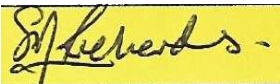


Policy for the Safe and Secure Handling of Medicines & Prescription Stationery in GP Practices

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Policy for the Safe and Secure Handling of Medicines & Prescription Stationery in GP Practices - Version Control Sheet

Version	Section	Description of Amendments	Date	Author / Amended by
6		Amalgamated Policies of The Safe and Secure Handling of Drugs (version 5) and the Policy for the Secure handling of Prescription Stationery (version 1) Revised and updated throughout to bring into line with local and national guidance.	March 2017	Allison Hirst
7	Front page	Title amended to include prescription stationery & GP practices.	August 2019	Allison Hirst / Olu Arikawe
7	Throughout	Revised and updated to make the policy specific to GP practices. All paragraphs relating to other organisations e.g. LCHS removed. PMOS changed to Optum Prescribing and Medicines Optimisation Service.	August 2019	Allison Hirst / Olu Arikawe
7	Policy statement	Updated to include prescription stationery.	August 2019	Allison Hirst / Olu Arikawe
7	Section 1 Introduction / scope of policy	Whole section revised and updated. Paragraphs 1.3, 1.4 & 1.8 new additions. Includes responsibilities for senior management.	August 2019	Allison Hirst / Olu Arikawe
7	Section 2 Terminology	Prescription stationery – new definition	August 2019	Allison Hirst / Olu Arikawe
7	Section 3 Ordering & receipt of medicines	Paragraph 3.7 – short dated items returned to supplier added Paragraph 3.8 – storage conditions added	August 2019	Allison Hirst / Olu Arikawe
7	Section 4 Storage & security of medicines	Paragraph 4.1 – medicine storage reworded Paragraph 4.2 – nominated person changed to accountable individual Paragraph 4.3 – shelves added	August 2019	Allison Hirst / Olu Arikawe
7	Section 5 Initiation of treatment / prescribing / prescription writing	Paragraph 5.2.4 – within NHS added Paragraph 5.4.2 – record in healthcare records as supplied under PGD added. Paragraph 5.5.1 – additional sentence on legal requirements of prescriptions Paragraph 5.5.5 – multiple identifiers. Paragraph 5.5.6 – ages on computer generated prescriptions added Paragraph 5.5.10 – wording changed around Latin abbreviations	August 2019	Allison Hirst / Olu Arikawe

Version	Section	Description of Amendments	Date	Author / Amended by
7	Section 6 Licensed / unlicensed medicines	Paragraph 6.1 – added reference to Lincolnshire Joint Formulary	August 2019	Allison Hirst / Olu Arikawe
7	Section 7 Specials	Removed reference to PACE bulletin - duplication	August 2019	Allison Hirst / Olu Arikawe
7	Section 8 Dispensing	Paragraph 8.5 – added statement about falsified medicines directive	August 2019	Allison Hirst / Olu Arikawe
7	Section 9 Administration of medication	Paragraph 9.1.8 – previous adverse drug reactions & consent added Paragraph 9.2.5 – or dispensed added	August 2019	Allison Hirst / Olu Arikawe
7	Section 10 Use of injectable medicines	Paragraph 10.1.3 – nurse changed to healthcare professional	August 2019	Allison Hirst / Olu Arikawe
7	Section 11 PGD administration and supply	Paragraph 11.6 – the PGD is in date and contains the legally required authorising signatures added	August 2019	Allison Hirst / Olu Arikawe
7	Section 14 Storage, distribution & disposal of vaccines	Paragraph 14.1.5 – The Leicestershire and Lincolnshire cold chain policy added for reference Paragraph 14.1.6 – added one person from nursing team & one person from management as clarification to the nominated people. Additional sentence on maintaining the cold chain supply Paragraph 14.2.15 – reworded over interruption of electricity supply Paragraph 14.2.18 – additional statement regarding thermometers Paragraph 14.6.1 – contact details in case of fridge failure updated	August 2019	Allison Hirst / Olu Arikawe

Version	Section	Description of Amendments	Date	Author / Amended by
7	Section 15 Untoward incidents	Paragraphs 15.1.1 & 15.1.2 – new additions. Reducing medication administrative errors	August 2019	Allison Hirst / Olu Arikawe
7	Section 17 Ordering & receipt of prescription stationery	Whole section moved from earlier in the policy. Paragraph 17.1.4 – within a lockable room or area added Paragraphs 17.1.6 & 17.3.3 – changed to in accordance with local retention policies Paragraph 17.3.4 – new addition; reference to more detailed guidance	August 2019	Allison Hirst / Olu Arikawe
7	Section 18 loss of controlled stationery, keys or medicine	Updated throughout with new procedures and contact details. The federated risk management team split into the CCG quality team & the federated quality team	August 2019	Allison Hirst / Olu Arikawe
7	Section 21 References	References updated	August 2019	Allison Hirst / Olu Arikawe
7	Appendix 1	Fraud and corruption line added	August 2019	Allison Hirst / Olu Arikawe
7	Appendix 2	Removed – no longer relevant	August 2019	Allison Hirst / Olu Arikawe

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Policy Statement

<p>Background Statement</p>	<p>The purpose of this policy is to implement a co-ordinated and standardised approach to strategic, operational and clinical management of all processes involving the safe and secure handling of medicines and their use.</p> <p>This policy also details the appropriate measures to ensure the safe and secure handling of prescription stationery.</p> <p>This policy offers 'best practice' advice and guidance to ensure that medicines are handled safely and securely.</p>
<p>Responsibilities</p>	<p>Compliance with the policy will be the responsibility of all staff and providers of services involving medicines. GP Partners are responsible for ensuring that Standard Operating Procedures are in place for all clinical situations involving the handling of medicines; and that they are in line with best practice/guidance and relevant legislations.</p>
<p>Training</p>	<p>It is the responsibility of GP Partner(s) to ensure that appropriate mechanisms are in place to support the implementation of this policy, including appropriate training and maintenance of competency.</p>
<p>Dissemination</p>	<p>Lincolnshire Clinical Commissioning Groups GP Practices Website: www.lincolnshire.nhs.uk GPTeamNet (for Lincs West CCG only)</p>
<p>Resource implication</p>	<p>This policy has been developed in line with Department of Health and wider national guidance to ensure the appropriate and safe management of medicines within all GP practices in Lincolnshire. There are no identified additional resource implications.</p>

1. Introduction / Scope of the Policy

- 1.1 This policy aims to offer practical advice and outlines steps that must be taken to ensure that medicines are handled safely and securely within both dispensing and non-dispensing GP practices. However, some sections (e.g. dispensing) may not apply to non-dispensing GP practices.

This policy also details the appropriate measures to ensure the safe and secure handling of prescription stationery.

- 1.2 The policy is underpinned by key legislation, for example, the Medicines Act, the Misuse of Drugs Act and associated regulations, the Health and Safety at Work Act, the Control of Substances Hazardous to Health Regulations and the regulations relating to the disposal of hazardous and other controlled waste.
- 1.3 The four core principles that underpin the framework for the safe and secure handling of medicines (RPS guidance) are: establish assurance arrangements, ensure capacity and capability, seek assurance and continually improve. These have been considered in the development of this policy.
- 1.4 The GP Partner(s) has overall accountability for the safe and secure handling of medicines in the GP Practice. The senior management team (e.g. practice managers, dispensary manager and lead GP) supports this through corporate governance systems which are maintained and regularly reviewed.

The senior management team appoints a **named individual** who is responsible for the overall framework and policy standards for the safe and secure handling of medicines and prescription stationery in the practice. The named individual is of sufficient seniority, knowledge and skills to provide leadership and to promote awareness of the potential risks involved in the safe and secure handling of medicines and how they impact patient and public safety.

