified clinical situation. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.

2. PGDs will be developed by the Medical Directorate, in accordance with Standards set down by the National Institute of Clinical and Healthcare Excellence (NICE) and will be signed by the Chief Executive Officer, The Medical director and the Trust's Pharmacy Advisor

3. It will be the responsibility of the Medical Director to:

- ensure that all PGDs are appropriate, reviewed according to the review date set or sooner if there is a change in drug information and/or prescribing guidance.

- ensure that staff operating within PGDs are competent in the management of patients to which specific directions apply.

4. Staff using PGDs

4.1 Before using a drug under a LAS PGD it is the responsibility of that member of staff to ensure that they are:

- A Registered Paramedic, Registered Nurse or other allied health professional registered with one of the UK statutory health regulatory bodies, and:
- Have undertaken the appropriate training to carry out clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in the specific PGD, and:
- Has undertaken appropriate training for working under PGDs for the supply and administration of medicines

1. Part D: Patient Specific Directions

1.1 A PSD is an instruction to administer a medicine to an individual patient under a given set of circumstances.

1.2 This includes medicines or doses that are not within the normal scope of practice of the clinician attending the patient, and may include controlled drugs.

1.3 Examples include:

- End of life Care Anticipatory Medicines
- Anti-seizure medicines

1.4 In all cases there will be a written direction held by the patient describing the indications, dose and route of the medicine. These are commonly found in the patient's notes and will often include a drug prescribing chart, and, in the case of CDs, a Patient Held CD Register.

1.5 In some cases the written direction will be in the form of an LAS issued patient Specific Protocol.

1.6 Ambulance clinicians are authorised to administer these medicines, but MUST ensure that:

- The patient has been correctly identified
- The presenting condition matches the indications identified on the PSD
- The route of administration MUST be within the clinician's scope of practice.
- All medicines administered in the patient's notes and on the patient report form
- In the case of controlled drugs, that patient-held CD register must be completed.

1.7 If there is any doubt as to the validity or appropriateness of the PSD, contact the Clinical Hub.

2. Patient's own medications

2.1 Any patient may be assisted to take their own prescribed medicines.

2.2 Clinicians must not advise or recommend that a patient take a medicine that does not fall within the scope of practice.

Part E: Medical Gases

1. General Guidance

1.1. This guidance provides advice on the secure and safe use of medical gases in the LAS
1.2. It is recognised that there is a potential for harm through misuse of gases, and that cylinder storage areas have been targeted by thieves seeking to obtain gases for recreational use and for the financial value of the contents and the scrap metal value of the cylinder.
1.3. As the contents are stored under pressure and either flammable or able to support combustion, there is a risk of harm if structural damage occurs to cylinders.
1.4. There is also a risk of harm if medical gases are accidentally or maliciously tampered with or contaminated.

2. Procurement and supply

2.1. Medical gases will only be procured from approved suppliers holding a contract with the LAS.
2.2. Cylinders may not be swapped or exchanged with other organisations
2.3. Stock levels must be monitored on a regular basis and orders placed through logistics.
2.4. Empty or near-empty cylinders must be returned to a secure store as soon as practicable
2.5. Cylinders (empty or full) must not be left at hospital or with patients
2.6. Where possible, deliveries should be supervised. If this is not possible, robust mechanisms must be put in place to allow the supplier access to only the area of the station that is needed, and to reconcile the delivery with the order.

3. Storage

3.1. Medical gases for ambulance use may only be stored in a purpose-designed locker. The locker must be in a secure, well ventilated location that is not open to the general public.
3.2. The contacted suppliers must be involved in the design and siting of storage areas. Where possible there should only be one storage are per site.
3.3. The location of the cylinder store should be clearly marked, and identifiable on the site plan in case of an emergency
3.4. Appropriate hazard warning signs should be in place, with warnings prohibiting smoking, welding and naked lights clearly visible
3.5. The locker must be kept locked at all times, and only people directly involved in the authorised use and movement of cylinders shall have access to the locker.
3.6. The locker should clearly separate medical gases by type, and separate full from empty cylinders. Adequate restraints should be in place to prevent falling
3.7. The store must be kept clean, dry and free from flammable material

3.8. Cylinder stocks should be rotated, and gases nearing their expiry date should be used first.

4. Ambulances and other response vehicles

4.1. Before a cylinder is placed on a vehicle, it must be checked and confirmed that it is clean, structurally intact, serviceable and in-date. The tamper-evident seal must be intact up until this point.
4.2. Cylinders stored on ambulances and other response vehicles must be secured either to the bodywork of the vehicle, or in purpose-designed storage areas or response bags.
4.3. Loose cylinders pose a missile hazard during hard braking or impact and must not be placed on the ambulance trolley, shelves or floor while the vehicle is in motion.
4.4. Bulk cylinder transport (HART, Emergency Preparedness and Events vehicles) must be in a purpose-designed vehicle or a cage system approved by LAS Fleet Services.
4.5. Pipeline systems in ambulances must be tested on an annual basis by an approved technician
4.6. No adjustments or repairs should be made by operational staff or other personnel. Lubricants of any sort must not be used on gas systems

5. Medical gas equipment – regulators, flow-meters, delivery systems and ventilators

5.1. In order to prevent the administration of the wrong gas, only non-interchangeable fittings are to be used.
5.2. All equipment used in the delivery of medical gases must be kept in good working order and serviced in accordance with the manufacturer's instructions.
5.3. All staff using this equipment must be trained in its use, and briefed on the serviceability checks needed to ensure safe operation. Records must be kept of this training

6. Damaged cylinders

6.1. Any cylinders damaged or noticed to be damaged on inspection must be removed from service and clearly marked as such
6.2. The cylinder is to be placed in the 'used / empty' section of the storage area
6.3. An LA52 must be completed.