An **accountable individual** should also be appointed to ensure that all organisation requirements are reflected in operational frameworks, procedures and plans; and are fit-for-purpose. In smaller organisations, an individual may perform more than one of these roles, e.g. the named individual, may also be an accountable individual.

- 1.5 It is recognised that whilst individuals have a duty to ensure that medicines are handled safely and securely, the GP practice also has statutory responsibilities and a duty of care to staff and patients.
- 1.6 The named individual will define the systems to ensure that:-
- Standard Operating Procedures (SOPs) are validated for all service areas;
 - Staff involved in any aspect of medicines understand their responsibilities, are competent and have access to training if required;
 - Suitable devices and clothing to protect the patient and staff from identified, avoidable hazards is provided;
 - Facilities and equipment being utilised are provided and maintained to the required standards;
 - Systems for routine audit, reviews of accidents, errors and patient complaints relating to the handling of medicines are in place.
- 1.7 However it must be recognised that compliance with this policy does not override any individual responsibility of healthcare workers to ensure that their practice:-

- Complies with current legislation;
 - Follows guidance issued by the Department of Health, professional bodies (e.g. Nursing and Midwifery Council, Royal Pharmaceutical Society (RPS), General Pharmaceutical Council (GPhC), General Medical Council (GMC)) or other government departments such as the Home Office;
 - Manages the risks to patients, relatives, carers and staff arising from the use of medicines;
 - Staff must practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct if applicable.
- 1.8 The policy considers the processes associated with the physical handling of medicines, including ordering, storing, prescribing, administering, supplying, transporting, recording and disposing safely of medicines as it applies to GP practices.
- 1.9 The senior management team in the practice should promote an open and honest safety culture that supports the safe and secure handling of medicines and prescription stationery. This is reinforced by proactive audit and review, and by reporting, sharing, learning and taking action on patient safety incidents
- 1.10 It is the responsibility of the GP partners with support from the Senior Management Team and Lead GPs to ensure that SOPs are in place which:-
- Describe processes so that the SOP is comprehensive and reproducible.
 - Describe each element precisely, comprehensibly and unambiguously and indicate who is authorised to perform it.

2. Terminology

- 2.1 The term 'medicines' is used throughout the document as a generic term that covers all products that are administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing or monitoring illness, contraception or inducing anaesthesia.
- 2.2 The generic term 'patients' is used throughout to refer to people receiving medicines.
- 2.3 Prescription Stationery (or controlled stationery) is any paperwork such as requisition forms or prescription pads that can be used to obtain medicines. Any unauthorised use may lead to the fraudulent acquisition of medicines.
Electronic ordering systems must have similar levels of security (e.g. user specific passwords).

3. Ordering and Receipt of Medicines

- 3.1 Procedures should be in place to facilitate the timely and efficient ordering of medicines.
- 3.2 Nominated staff, with appropriate qualifications and competencies may order medicines from a number of sources including:-
- a local community pharmacy;
 - a pharmaceutical wholesaler;
 - directly from the manufacturer;
 - a hospital pharmacy;

- a dispensing doctor.
- 3.3 Written orders for stock medicines should be made on an official requisition, signed and dated by the authorised person ordering the medicine. Electronic ordering systems must ensure that a permanent record of the order is maintained.
 - 3.4 Verbal requests should not be made for any medicines supply.
 - 3.5 Order records / delivery notes should be retained for a minimum period of 2 years.
 - 3.6 On receipt of the medicines, the order should be checked by a suitably qualified person against the requisition / delivery note and any discrepancies investigated and documented. Packaging should be sealed and should show no sign of being tampered with. Depending on the outcome of any investigation, consideration should be given to reporting an untoward incident in accordance with local policy.
 - 3.7 Medicines should be checked that they are in date. Any short dated items should be noted and returned to the supplier imminently if they cannot be safely dispensed.
 - 3.8 All medicines should be put away as soon as possible, using stock rotation, into an appropriate storage area according to the level of security and storage condition required (see Storage and Security of medicine section).
 - 3.9 Controlled drugs (CDs) will need to be entered into the controlled drugs register where required and then stored in the controlled drugs cabinet.

4. Storage and Security of Medicines

- 4.1 Medicine storage should meet national guidance, manufacturers' and regulatory requirements. Governance arrangements are established and audit trails are in place to underpin the storage of medicines.
- 4.2 The accountable individual will be responsible for the safekeeping of all medicines stored in the practice.
- 4.3 Access to the medicines storage (cupboards or shelves) should be restricted to authorised staff only. Staff in any supervisory position should be aware of signs that may indicate abuse or diversion of medicines (e.g. changes in an individual's behaviour, regular unexplained absences from the work area, loss of stock or excessive ordering) and take appropriate action as locally defined.
- 4.4 The location of medicines cupboards should preferably be sited as follows:
 - in a room without direct access (e.g. door or window) to the exterior of the building;
 - where it is not obvious to prying eyes (e.g. not in front of a window or door);
 - adjacent to storage units of similar appearance;
 - in a room that can be secured when unattended;
 - away from sources of heat (e.g. radiators, hot water pipes or direct sunlight) and humidity (e.g. sinks);
 - in a position of good illumination.
- 4.5 All medicines, with the exception of medicines for emergency use and wound care products, must be stored in lockable cupboards, which comply with the current British Standards for Medicines Storage (BS 2881), at a temperature not exceeding 25°C.

- 4.6 For controlled drugs, the Misuse of Drugs (Safe Custody) regulations apply as detailed in the Controlled Drugs policy.
- 4.7 All CDs, including dispensed prescriptions containing CDs awaiting collection and returned medicines, must be stored in areas that comply with current regulations. The CD storage facility must have its own dedicated key. The key for the CD storage facility should be kept in control of the assigned person in charge when not in use or in a locked key safe. This key should be kept separate from other medicine keys.
- 4.8 Doctors' bags containing CDs must be locked at all times when not in use. The person in lawful possession of this bag or an individual authorised by them should always retain the keys. Doctors' bags must be stored in a safe manner when not in use to prevent unauthorised access, i.e. not left unattended in an unlocked consulting room. Doctors' bags containing CDs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods of time. If a bag is left unattended at any time in a car it should be locked and kept out of sight.
- 4.9 Refrigerated medicines should be stored as outlined in section 14.2.
- 4.10 All medicines must be stored in their original containers. They should not be transferred from one container to another.
- 4.11 Medicines that are for internal use (e.g. oral, injectables) and medicines for external use (e.g. medicated dressings, topicals) should be stored separately from each other in different medicines cupboards or different parts of the cupboard.
- 4.12 Injection ampoules and vials must be stored in the outer packaging in which they are supplied. It is good practice only to remove ampoules from their outer packaging at the time they are required and to avoid returning ampoules to boxes.
- 4.13 If medicines are stored in readiness for domiciliary visiting, there must be clear procedures for access to these, and for their replacement if used during the visit.
- 4.14 Adequate provision must be made to facilitate access to medicines in an emergency. The local storage arrangements will by necessity be a balance between quick access and the risks associated with misappropriation.
- 4.15 Once an emergency drug kit has been used it should be checked and missing items replaced as soon as possible. There must be a system of checks in place for emergency kits that are assembled and stored ready for use, to ensure that they are complete and any medicine included is correct and within its expiry date.
- 4.16 Regular expiry dates checks should be carried out for all medicines. Stock must be rotated according to the expiry date so that the oldest stock is used first.
- Out of date CD stock should be segregated from normal stock but remain in safe storage until an authorised person can destroy the product.
- 4.17 Community staff have responsibility to advise patients and their carers on the safe and secure storage of medicines in the home.
- 4.18 All incidents involving a breach of security that cause actual or potential loss or theft of medicines should be investigated and the appropriate corrective and preventative action taken in accordance with local SOPs. This may involve contacting the police.

5. Initiation of Treatment / Prescribing

5.1 Medication may be administered or supplied in one of four ways:

- The production of a prescription by an authorised prescriber.
- A Patient Specific Direction (PSD) by an authorised prescriber.
- An approved Patient Group Direction (PGD).
- By buying Pharmacy medicines or over the counter (OTC) medicines from a registered pharmacy or OTC medicines from retail outlets.

Certain specified medicines can also be administered without the need for a prescription, PSD or PGD for the purpose of saving a life in an emergency e.g. adrenaline injection.

5.2 Prescriptions

5.2.1 Medicines can be prescribed by UK registered doctors, dentists, and registered supplementary / independent prescribers e.g. nurses or pharmacists.

5.2.2 Dentists can legally write a prescription for any Prescription Only Medicines (POM), but when prescribing on an NHS dental prescription they are restricted to medicines listed in the Dental Prescriber's Formulary. The formulary is contained within the BNF (British National Formulary).

5.2.3 Independent non-medical prescribers must only prescribe within their scope of practice and competency and supplementary prescribers only under clinical management plans (individualised for each patient) and within their scope of practice. Further guidance is available in the Non-Medical Prescribing Policy.

5.2.4 All prescribers must be registered with the NHSBSA (NHS Business Services Authority) before undertaking prescribing within NHS.

5.2.5 Midwives (Prescription-Only Medicines [Human Use] Order 1977) may prescribe from a limited range of medicines.

5.2.6 The law contains "exemptions" for certain professionals to administer, sell or supply from a list of specific medicines on their own initiative, when that would normally be restricted to independent prescribers. These groups include paramedics, podiatrists & orthoptists.

5.2.7 Any person issued with a blank prescription form will be responsible for its security.

5.3 Patient Specific Direction (PSD)

A patient specific direction is a written instruction from a doctor, dentist or appropriate independent prescriber to enable medicines to be supplied or administered to a named patient.

5.4 Patient Group Direction (PGD)

5.4.1 A patient group direction is a written instruction to enable a healthcare professional to supply and/or administer a medicine to groups of patients who may not be individually identified before presentation for treatment.

5.4.2 If treatment is being initiated for administration or supply under a PGD, then the requirements of that PGD must be adhered to as a legal document authorising medicines

use under the Medicines Act (and amendments) and recorded in the healthcare records as being supplied under PGD.

- 5.4.3 A record of all medicines prescribed and administered to patients or supplied via PGD or PSD must be maintained in the relevant case notes or documentation e.g. nursing or medical notes. If the medicine is a CD then a record of administration must also be recorded in the Controlled Drugs Register.

5.5 Prescription Writing

- 5.5.1 When generating a prescription, the current guidelines (Human Medicines Regulations 2012) for prescription writing should be followed. There is also comprehensive guidance on prescription writing in the BNF. It is important that prescription legal requirements are met in accordance with the class of drug being prescribed. This will help to prevent any inconvenience for the patient in obtaining their medication.

- 5.5.2 Prescriptions must be written / printed legibly in ink or otherwise so as to be indelible. Prescriptions must be printed / written on the current approved prescription form appropriate to the prescriber. If any changes are required on a prescription form then consideration should be given to rewriting / reprinting it. If this is not feasible then changes must be written clearly and initialled by the prescriber. Under no circumstances should correction fluid e.g. Tippex® be used to change a prescription form.

- 5.5.3 Each prescription must be signed in ink by the prescriber. The exception to this is electronic prescribing where prescriptions are:

- created in electronic form;
- signed with an advanced electronic signature;
- sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries).

- 5.5.4 Prescriptions must state:

- The appropriate date.
- The name and address of the patient.
- The address of the prescriber.
- The type of prescriber.

- 5.5.5 To ensure correct patient identification, use multiple identifiers like first name, last name, address and date of birth.

- 5.5.6 It is a legal requirement to state the age of children under 12 years if a prescription only medicine (POM) is being prescribed. On computer issued prescriptions, for children under 5 the age should be printed in years and months. The age of adults over 60 should also be printed. It would be preferable to always state the age and date of birth of the patient.

- 5.5.7 Where appropriate the prescriber should state the current weight of a child to enable the dose prescribed to be checked.

- 5.5.8 Prescriptions for controlled drugs have additional legal requirements.

- 5.5.9 For computer-issued prescriptions, the recommendations of the Joint GP Information Technology Committee should also be noted. See section on computer issued prescriptions in the current BNF under prescription writing.

- 5.5.10 The following are held to be good practice:

- The names of drugs should be written clearly and not abbreviated. Medicines should be prescribed by approved names unless the brand name is clinically significant.
- The strength or quantity to be contained in the tablets, capsules, lozenges etc. should be stated by the prescriber. In particular, strength of liquid preparations should be clearly stated (e.g. 125mg/5ml).
- The unnecessary use of a decimal point should be avoided e.g. 3mg and not 3.0mg. Quantities less than 1 gram should be written in milligrams e.g. 500mg not 0.5g. Quantities less than 1mg should be written in micrograms eg. 100 micrograms not 0.1mg. When decimals are unavoidable a zero should be written in front of the decimal point where there is no other figure e.g. 0.5 ml and not .5 ml.
- ‘Micrograms’ and ‘nanograms’ should always be written in full. Similarly ‘units’ should be not be abbreviated. Abbreviations such as ‘U’ and ‘IU’ should never be used.
- The term “millilitre” (ml or mL) is used in medicine and pharmacy and the cubic centimetre should not be used.
- Dose and dose frequency should be stated; avoid vague dosage direction, i.e. as necessary, as before, as directed. A minimum dose interval should be specified. Particular attention should be paid when prescribing once weekly medicine, e.g. methotrexate for rheumatoid arthritis or bisphosphonates for osteoporosis.
- The quantity to be supplied should be clearly stated either by directly writing the total quantity or by indicating the number of days treatment required (this requires a specific dose to be clearly stated).
- Although directions should preferably be in English without abbreviation, it is recognised that some Latin abbreviations are used.
- Due regard should be taken of any known hypersensitivity to medicines.

5.5.11 Medicines should be prescribed in line with local and national guidelines and the Lincolnshire Joint Formulary.

5.5.12 Prescribing for self, family or colleagues should only be done in emergency or exceptional circumstances.

5.5.13 Non-medical prescribers are advised not to issue private (non NHS) prescriptions due to the lack of a clear audit trail.

6. Licensed / Unlicensed Medicines

6.1 Unlicensed medicines may be prescribed by medical prescribers; however responsibility for the use of these medicines rests with the prescriber, who remains professionally accountable for their judgement. The prescriber should inform the patient that the product does not have a marketing authorisation. Further guidance is incorporated within PACE bulletin Vol 6 No 11 – “Alternatives to prescribing unlicensed pharmaceutical specials September 2012” or the current Lincolnshire Joint Formulary www.lincolnshirejointformulary.nhs.uk

6.2 Nurse and Pharmacist Independent Non-Medical Prescribers can prescribe unlicensed medicines for their patients, on the same basis as medical prescribers and dentists (DH 2010). The responsibility for the use of these medicines rests with the prescriber, who remains professionally accountable. Licensed products should be used for preference. The

prescriber should agree the treatment choice with the patient and a clear rationale for choice of medicine should be documented.