IMPLEMENTATION PLAN				
Intended Audience	For all LAS staff			
Dissemination	Available to all staff on the Pulse			
Communications	Revised Procedure to be announced in the RIB and a link provided to the document			
Training	Core paramedic education and training, Annual CSR updates, and via Team Leaders			
Monitoring:				
Aspect to be monitored	**Frequency of monitoring AND Tool used**	**Individual/ team responsible for carrying out monitoring AND Committee/ group where results are reported**	**Committee/ group responsible for monitoring outcomes/ recommendations**	**How learning will take place**
Adherence to policy and procedure by staff	1)Quarterly Area Quality Report (includes CPI checks) 2) Unannounced visits by the Met Police Controlled Drugs Liaison Team	1)Assistant Director of Operations for each area reports to the Clinical Safety, Development and Effectiveness Committee 2) Reports to Trust Board	Quality Committee (and Trust Board if required)	Learning disseminated via the Medicines Management Group and / or Education and development Department as required
How any adverse reactions to medication are recorded and how incidents and near misses involving medicines are managed	1) Bi-monthly reports 2) Quarterly reports	1) The Chair of the Medicines Management Group reports to the Clinical Safety, Development and Effectiveness Committee 2) The Medical Director as the Accountable Officer for controlled drugs reports to NHS England (London		

		Region) Local Intelligence Network		
How medicines are disposed of safely	Quarterly audit of completed out of date stock sheets	Assistant Director of Operations for Operational Support reports results to the Medicines Management Group	Clinical Safety, Development and Effectiveness Committee	
Storage of medicines	Quarterly audit of storage arrangements			

Appendix 1

London Ambulance Service NHS Trust - Controlled Drug Register

NAME, FORM OF PREPARATION AND STRENGTH……Morphine Sulphate 10mg/1ml…….(Ampoule / ~~Unit / Box~~) Delete as Necessary

STOCK CHANGE

DRUG ADMINISTRATION / USAGE / WASTAGE

		C/FWD						PRF No. and CAD No	Quantity			When used by single responder Callsign of other vehicle Witness signature for DRUG USED
Amount		100							Administered	Wasted	Administered by	
OUT	IN	Running Total	Date	Req No	Authorised User Stock Change Printed Name & Signature	Witness Signature for Change Printed Name & Signature					Printed Name & Signature	Printed Name & Signature
	30	130	02/01/2010	357	P Joe Bloggs	P A N Other	**1**	PRF			P	P
					S *J Bloggs*	S A N Other		CAD			S	S
1		129	02/01/2010		P Frank Nurk	P Ivan Harvat	**2**	PRF 12345678	7.5	2.5	P Frank Nurk	P Ivan Harvat
					S F Nurk	S I Harvat		CAD 3211			S F Nurk	S I Harvat
1		128	02/01/2010		P Frank Nurk	P Ivan Harvat	**3**	PRF			P	P
					S F Nurk	S I Harvat		CAD			S	S
	2	130	02/01/2010		P Billy Bodger	P Sam Splint	**4**	PRF			P	P
					S B Bodger	S S Splint		CAD			S	S
			/ /		P	P	**5**	PRF			P	P
					S	S		CAD			S	S

Appendix 2

Drugs Licensing & Compliance Unit
5th Floor SE Fry Building,
2 Marsham Street, London SW1P 4DF
Tel: 020 7035 8972
E:licensing_enquiry.aadu@homeoffice.gsi.gov.uk
www.gov.uk/controlled-drugs-licences-fees-and-returns

Notification of Theft/Unaccounted Loss of Controlled Drugs/Category 1 Precursors

Please complete the below form and submit to the Drugs Licensing and Compliance Unit at the above address.

Name of Licensee (as it appears on the licence)	
Address of Licensed Premises (as it appears on the licence):	
Home Office company number and/or Home Office licence number **Application reference number (if known)**	
Date that the Theft/ Loss occurred	
Has there been a delay in reporting the Theft/Loss? **If so please state the reason for the delay.**	
Location of Theft/Loss (if different from above)	
Were any other companies involved/affected by the theft/loss? i.e customer/supplier/carrier **If so please provide name, address and the relationship to your company**	
Please provide the details of the CD(s)/PC(s) Lost/Stolen – including the drug type(s), form(s), quantities and Schedule(s) they fall under	
Please provide the circumstances of Theft/Loss	

Please provide the details and actions taken by the Police, including contact details, date and Crime Reference number **If the police have not been notified please provide an explanation to why no contact has been made**	
Has this particular type of incident occurred before, i.e. is there any emerging pattern? **If so, please provide details, including dates reported to the Home Office, any remedial action taken at the time and the outcome of the incident(s)**	
Has the company suffered seemingly unrelated CD or PC thefts/losses previously? **If so please provide details of the incident(s) that have occurred, including dates reported to the Home Office, any remedial action taken and the outcome of the incident**	
Please provide a summary of the internal investigation undertaken including details of any remedial action, change of procedure(s) and the outcome of the incident– (please submit with this form all documents produced relating to the investigation)	
Name of person completing this form:	
Date:	

If your investigation has not been completed at the time of submitting this form, please forward the outstanding information at your earliest opportunity to the e-mail address above, making reference to original notification.

The Home Office will handle all information submitted in accordance with the Data Protection Act 1998 and the Freedom of Information Act 2000 and connected legislation.

We may share information contained within your theft/unaccounted loss form or obtained in the course of processing your form with other government departments, regulatory bodies or enforcement agencies in the course of preventing the misuse of drugs. Any information shared would be shared in accordance with data sharing protocols. We do not share your personal or company details with other licensees or members of the public and treat information contained within the theft/unaccounted loss form as commercial in confidence but individuals and companies should be aware that we may be required to disclose some information in accordance with the legislation referred to above.

Appendix 3.

Procedure for the Destruction of out of Date Pharmaceuticals

1. Out-of-Date Drugs

Out-of-date diazepam and oral morphine will be removed from circulation via the routine checking of returned paramedic drugs bag. All diazepam and oral morphine so removed will be placed into the “out of date” controlled drugs safe and the Out of Date Controlled Drugs Register updated accordingly.

The Corporate Logistics Manager or their designated deputy will monitor the expiry date of stocks of morphine for injection and advise stations when withdrawal is required of any ‘out of date’ stock. The designated person on a main station will also monitor expiry dates and notify the Corporate Logistics Manager or their deputy, that there are stocks of ‘out of date’ morphine to collect. The ‘out of date’ stock should be accompanied by a duplicated ‘Out of Date Controlled Drugs Form’. The designated person on the main station should record the quantity of the out of date drug being returned, and sign and date the form (on the line stating: ‘Drugs returned by: ’).