6.3 Supplementary prescribers may prescribe an unlicensed medication as part of a clinical management plan; however, reference must first be made to the guidance outlined within the PACE bulletin and the following criteria must be followed:

- The doctor / dentist acting as the independent prescriber must have agreed the plan and must agree to take responsibility for prescribing the unlicensed medicine.
- An alternative, licensed medicine would not meet the patient's need.
- There is sufficient robust evidence to support use.
- The patient has agreed to the use of an unlicensed product.
- The medication chosen and the reason for doing so is clearly documented.

7. Specials

7.1 Special-order products (more commonly known as "specials") are made-to-order unlicensed medicines designed to meet the needs of individual patients.

7.2 Specials are unlicensed and, like any unlicensed medicine, should ONLY be prescribed where a licensed alternative does not meet the clinical needs of the patient.

7.3 Prescribers are potentially liable for any adverse event or harm arising from the use of an unlicensed special and are professionally accountable for their judgement in prescribing an unlicensed product for their patient.

8. Dispensing

8.1 Dispensing services should be provided in a way that can be reasonably expected to support the safe, effective and appropriate supply and use of medicines.

8.2 Where dispensing takes place, this must be within an agreed medical or pharmaceutical contractual framework.

8.3 As a minimum standard, each service / healthcare setting must have Standard Operating Procedures (SOPs) in place as detailed in the relevant contractual arrangements.

8.4 Medicines must not be transferred from one container to another, except in a designated dispensary area.

8.5 The dispensing processes should be FMD (Falsified Medicines Directive) compliant with the current legislation. Dispensaries are currently awaiting IT support for compliance.

9. Administration of Medication

9.1 Process of Administration

- 9.1.1 No person should administer any medicine unless they are competent to do so and are acting within their sphere of professional practice. The Standard Operating Procedure (SOP) should define the qualifications and competencies required by the staff, including the provision for training student professionals.
- 9.1.2 A health care professional must not administer medicines without the authorisation of a prescriber, a patient specific direction (PSD), a dispensed medicine, or a patient group direction (PGD), unless they have legal exemptions during the course of their professional practice (e.g. midwives, podiatrists). Pre-registration practitioners must only administer or supply medicines under direct supervision (NMC 2008).
- 9.1.3 The identity of each medicine should be clear at all times up to and including the point of administration.
- 9.1.4 Medicines dispensed for an individual patient must only be administered to that patient (supplies labelled for individual patients must not be shared).
- 9.1.5 When selecting the medicine, the following should be checked and any concerns clarified before proceeding:
- name of the medicine;
 - strength;
 - form;
 - expiry date.
- 9.1.7 Medication must be prepared for administration at the time it is due to be given. Medication for multiple patients must not be prepared in advance.
- 9.1.8 Before administration, the following should be checked and any concerns raised with the prescriber before proceeding:
- patient's name;
 - NHS number;
 - age and weight if appropriate;
 - any allergies / hypersensitivities / previous adverse drug reactions
 - date and time the dose is due;
 - name of medicine, dose and frequency;
 - time of previous dose if any;
 - route of administration;
 - signature of prescriber or requirements of a patient group direction.
- All aspects of patient consent must be considered
- 9.1.9 A record of each medicine administered to a patient should be made and the administering person identified.
- 9.1.10 Any omitted, refused or wasted doses should be documented.
- 9.1.11 Any dose prepared for administration and subsequently not given should be destroyed. If a controlled drug is prepared and not used it must be destroyed by denaturing and placing in a sharps bin and a record must be made in the register in accordance with the Controlled Drug Policy.
- 9.1.12 Medicines shall not be returned to the container from which they were taken.

- 9.1.13 Omissions and refusals should be reported to the prescriber if it is considered that the non-administration may affect the patient's condition.
- 9.1.14 For additional information regarding the administration of injectable medicines further reference should be made to Section 10 within this document.
- 9.1.15 A 5ml spoon should only be used for doses of 5ml or multiples thereof.
- 9.1.16 When patients or carers are required to administer oral liquid medicines with a syringe, they should always be supplied with an oral syringe.

9.2 Administration – Verbal Orders

- 9.2.1 Instruction by telephone to administer a previously unprescribed medicine is not acceptable, except in a life threatening situation.
- 9.2.2 A verbal order may **not** be given or taken for a controlled drug (CD) under any circumstances.
- 9.2.3 In exceptional circumstances, where the medication has been prescribed previously (not including CD) and the prescriber is unable to issue a new prescription but where changes to the dose are clinically necessary, technology, such as fax or email, may be used to confirm changes to the original prescription. However, the practitioner must be satisfied that the prescriber's absence is unavoidable and change is essential. A clear record should be made in the relevant organisational documentation.
- 9.2.4 Written confirmation of the dosage adjustment must be provided within 24 hours by the prescriber who authorised the change remotely.
- 9.2.5 In exceptional circumstances a medical practitioner may need to prescribe remotely for a previously unprescribed medicine – the receipt of a fax or email must confirm the prescription before it is administered or dispensed. The confirmation of the prescription change must be signed by the prescriber who gave the remote order within 24 hours.
- 9.2.6 Non medical prescribers may not prescribe remotely a medication which has not been previously prescribed if he or she has not assessed the patient, except in life threatening situations (NMC 2007).
- 9.2.7 The use of written instructions (for example fax or email) is the preferred method of dealing with such emergency situations if at all possible. If a fax is used ensure it is a 'safe haven' fax.

10. Use of Injectable Medicines

10.1 Prescribing of injectable medicines

- 10.1.1 Medicines should only be given by injection when the practicality and appropriateness of other routes of administration have been excluded. The use of this route should be regularly reviewed in favour of switching to oral administration as soon as clinically appropriate (NPSA 2007).
- 10.1.2 Prescriptions for injections must clearly specify the medicine name, dose, frequency and route of administration. Where relevant, the prescription, or a readily available local protocol, must specify the following: name and volume of diluent and/or infusion fluid, concentration of final infusion, rate of administration, duration and rate control pump or device to be used.

10.1.3 The practitioner who prepares a medicine for injection must be the practitioner who gives the injection. The exception to this is where a student healthcare professional is being supervised by a qualified healthcare professional in which circumstances the student healthcare professional may prepare the injection under the direct supervision of the qualified healthcare professional who will then administer the injection.

10.2 Mixing of medicines

10.2.1 The Medicines and Healthcare products Regulatory Agency (2010) (MHRA) states that the mixing of two or more separate medicinal products will result in a new, unlicensed product if one product cannot be described as a vehicle for the administration of the other e.g. as a reconstitution or diluting agent.

10.2.2 Mixing two licensed medicines, for example in a syringe driver, results in a new, unlicensed product being administered.

10.2.3 Following consultation by the MHRA, medicines legislation was amended:

1. To enable doctors and dentists to direct other healthcare practitioners to mix medicines;
2. To allow Nurse and Independent Prescribers to mix medicines themselves and to direct others to mix;
3. To enable Supplementary Prescribers to mix medicines themselves and to direct others to mix, only where this is clearly outlined within an individualised patient Clinical Management Plan;
4. To allow all registered healthcare professionals who are independent prescribers to prescribe unlicensed medicines for their patients;

10.2.4 Optometrist prescribers are not authorised to prescribe unlicensed medicines (MHRA 2007).

10.2.5 Mixing should be avoided where possible; it must only be undertaken when clinically appropriate and essential to meet the needs of the patient.

10.2.6 All healthcare practitioners who prescribe, mix and administer unlicensed medicines must be satisfied that they have sufficient information to administer the drug safely and wherever possible ensure there is acceptable published evidence for the use of that product for the intended indication.

10.2.7 All practitioners who are required to mix medicines should ensure that they are competent to do so and are acting within their sphere of professional practice. Local guidance should be in place to support all those practitioners' involved in the mixing of medicines.

10.2.8 The changes in legislation do not apply to Patient Group Directions (PGDs). Mixing of two licensed medicines, resulting in a new unlicensed product, cannot be supplied or administered under a PGD. Only licensed products can be supplied / administered against a PGD.

10.3 Supply and storage

10.3.1 A risk assessment of all injectable medicines must be undertaken by a senior practitioner to determine the safest presentation and location for storage and preparation.

10.3.2 Ready-to-administer or ready-to-use products should be stocked in all clinical areas in preference to those needing preparation before use, or those which are classified as high-risk. Concentrates should only be supplied where safer alternatives are not available.

10.3.3 Multiple use of an unpreserved injectable medicine should be eliminated. Most injectable medicines are licensed for 'once-only' use. Unless the manufacturer's label specifically

indicates that the injection contains a preservative, the container should only be used to prepare a single dose for a single patient on one occasion.

10.4 Preparation

10.4.1 Injections should be prepared only by healthcare staff who:

- understand the risks involved
- have been trained to use safe procedures
- have demonstrated their competence for the task.

10.4.2 Preparation should only take place if there is a prescription; a Patient Group Direction (PGD) or other written instruction, for example Patient Specific Direction (PSD). Essential information must be available about the product(s) and processes needed for safe preparation and administration.

10.4.3 Only one unlabeled medicine must be handled at one time.

10.4.4 Medical devices with luer connectors must be used only for preparation and administration of injections. Medicines for oral/enteral use must be prepared and administered using only devices with non-luer connections.

10.4.5 Risk assessment is required to identify those products representing the highest risk to patients at the time of preparation. Consideration must be given to the use of safer products and systems, for example, double-checking.

10.5 Administration of injectable medicines

10.5.1 An up to date Standard Operating Procedure (SOP) should be available and accessible within all clinical areas to support all stages of the safe and secure handling of injectable medicines.

10.5.2 The SOP should be referred to at all times and should clearly outline the qualifications and competencies required by practitioners to enable them to undertake this role.

10.5.3 The SOP should clearly outline the requirements for prescribing, preparation and administration of an injectable medicine.

10.5.4 Practitioners must not prepare substances for injection in advance of their immediate use or administer medication drawn up into a syringe by another practitioner when not in their presence (NMC 2007).

10.5.5 Injections should be administered only by healthcare staff who understand the risks involved, have been trained to use safe procedures, and who have demonstrated their competence for the task.

10.5.6 No practitioner should administer any injectable medicine unless they have been assessed as competent to do so and are acting within their scope of professional practice. All practitioners are accountable for their practice including acts and omissions regardless of advice or direction received from another professional (NMC 2006).

10.5.7 Before administration, the following should be available: a current prescription, a Patient Group Direction (PGD) or other written instructions for example a patient specific direction (PSD), essential technical information and a prepared and labelled injectable medicine. The patient's identity and details should be confirmed.

10.6 Training

10.6.1 All practitioners and healthcare staff who prescribe, prepare and administer injectable medicines, including insulin, must have access to or receive training and have the appropriate work competencies to undertake their duties safely.

10.6.2 All individuals are responsible for maintaining their professional knowledge and working within the limits of their competence.

10.7 Injectable medicines audit

10.7.1 Practice Managers and Lead GPs should ensure that they have systems in place for routine audit and review of incidents.

11. Administration and / or supply of medicines under a PGD

11.1 Reference should be made to the organisation's SOP and Policy for the development and control of PGDs.

11.2 The supply and administration of medicines under Patient Group Directions (PGDs) should only be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety (HSC 2000/026).

11.3 When supplying or administering a medicine under a Patient Group Direction, the patient must fall exactly into the criteria determined by the PGD. If not the patient must be referred in line with the guidelines outlined within the individual PGD.

11.4 If a medicine is unlicensed it should only be administered against a patient specific prescription and not under a PGD.

11.5 Medication that is licensed but used outside of its licensed indications may be administered under a PGD if such use is exceptional, justified by best practice and the status of the product clearly described. In such circumstances the patient should be informed that it is an unlicensed use; and of any alternative treatments that are licensed.

11.6 Service leads have responsibility for ensuring that only fully competent, qualified and trained professionals operate within the PGD; and that the PGD is in date and contains the legally required authorising signatures.

11.7 The use of PGDs does not remove inherent professional obligations or accountability. It is the responsibility of each practitioner to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

12. Transport and Security

- 12.1 Medicines should not be transported unless it is absolutely necessary to do so and transfers should be initiated through a system in which all orders and dispatches are recorded.
- 12.2 If staff are authorised to transport medicines in the course of their duties, the competencies and equipment required to ensure that this occurs with minimum risk must be documented in the service SOP as dependent on local circumstances.
- 12.3 Medicines in transit, whether professionals' own stock or an individual supply, should not be left unattended even in a locked vehicle.
- 12.4 Cold chain control, within the limits appropriate to the individual product, should be maintained for items requiring refrigeration. See section 14.2

Medicines should not be removed from refrigerators until the individual transporting the medicine is available and ready to go.
- 12.5 Arrangements for the transport of controlled drugs must comply with the current legal requirements and as specified in the Controlled Drugs Policy. Reference should be made to the CCG's Controlled Drugs Policy for specific issues in relation to the transportation of controlled drugs.

13. Return and Disposal of Unwanted Medicines

- 13.1 The storage, carriage and consignment of waste are all subject to stringent controls via Environmental, Waste, Transport and Health and Safety legislation.
- 13.2 Guidance on the disposal of pharmaceutical waste is governed by the 'Environment and Sustainability Health Technical Memorandum 07 – 01: Safe Management of Healthcare Waste (2013). Reference should be made to this document. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167976/HTM_07-01_Final.pdf
- 13.3 Clinical waste generated by GPs and dentists and medicines waiting to be disposed of, including those returned by patients to community pharmacies or dispensing doctors should be placed in the containers provided by the company contracted to uplift waste on behalf of the CCG and disposed of as part of the standard uplift schedule.
- 13.4 There are additional requirements for the return and disposal of controlled drugs. Reference should be made to the CCG CD Policy (The Management of Controlled Drugs in Primary Care in Lincolnshire) relating to the prescribing, supply, storage and disposal of controlled drugs. This information should also be detailed within local operating procedures relating to the management of controlled drugs.
- 13.5 When disposing of solid non-hazardous pharmaceutical waste (e.g. tablets and capsules) blister packs can be removed from outer cartons, but individual tablets and capsules should not be removed from blisters.
- 13.6 Liquids should generally not be decanted and mixed. Where liquids are being discarded they should be retained within their individual containers and placed in leak proof waste bins provided for the purpose.
- 13.7 All policies and procedures of the company currently contracted to uplift waste for the CCG must be followed.

13.8 Protective equipment such as gloves will also need to be provided and used.

13.9 Medicines that have been issued directly to a patient should not be reused.

14. Storage, Distribution and Disposal of Vaccines

14.1 Management of vaccines

14.1.1 This section should be read in conjunction with Chapter Three of the 'Green Book' (DH 2006) accessible via <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3> and Public Health England's document 'Protocol for Ordering, Storing and Handling Vaccines (2014) accessible via <https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

These resources are updated periodically and all practitioners should ensure they keep themselves up to date with changes.

14.1.2 This section outlines a summary of guidance provided by the 'Green Book', on the storage, transport and equipment necessary for the maintenance of the cold chain as well as highlighting the need for monitoring and audit.

14.1.3 To ensure that the trend of low levels of disease notification continues into the future, it is essential to maintain the efficacy of the vaccines used. This requires maintenance of the 'cold chain' to ensure that the optimum temperature range for vaccine storage (between +2°C and +8 °C) is maintained throughout the distribution process from manufacture to user. Fluctuations and breaks in the cold chain can result in a reduction of the efficacy of the vaccine and a potential failure to produce satisfactory levels of immunity.