On arrival at the station the designated member of Logistics staff should check with the designated member of station staff that the quantity being returned matches the amount identified on the form. If so, they should sign and date the form and place the morphine in the container provided. The out of date drugs should then be secured in the vehicle safe and returned to the Storage and Distribution Centre. A copy of the Out of Date drugs form should be retained by the station for a period of two years from date of the last entry.

When the out of date drugs are received in the store, the Logistics Manager (SMM), or their designated deputy, should check the out of date form in the presence of the designated member of Logistics staff and sign and date the form if the quantity listed is present, on the line stating ‘Drugs Received by:’ If the quantity listed is not present, an investigation should be immediately initiated. The out of date drugs form should be kept for a period of two years from the date of the last entry.

The out of date morphine should be stored in the Out of Date Controlled Drug Safe. An ‘out of date’ controlled drugs register should be kept in the safe. This

should list the date, quantity, batch number, origin of the out of date stock, and date of disposal. When placing the out of date stock in the Out of Date Controlled Drug Safe, the Logistics Manager (SMM), or their designated deputy, should complete the relevant details and witness the entry by signature. A daily audit of the register and a 'checked and correct form', should be completed for 'out of date' stock in the same way as for 'in date' stock. The register and forms should be kept for a period of two years from the date of the last entry.

2. Destruction of out of date controlled drugs

The Accountable Officer is empowered to nominate individuals who are authorised to witness the destruction of controlled drugs.

The Corporate Logistics Manager and The Medicines Safety Officer are the LAS Managers appointed by the LAS Accountable Officer to oversee and witness the destruction of all out of date controlled drugs held by the LAS.

Any destruction day set is to ensure that all out of date controlled drugs since the last destruction is destroyed. All destructions will take place at Deptford Logistics Depot.

The Accountable Officer cannot witness the destruction of controlled drugs as they must remain independent from the day to day management of controlled drugs.

Once a date has been set for destruction of out date controlled the Corporate Logistics Manager will ensure that, including themselves, there are least two persons present to affect the destruction of the controlled drugs.

The Medicines Safety Officer will inform the Metropolitan Police Controlled Drugs Liaison Officer Team, of any destruction dates and ascertain if they wish to be present at the destruction.

On the appointed date the Corporate Logistics Manager will ascertain how many destruction of out of date pharmaceutical (DOOP) kits will be required, and draw said amount from a stock held at Deptford Logistics Depot.

All the out of date controlled drugs will be signed out of the Out of Date Controlled Drugs Safe and the Out of Date Controlled Drugs Register amended accordingly.

All the out of date controlled drugs will then be disposed of into the DOOP Kits and de-natured as per the manufacturer's instructions. Once the de-naturing process has taken effect the DOOP Kits will be disposed of via the LAS clinical waste disposal services.

Once the whole process has been completed the Corporate Logistics Manager will ensure that all the requisite entries in the Out of Date Controlled Drugs Register are completed correctly and all signatures witnessed.

Appendix 4

London Ambulance Service NHS
NHS Trust

Controlled Drugs Ordering Process – October 2015

These notes are designed to summarise and clarify the movement and ordering of Controlled Drugs within the Trust, as prescribed in the relevant Operational Procedures (OP/002 & OP/030)

1. Group main stations order and manage controlled drugs within the station group. Logistics will only supply Group Main Stations or specialist sites.
2. Local stations must use a **requisition book** to order drugs from a main station in the same way that a main station uses a requisition book to order CDs from Logistics Support Unit.
3. Controlled drugs may only be requisitioned by a registered healthcare professional who has been authorised by a manager. Where the GSM is not a registered clinician this should be undertaken by a Team Leader. Although staffing levels may occasionally dictate that a Senior Paramedic be approved as a signatory, it is the expectation that CDs are not ordered by staff less than Clinical Team Leader level.
4. There are different signatory sheets for different groups
    1. Local Stations authorised by GSM
    2. Group Main Stations authorised by ADO
    3. Advanced Paramedic Practitioners authorised by line manager
    4. Clinical HUB Paramedics authorised by Clinical Hub Manager
    5. HART authorised by head of CBRN and HART
    6. EPRR & Events authorised by ADO resilience
    7. Medical Directorate authorised by Deputy Medical Director

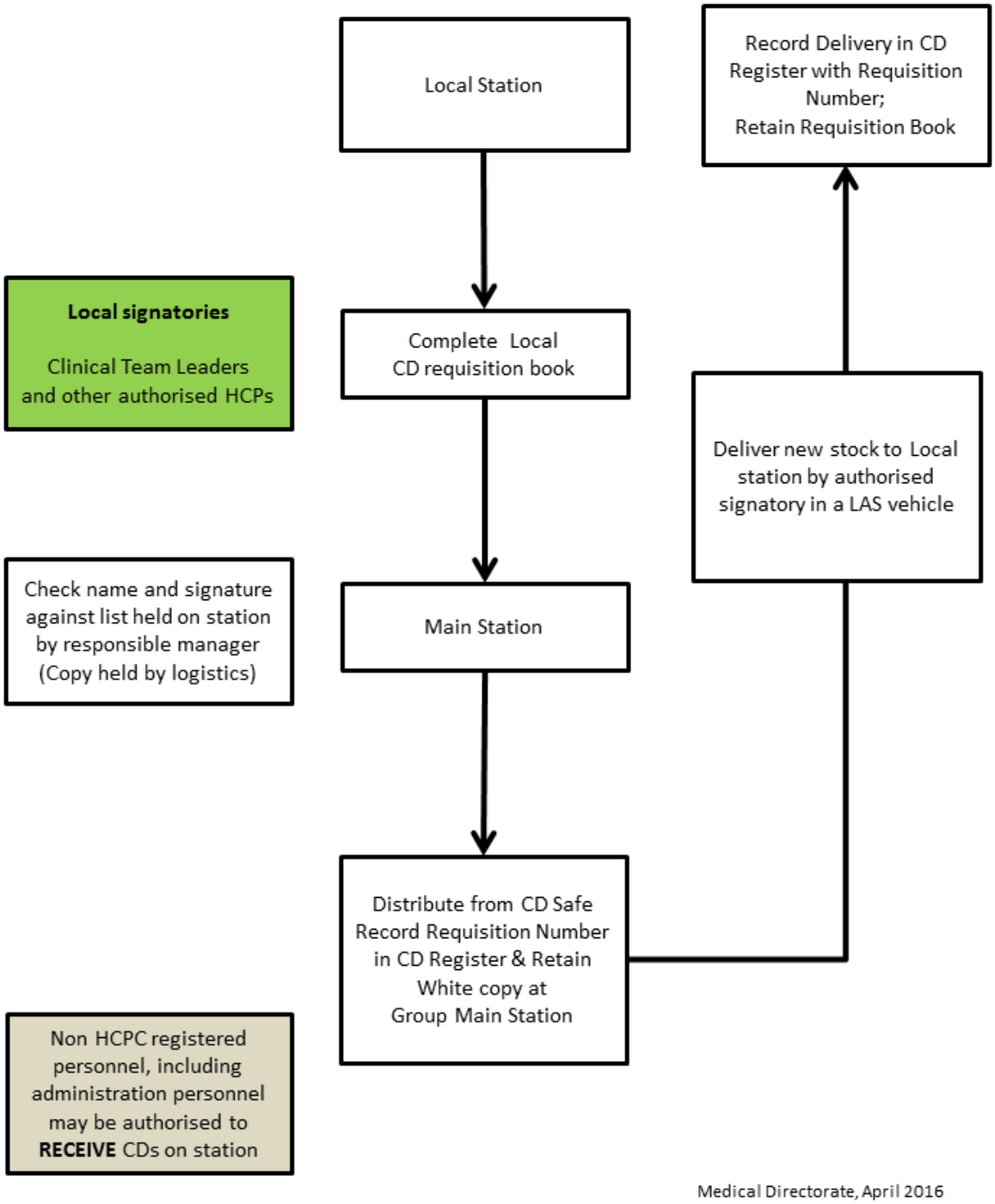
Names and Sample signatures of staff authorised to order and / or receive CDs must be on an up-to-date LA227.