14.1.4 Vaccines are biological substances that may lose their effectiveness quickly if at any time they become too hot or too cold. Vaccines are biodegradable over time and storage outside the recommended temperature range may cause a loss of potency which cannot be reversed.

14.1.5 It is essential that all those handling vaccines follow appropriate recommendation and policy to ensure cold chain compliance. Appropriate guidance and policy includes the Public Health England Protocol for ordering, storing and handling vaccines March 2014. This document was summarised for nurses in June 2017 and the Leicestershire and Lincolnshire Policy for maintaining the vaccine cold chain November 2017.

14.1.6 At least two named, trained people (one from the nursing team and one from administration or dispensary) need to be responsible for ordering, receipt and care of vaccines including rotation and checking of expiry dates as well as safe storage of vaccines and recording of refrigerator temperatures (PH England 2014). Vaccines must be stored in a refrigerator promptly after delivery and maintenance of the cold chain must be continued at all stages.

14.1.7 All procedures being followed for storage, distribution and disposal of vaccines should be monitored and regular audits undertaken to ensure they comply with expected standards.

14.1.8 Some vaccines are packaged in multiple quantities. Care should be taken to order correctly to avoid waste.

14.1.9 Vaccines for routine immunisation programmes must be ordered via the ImmForm website as set out in the 'Public Health England Protocol for Ordering, Storing and Handling Vaccines' published March 2014 accessed via

14.1.10 All other vaccines are ordered directly from the manufacturer or through pharmacies and wholesalers. Details of suppliers are shown in the associated chapters of the 'Green Book'.

14.2 Storage of vaccines and other refrigerated medicines

14.2.1 In general vaccines / medicines should be stored at temperatures between +2° - +8°C, a mid range of +5°C is good practice.

14.2.2 Vaccines should be appropriately stored to protect from light. Exposure to ultraviolet light is known to cause loss of potency.

14.2.3 All vaccines are sensitive to extremes of heat and cold. Heat will speed up the decline in potency of most vaccines and will therefore reduce shelf life whilst freezing causes deterioration and can give rise to increased adverse reactions due to alteration of the composition of the vaccine or contamination as a result of cracks appearing in the vial or syringe.

14.2.4 Avoid over ordering, stockpiling and overfilling refrigerators. It is important that air must be able to circulate around the packages.

14.2.5 All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Refrigerators must be lockable or within a room that can be kept locked when not occupied by a staff member. Vaccines should never be left unattended.

14.2.6 Vaccines should be kept in their original packaging to retain batch numbers and expiry dates. The package also helps to protect against changes in light and temperature.

14.2.7 Ordinary domestic refrigerators must not be used. All service areas should have a validated vaccine fridge.

14.2.8 Refrigerators for the storage of vaccines should not be situated near a radiator or heat source as this may affect their efficiency.

14.2.9 Regular servicing of the refrigerator should be undertaken and documentation should be maintained to demonstrate regular servicing, defrosting and cleaning. Ice should not be allowed to build up as this reduces effectiveness.

14.2.10 During defrosting or cleaning, vaccines should be transferred to another refrigerator or placed in an approved cool box to ensure that they remain under 8°C. They should not be left in the refrigerator where the temperature will fluctuate and water could leak onto packaging.

14.2.11 Vaccines should only be replaced in the refrigerator once the refrigerator has returned to the correct temperature.

14.2.12 Food, drink and clinical specimens must never be stored in the same refrigerator as vaccines.

14.2.13 Opening of the refrigerator door should be kept to a minimum to ensure maintenance of a constant temperature.

14.2.14 Refrigerators must be maintained and defrosted in line with the manufacturers' guidelines.

- 14.2.15 Steps should be taken to reduce the probability of accidental interruption of electricity supply, such as installing a switchless socket or clearly labelling the vaccine refrigerator plug.
- 14.2.16 In the event of refrigeration breakdown or interruption in electricity supply then arrangements must be in place for alternative storage facilities to be made available.
- 14.2.17 As a minimum the fridge should be serviced annually and the temperature gauge should be calibrated.
- 14.2.18 The temperature within the vaccine refrigerator must be monitored continually with a maximum–minimum thermometer. This will identify when the temperature may have been outside the recommended range. Digital thermometers are the most reliable. More sophisticated temperature-recording devices are now available, including alarmed digital maximum–minimum thermometers and data loggers.
- 14.2.18 A sample refrigerator temperature record chart can be accessed via NHS England Policy and procedure for Maintaining the Vaccine cold chain and / or via 'The Green Book'. This can be accessed at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_OW.pdf

14.3 Monitoring of Stock

- 14.3.1 Appropriate documentation should be completed to record receipt of vaccines. This includes vaccine types, brands, quantities, batch number and expiry dates.
- 14.3.2 Fridge stocks should be monitored once per week by the designated person to avoid over ordering and accumulation of waste / stockpiling.
- 14.3.3 Vaccine stock should be audited and recorded every month.
- 14.3.4 It is best practice to order small quantities on a regular basis and hold no more than two weeks supply of vaccines at any time as per the Protocol for ordering, storing and handling vaccines (Public Health England 2014).
- 14.3.5 Out of date stock should be labelled clearly, removed from the refrigerator and destroyed as soon as possible in line with local procedures.
- 14.3.6 Vaccines must never be used when past their expiry date.

14.4 Thermometers

- 14.4.1 All fridges should ideally have two thermometers, one of which is a max / min thermometer independent of the mains power.
- 14.4.2 If only one thermometer is used then a monthly check should be undertaken to ensure the accuracy of the calibration.
- 14.4.3 Care should be taken to ensure that the thermometer probe cable does not interfere with the door seal. This could cause the temperature of the fridge to fall outside of the permitted range.
- 14.4.4 Temperatures in the refrigerator should be monitored and recorded as described for best practice in the Protocol for Ordering, Storing and Handling Vaccines' (Public Health England 2014).

14.4.5 Thermometer calibration should be checked monthly against an independently powered external thermometer and records maintained for audit purposes.

14.5 Storage in a cool box

14.5.1 Domestic cool boxes should not be used to store, distribute or transport vaccines.

14.5.2 Should vaccines be required to be stored in cool boxes, e.g. for transportation, then a validated cool box with a facility to record a maximum / minimum temperature either electronic (i.e. plug in to a car cigarette lighter socket) or insulated box with cool packs (never ice packs) from a recognised medical supply company, should be used.

14.5.3 Specific manufacturer's instructions should be adhered to at all times.

14.5.4 Vaccines must be kept in their original packaging and wrapped in insulation material (for example bubble wrap) before being placed in a cool box. This will ensure that where cool packs are used they do not come into direct contact with the vaccines.

14.5.5 Cool boxes should only be packed immediately prior to transportation.

14.5.6 Vaccines should remain in the closed cool box until required for use / or placed in an appropriate refrigerator if the cool box is not electronic.

14.6 In the event of a fridge failure

14.6.1 The NHS England screening and immunisation team for Lincolnshire, Leicestershire and Northamptonshire should be informed and any follow up advice given should be acted upon. They can be contacted on 0113 824 9543 or england.limms@nhs.net (Note this is the generic email for all immunisation enquiries). More information on fridge failure is included in their policy – Policy and procedure for maintaining the vaccine cold chain.

14.6.2 All vaccines affected by the incident should be maintained within the cold chain but separated from all other vaccines. These vaccines should be labelled to ensure clear identification.

14.6.3 The incident should be clearly documented and reported in accordance with the Practice's Incident reporting policy.