1. The above authorised persons may also transport CDs between a main station and a local station (or to an event specific site - EPPR/Medical Directorate only)
2. Equipment Support Personal are authorised to deliver CDs to main stations.
3. Persons other than Registered Healthcare Professionals (including administration staff) may **receive and / or witness delivery of controlled drugs**, and update the CD register accordingly provided that the responsible manager is satisfied that they have received adequate training to perform these functions and that their name and signature appear on the relevant authorised signatories sheet. Only authorised registered healthcare professionals may order CDs
4. The paramedic ordering a CD for a Local Station may not be the same person as the paramedic supplying the order from the Main Station
5. Only APPs and Medical Directorate staff are permitted to order CDs other than morphine.

Dr Fenella Wrigley
Medical Director & Accountable Officer
6th April 2016

London Ambulance Service NHS
NHS Trust

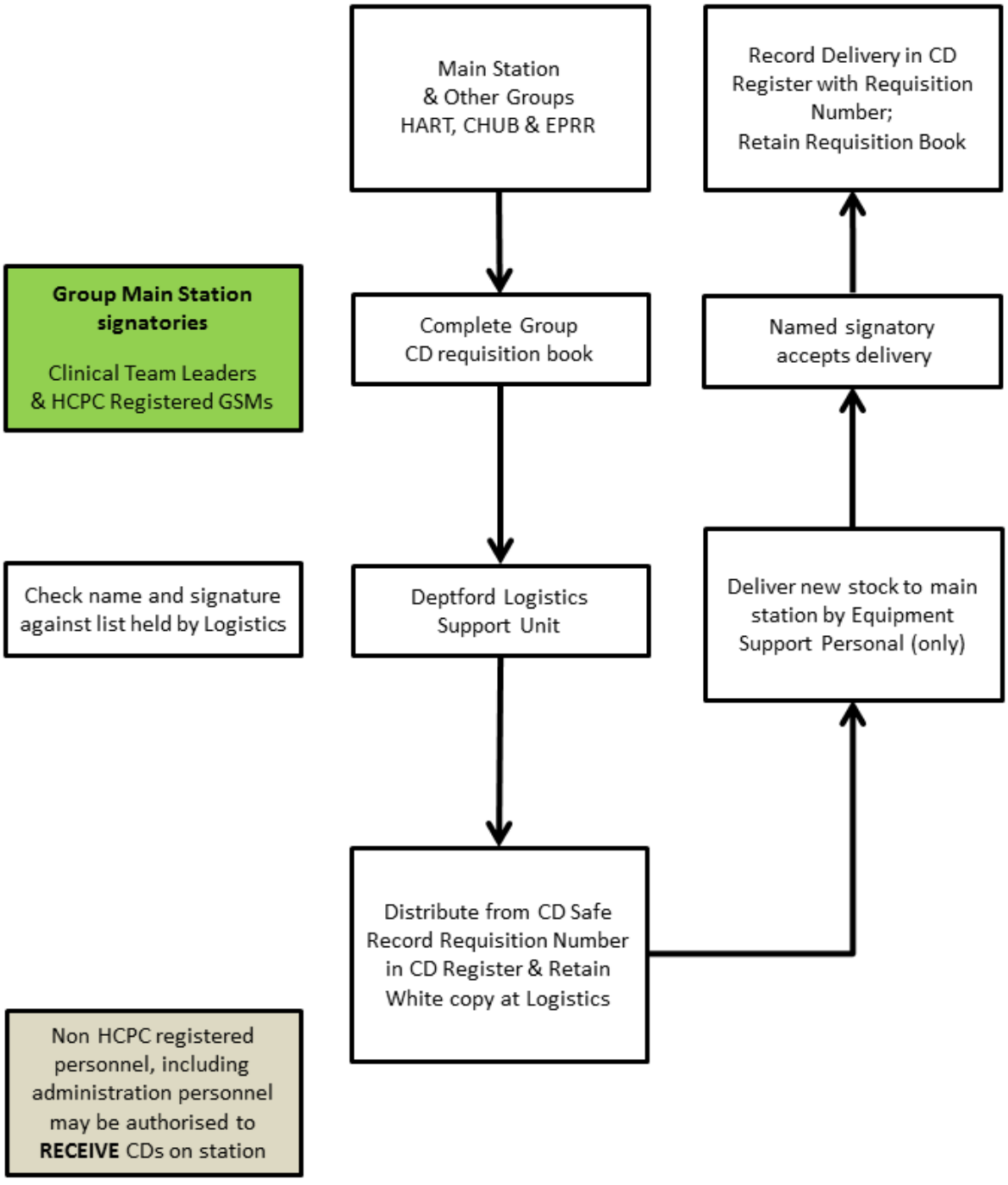
Ordering CDs within a Station Group



Medical Directorate, April 2016

London Ambulance Service NHS
NHS Trust

Ordering CDs from Deptford Logistics Support Unit



Medical Directorate, April 2016

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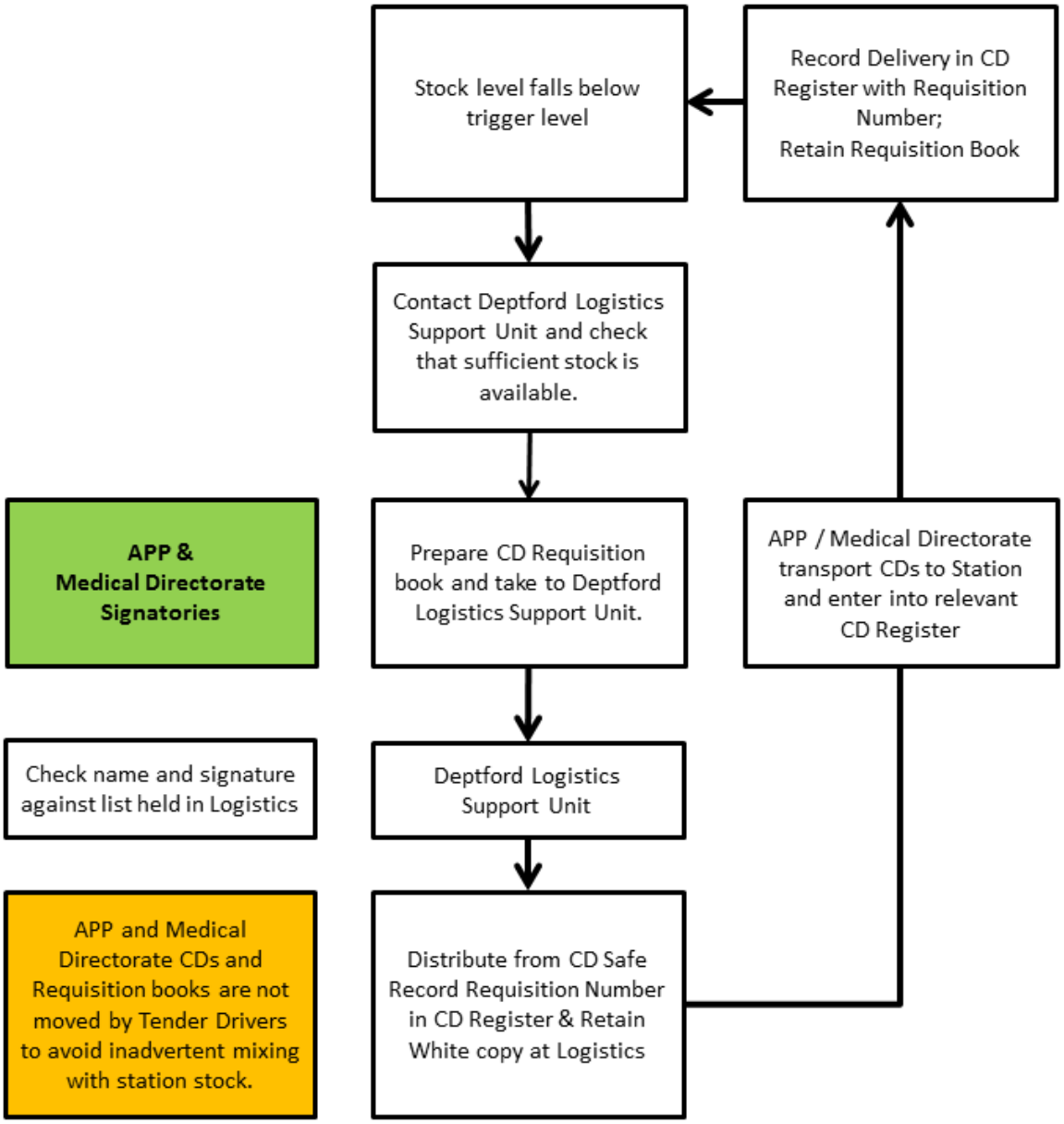
NHS Trust

Advanced Paramedic Practitioner & Medical Directorate CDs



Medical Directorate, April 2016

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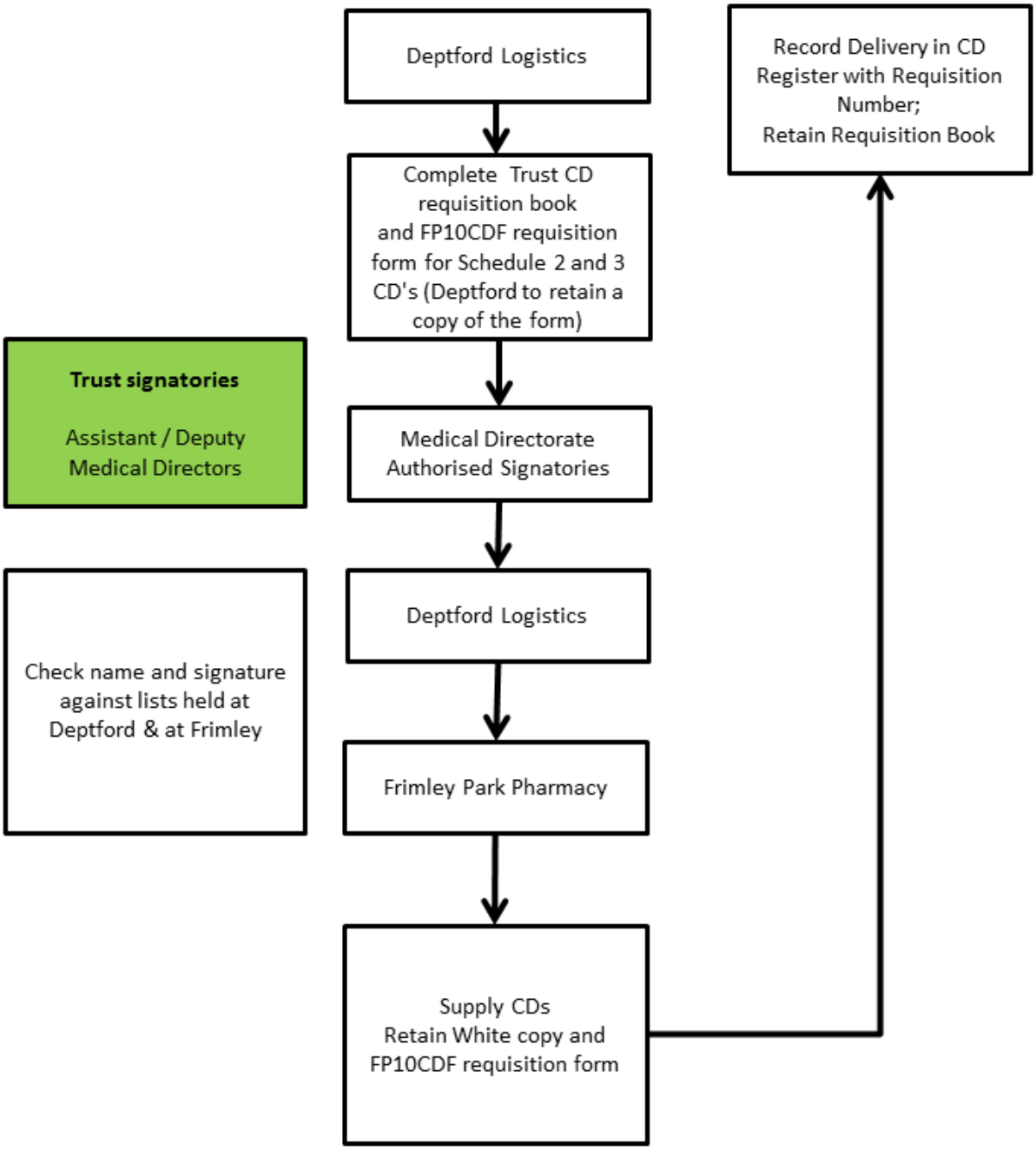
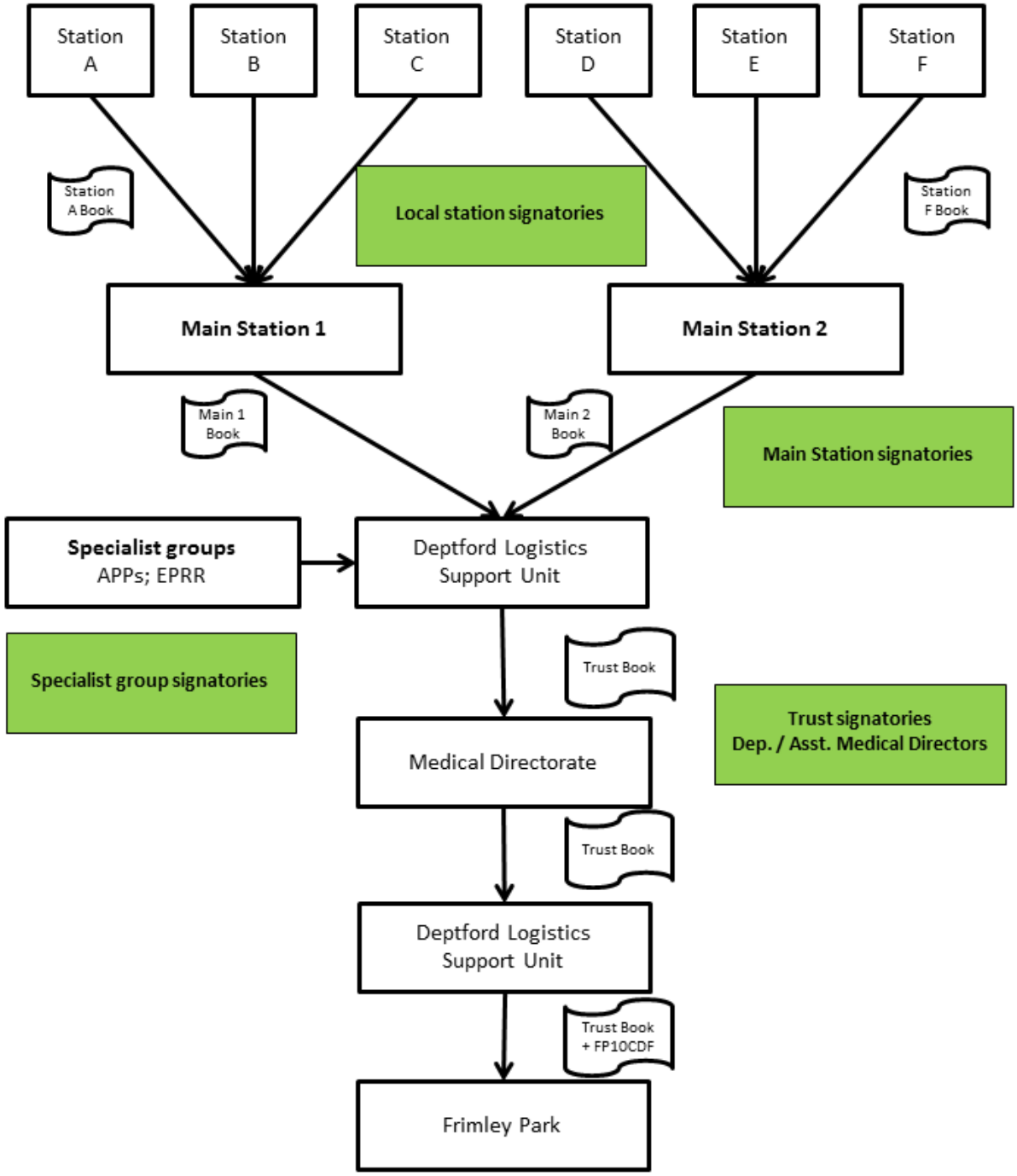
Logistics CD Ordering Process