14.6.4 The incident should be reported on the ImmForm website if appropriate: <http://www.immform.dh.gov.uk>

14.7 Spillage

14.7.1 Reference should be made to local policy and COSHH which should outline all cleaning requirements when dealing with spillage.

14.7.2 Initially the spillage should be soaked up with paper towels. Appropriate personal protective equipment (PPE) should always be worn. Care should be taken to avoid puncture wounds from associated glass or needles.

14.8 Disposal / Vaccine Waste

14.8.1 All vaccines should be used within the period recommended by the manufacturer or should be disposed of by sealing in a puncture – resistant sharps box intended for this purpose.

14.8.2 Sharps boxes should be disposed of once they are two-thirds full.

14.8.3 Any wastage of vaccine as a result of disruption of the cold chain must be reported to the NHS England Screening and Immunisation Team (Telephone number 0113 824 9543). If

the vaccine has been ordered from ImmForm then the wasted vaccine needs to also be recorded on the ImmForm site.

14.8.4 Any disruption to the cold chain must be recorded as an incident in accordance with the Practice's incident reporting policy.

14.9 Storage of Immunoglobulins

14.9.1 Immunoglobulins should be refrigerated immediately upon receipt and stored at temperatures of 2°C to 8°C.

14.9.2 They should be protected from light and should not be frozen.

14.10 Equipment suppliers

14.10.1 Advice on suppliers of refrigeration equipment and accessories is available from:

*Immunisation Policy, Monitoring and Surveillance.
Department of Health
Area 512
Wellington House
133 – 155 Waterloo Road
London
SE1 8UG
Tel: 020 7972 1227*

15. Untoward Incidents

15.1 Untoward incidents involving medicines

15.1.1 To reduce medication errors, prescribing, dispensing / supply and administration should be performed by separate healthcare professionals. Exceptionally where clinical circumstances make it necessary and in the best interests of the patient the same healthcare professional can be responsible for the prescribing and supply / administration of medicines; Where this occurs an audit trail, documents and processes are in place to limit errors (RPS 2019).

15.1.2 To prevent duplication of the administration of medicines healthcare records should be completed at the time of administration / refusal or as soon as possible thereafter and are clear, legible, accessible and auditable (RPS 2019)

15.1.3 If there is any risk of harm to an individual due to an incident involving medicines, priority must be given to the clinical care of that person(s).

15.1.4 **Any** incident or near miss in which medicines are involved must be reported and managed in accordance with the Practice's incident reporting policy.

15.1.5 The incident must immediately be reported to and investigated by an appropriately identified professional within the Practice.

15.1.6 Any incident identified to meet the serious incident reporting criteria outlined in the NHS England Serious Incident Framework should be escalated immediately to the appropriate CCG Quality Lead.

15.1.7 On notification of a serious incident the CCG will assess and undertake the necessary reporting arrangements on STEIS (Strategic Executive Information System). The CCG will

provide support and guidance to the Practice as required to support the level of investigation required for a serious incident.

15.2 Administration errors

15.2.1 As soon as it is realised that there has been an error of medicine administration:

The appropriate prescriber should be contacted and when necessary, remedial action taken to ensure the safety of the patient. The patient and / or carer should be informed of the error, remedial action and possible consequences.

Supporting statements may be required from all staff concerned. These are essential if there is any possibility of serious injury to the patient or of litigation. This is in addition to the responsibilities outlined above.

15.3 Adverse reactions to drugs

15.3.1 If any patient experiences an adverse drug reaction (ADR), action must be taken to remedy any resulting harm caused by the reaction. The reaction must be recorded in the patient notes and the prescriber should be notified.

15.3.2 An anaphylaxis pack must always be readily available when administering vaccines or other injections.

15.3.3 Any drug may produce unwanted or unexpected adverse reactions. Detection and reporting of these is of vital importance. Doctors, dentists, nurses, pharmacists, coroners and therapists are urged to report suspected adverse reactions on yellow cards to the Medicines and Healthcare products Regulatory Agency (MHRA). Patients and carers can also now report ADRs to the MHRA using the yellow card system <http://www.mhra.gov.uk>

15.3.4 Yellow cards can be found in the back of the British National Formulary (BNF) and online at the following link <http://www.yellowcard.gov.uk>.

15.3.5 All suspected adverse drug reactions to “black triangle” drugs and any serious or unusual suspected reactions to established products should be reported.

15.3.6 Reporting should be carried out for all prescribed drugs, medicines obtained over the counter and herbal medicines.

15.3.7 Any adverse reactions should also be reported in line with the Practice’s Incident reporting policy and procedure.

15.4 Defective medicines

15.4.1 Official notification of a defective medicine is issued as a Drug Alert from the Medicines and Healthcare products Regulatory Agency (MHRA) or the manufacturer / supplier. These are disseminated by NHSE to GPs and various other primary care services.

15.4.2 The designated Practice Manager (or Responsible Pharmacist in the community setting) must ensure that there are systems in place to check if the defective medicine is in use within their healthcare service area.

15.4.3 If found, the defective medicine must be withdrawn from use within the required timescale for action. Medicines are usually quarantined and returned to the manufacturer as directed.

15.4.4 If any member of staff suspects a defect in a medicine it should be reported to the Defective Medicines Report Centre at the MHRA and / or the manufacturer.

- 15.4.5 Reports on suspected defective medicinal products should include the brand or the non-proprietary name, the name of the manufacturer or supplier, the strength and dosage form of the product, the product licence number, the batch number and the nature of the defect.
- 15.4.6 The person who discovers the defect must ensure that the product, container and other packaging are retained. If the defect has been discovered following reconstitution or mixing with another preparation, then the mixture, remaining unmixed constituents, and all containers and other packaging must also be retained. All retained materials must be placed in a sealed container, clearly marked "Do Not Use", and stored in a secure place. Other potentially affected stock should be withdrawn. Follow the directions given by the MHRA / manufacturer.
- 15.4.7 If the defective medicine has been administered to a patient the prescriber should be notified and reported in accordance with the Practice's incident reporting policy.
- 15.4.8 If any staff member suspects that a package containing medicines has been tampered with prior to them receiving it then he / she should refuse to accept it and speak to the practice (or dispensing) manager as appropriate.

16. Training

- 16.1 All healthcare professionals and other staff who deal with medicines must undertake regular training as identified through the local training matrix to ensure they have the appropriate competencies to carry out their role safely and in line with local SOPs and service specific requirements.
- 16.2 All individuals are responsible for keeping up to date and maintaining their own professional knowledge and working within the limits of their competence.

17. Prescription Stationery

17.1 Ordering and receipt of Prescription Stationery

- 17.1.1 Prescription stationery is ordered directly from Primary Care Services England (PCSE) <http://pcse.england.nhs.uk/> and delivered by courier.
- 17.1.2 Upon delivery, and prior to the delivery driver leaving, a full check of the items should be made against the delivery note. Any discrepancies should be noted on the driver's delivery note, queried with PCSE and documented in the records.
- 17.1.3 The named prescriber or other nominated person should sign and date for receipt of the prescription forms. Serial numbers of the prescription forms should be recorded.
- 17.1.4 Prescription stationery is designated a secure item and should be stored in a locked cabinet within a lockable room or area.
- 17.1.5 Any further transfer of prescription forms e.g. from the secure store to individual prescriber should also be on the basis of signatures, dates and recording of serial numbers.
- 17.1.6 Records of serial numbers received and issued should be retained in accordance with local retention policies.