Medical Directorate, April 2016

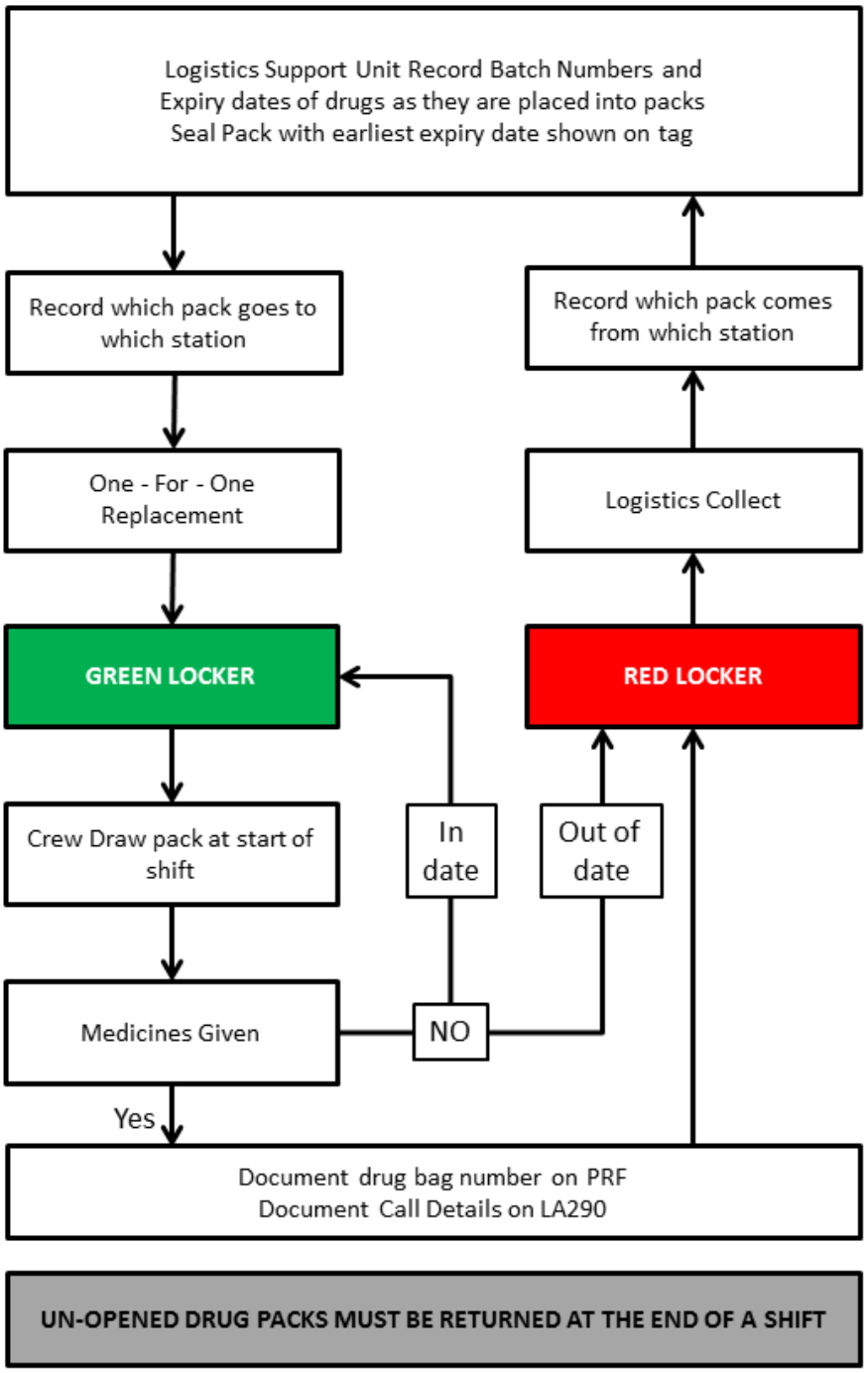
London Ambulance Service NHS
NHS Trust

Trust CD Ordering Process



Medical Directorate, April 2016

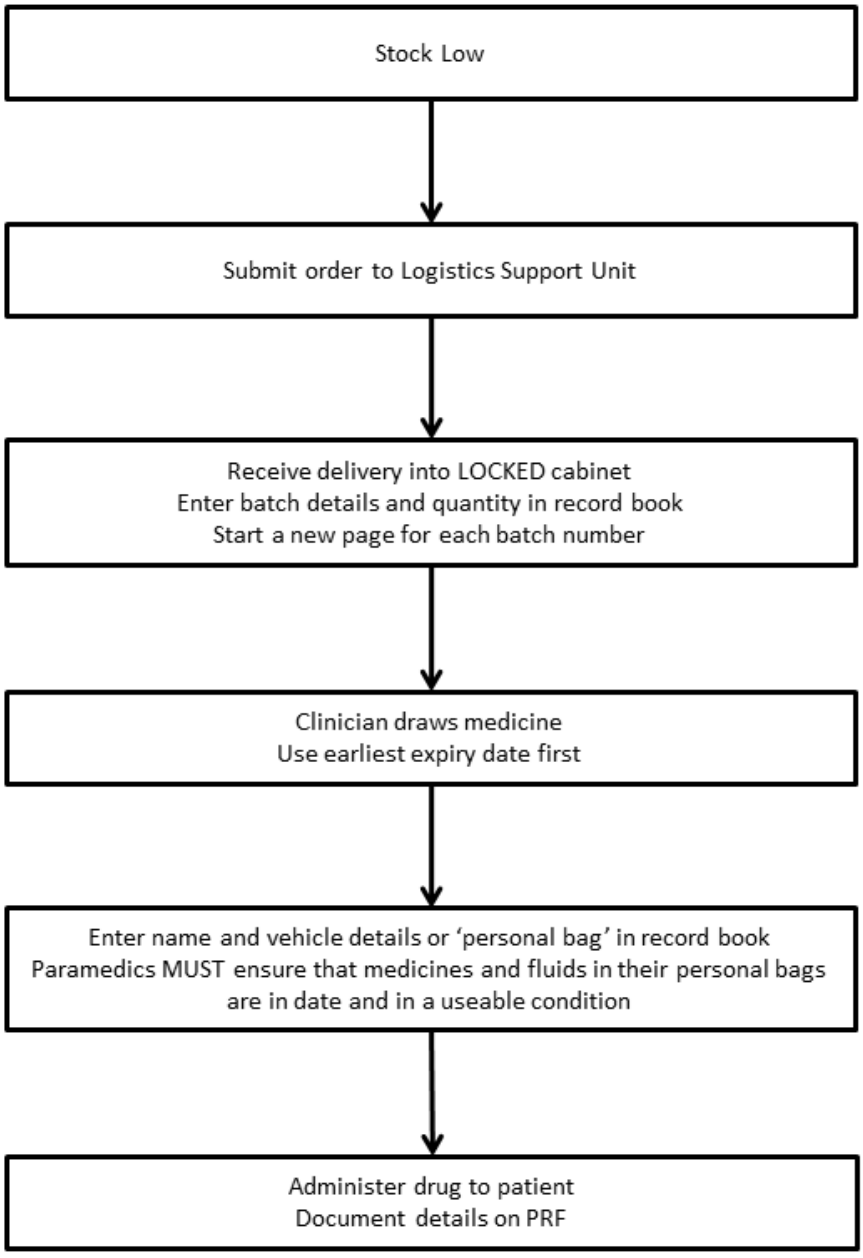
Paramedic & General Drugs Process



Medical Directorate, April 2016

London Ambulance Service NHS
NHS Trust

'Station Based' Medicines and IV Fluids Process



Medical Directorate, April 2016

Appendix 5

Abstract from the Controlled Drugs Daily Audit Check Record book that details the process for the daily CD Check on Stations (April 2016).

Responsibility of signatory

To be compliant with the Home Office requirements and to remain within the spirit of the law for the LAS to hold stocks of Morphine Sulphate on Stations and at the LAS Central Store nominated authorised signatories at all Stations and Central Stores must complete on a daily basis a checked and correct audit.
This audit document does not replace the station CD Register but must be used on a daily basis at any time to independently ensure the stock values within the register and the safe tally. It is the duty of the AOM's and the appropriate signatories to ensure that the audit is conducted.
If there is a discrepancy between the register and the stock then the safe must be put on quarantine i.e. no further removal or replacement of morphine by staff. The procedure for investigating stock discrepancy must be immediately followed. Where there are discrepancies this book may be used in a court of law as evidence (The LAS policy on Controlled Drugs details these procedures).
This book must be available on Station for audit by Trust Managers, Home Office Officials, Police and Customs and Excise. The audits by external agencies can occur at any time and they do not have to be pre-arranged.

Daily Controlled Drugs Audit Check
The daily check will be carried out in the following manner;

1. There must be NO other drugs other than morphine sulphate for injection kept in the CD Safe. Any deviation from this must be agreed by the Medicines Safety Officer, (APP CD safes as an example)
2. Any box with the original seal still intact and no tampering evident can be considered to hold the quantity printed on the box.
3. Number of Morphine in Safe:
4. Number of Morphine in Controlled Drug Register:
5. Controlled Drug Authorised Signatories document held at main Station: Yes / No
6. Controlled Drug Order book held at main Station: Yes / No

Examine the current and previous two pages of the Morphine Controlled Drug Register in order to answer questions 7 to 12

7. Morphine Sulphate 10mg / 1ML written on the top of each page: Yes / No
8. Has the carried forward balance been recorded on every page: Yes / No
9. Have all Morphine withdrawals been counter signed: Yes / No
10. Has all Morphine administration, wastage and usage details been fully completed with the amount in Mg: Yes / No
11. Has all Morphine administration, wastage and usage been counter signed: Yes / No
12. Has a PRF number and CAD number been recorded for all Morphine administration, wastage and usage: Yes / No

Appendix 6

Procedure for dealing with incidents involving the storage, use, theft or loss of controlled drugs. IF the scenario in the following flowcharts are not catered for, the member of staff must inform their Station Management Team immediately, who will in turn inform the Chair of the Medicines Management Group and the Medicines Safety Officer who in discussion will take action appropriate to the scenario. If there is no member of the Station Management Team present then the member of staff will ask the Senior Clinical On Call to be contacted via EOC.

Member of staff discovering incorrect count in the CD Safe

Immediate actions

- Inform Station Management Team if available.
- If Station Management Team not available, the crew are to contact EOC (PD33) and ask them to contact the Incident Delivery Manager. The crew are to be placed 'out of service' until the IDM has reviewed the case or another manager is on site.
-
- Incident Delivery Manager (IDM) to make a decision on whether to "lock down" the CD Safe or not.
- IDM to designate person to attend the station to investigate the incident, releasing the crew to return to duty as soon as possible.

Subsequent Actions

- If loss / theft is established then the Met Police and the Home Office to be notified as per policy.
- IDM to inform Group Station Manager (GSM) concerned on order for investigations to continue.
- LAS Accountable Officer (The Medical Director), Chair of Medicines Management Group (Chair MMG) and Medicines Safety Officer (MSO) to be informed.
- Chair MMG, MSO to inform Met Police CD Liaison Team.
- LAS Accountable Officer, GSM, Chair MMG and MSO to discuss investigation and resolution. (Met Pol CDLO Team to be involved as required).

Member of Staff Reporting Controlled Drugs lost / missing during shift

Immediate actions

- Inform Station Management Team if available.
- If Station Management Team not available, then EOC must be asked to contact the Incident Delivery Manager.

Subsequent Actions

- IDM to designate person to attend last known locations before the loss was discovered..
- If loss / theft is established then the Met Police and the Home Office to be notified as per policy.
- LAS Accountable Officer (The Medical Director), Chair of Medicines Management Group (Chair MMG) and Medicines Safety Officer (MSO) to be informed.
- Chair MMG, MSO to inform Met Police CD Liaison Team.
- LAS Accountable Officer, GSM, Chair MMG and MSO to discuss investigation and resolution. (Met Pol CDLO Team to be involved as required).

Controlled Drugs not Returned to CD Safe but Whereabouts are Known

Immediate actions

- Inform Station Management Team if available.
- If Station Management Team not available, then EOC must be asked to contact the Incident Delivery Manager.
- Member of staff to return to station immediately with the controlled drugs
- If member of staff unable to return to station immediately, they must discuss the return directly with the IDM.

Subsequent Actions

- GSM of member of staff to be informed and the matter investigated.
- LAS Accountable Officer, GSM, Chair MMG and MSO to discuss investigation and resolution. (Met Pol CDLO Team do **not** need to be involved).