17.2 Security of prescription forms

- 17.2.1 Prescription forms have a legal status, remain the property of the NHS and should be used appropriately.
- 17.2.2 Prescription forms have a number of functions including:
- legal entitlement for the possession of a prescription only medicine
 - transfer of confidential data from prescriber to dispenser
 - claim/authorisation of payment for goods and services
- 17.2.3 Qualified practitioners are responsible for the security and safe handling of their prescription forms / pads. Prescription forms / pads should always be stored securely when not in use.
- 17.2.4 Under no circumstances should blank prescription forms be pre-signed before use.
- 17.2.5 Patients should not be left unattended in any area where they could potentially access prescription forms (either blank or completed).
- 17.2.6 Where it is necessary for prescribers to carry prescription forms e.g. for home visits, the number carried should be kept to a minimum. Before leaving the premises, the serial numbers of any prescription forms or pads they are carrying should be recorded. Prescription forms should be carried in a locked case. Where it is necessary to leave prescription forms in a car they should be stored out-of-sight in the boot of a locked car. Do not leave prescription forms in vehicles overnight.
- 17.2.7 At the end of the day / session prescription forms should be stored as securely as possible, as a minimum this should be in a locked drawer / room. The serial number of the top and bottom prescription form should be recorded for prescription pads in drawers or prescription forms in printer trays, and checked at the next session to ensure that no prescription forms are missing.
- 17.2.8 To ensure clarity regarding the identity of prescriber and the organisation for which they are working:
- GP Locums should use the prescription forms of the senior partner, and legibly add their own name, as well as signing the prescription.
 - Non - medical prescribers (NMPs) should only use a prescription pad / form which clearly shows their name, prescribing status and individual PIN / registration number.
 - Community nurses will need to ensure they add the appropriate GP practice code to the prescription form.
 - Prescribers using prescription forms that carry an organisation's name and prescribing code in place of an individual prescriber's name and code should legibly add their own name as well as signing the prescription.
 - Prescribers working for more than one employer or in more than one setting must have a separate prescription pad for each organisation/scenario.
- 17.2.9 Appendix 1 provides an Aide Memoir for prescribers regarding security of prescription stationery.

17.3 Destruction of Prescription forms

- 17.3.1 Personalised forms which are no longer in use should be securely destroyed by shredding before being put into confidential waste, with the appropriate records kept. The person who destroys the forms should make a record of the forms destroyed. This would also apply when a prescriber leaves a practice or service.

- 17.3.2 For those staff remaining as temporary staff / locums prescription pads should be securely stored.
- 17.3.3 Records of forms destroyed should be kept in accordance with local retention policies.
- 17.3.4 For more detailed guidance in all aspects of prescription forms refer to 'Counter Fraud Authority, Management and control of prescription forms. 'A guide for prescribers and health organisations, March 2018'.

18. Loss of controlled stationery, keys or medicine

18.1 Custody and safe keeping of keys

- 18.1.1 At all times a designated member of staff will have responsibility for custody of keys to medicines cupboards / controlled stationery.
- 18.1.2 Keys will be kept securely in key cupboards with restricted access to authorised staff.

18.2 Loss of controlled stationery, keys or medicine

- 18.2.1 On discovering a loss, the member of staff must immediately inform the designated manager. The member of staff should complete a relevant incident report form.
- 18.2.2 The designated manager will immediately investigate any loss (including consideration of notifying the police) and follow the Practice's incident reporting procedure.

18.3 Loss of keys

- 18.3.1 If necessary a duplicate set of keys may be issued, to allow continued provision of clinical services, until such time as the original keys are located.
- 18.3.2 If duplicate keys are not available or if the lost keys are not found, the authorised person in charge in conjunction with their manager should arrange for new locks to be fitted and for the cupboard to be effectively secured. Maintenance staff should not be allowed to work on the cupboard unsupervised.

18.4 Prescription Fraud

- 18.4.1 Prescriptions for medicines may be stolen / forged or otherwise fraudulently obtained or amended. All staff should be alert to this possibility. Practices, pharmacies, GP dispensaries etc., must have systems in place to ensure that prescriptions are obtained only by the patient designated on the prescription form or an appropriate deputy.
- 18.4.2 Pharmacists have particular responsibility for verifying prescriptions for authenticity. Unusual expensive items, large quantities or doses, evidence of alteration (that are not signed and dated by the prescriber) should always be queried with the prescriber. The level of suspicion should be raised for medicines liable to abuse or where the prescriber is not local / not known. Verifying the prescription includes checking prescriber details including registration and phone number. Pharmacists and dispensers should keep an up-to-date file of details of local prescribers including contact numbers and sample signatures. Specimen signatures of non-medical prescribers for CCG staff can be obtained from the Optum Medicine Management and Optimisation Service.

18.4.3 If a Pharmacist has concerns regarding a prescription which cannot be allayed by contact with the prescriber, the concern should be reported to the local Counter-Fraud Specialist for NHSE and / or the NHS Fraud and Corruption Reporting Line - 0800 028 4060 or online <https://cfa.nhs.uk/reportfraud>. If warranted [e.g. an attempt to fraudulently obtain a Controlled Drug (CD)], the police should be contacted immediately. A report should also be sent to NHSE CDAO via the online CD reporting tool www.cdreporting.co.uk. Any action taken should not compromise staff safety.

18.5 Loss of Prescription Pad

18.5.1 Where prescription forms are lost (whether or not theft is suspected), this must be reported immediately to the practice manager.

18.5.2 The practice manager should immediately inform:

1. The police.
2. The controlled drugs accountable officer 0113 8249614 /8248678 or England.centralmidlands-cd@nhs.net
3. The NHS England Contracting Team at Lincoln 0113 8248642 or england.primarycarelincoln@nhs.net. This generic email is monitored daily.

18.5.3 Any report of loss of prescription forms should as a minimum include: date and time of loss / place where loss occurred / type and quantity of prescription stationery / serial numbers / details of to whom the incident has been reported.

18.5.4 The NHS England Contracting Team at Lincoln is responsible for:

- requesting the practitioner signs prescriptions in a designated alternative colour
- informing the CD Accountable Officer (if not already contacted)
- notifying the CD Liaison Officer at Lincoln Police Headquarters (if not already contacted)
- informing the local Counter Fraud Specialist for NHS England and / or the NHS Counter Fraud Authority – reporting line 0800 028 4060 or online <https://cfa.nhs.uk/reportfraud>
- informing Primary Care Services England (PCSE)
- informing Optum Medicines Management and Optimisation Service via the MMO inbox – ohs.mmo.sharedservice@nhs.net
- informing the CCG Quality Team
- alerting local pharmacies
- if 'local pharmacies' include 'cross-border pharmacies' the appropriate department in neighbouring CCG(s) must be contacted.

18.5.5 The NHS England Contracting Team at Lincoln should maintain contact with their opposite numbers in bordering CCGs to ensure cross-border intelligence is shared regarding lost prescription forms and suspected drug users (see 18.6 below), and to ensure that relevant information reaches all appropriate individuals and organisations.

18.5.6 Independent Contractors should report the incident as soon as possible to the NHSE contracting team for Lincoln via email or phone above.

18.5.7 Practice staff must complete an incident reporting form in accordance with their own incident reporting policy.

18.5.8 The Practice where the loss occurred must investigate how this happened and ensure appropriate measures are put in place to prevent this happening again.

18.5.9 The practice should share their investigation findings with the CCG Quality Team and Federated Quality Team.

18.5.10 The CCG Quality Team will assess the investigation findings with the Federated Quality Team to establish if appropriate actions have been taken by the Practice

18.6 Suspected Drug User Alerts

18.6.1 Where an individual is suspected of attempting to fraudulently obtain prescriptions or medicines, these suspicions should be reported to The NHS England Contracting Team at Lincoln. A process similar to that for lost or stolen prescription forms will then be instigated.

18.6.2 The NHS England Contracting Team at Lincoln is responsible for alerts regarding persons trying to fraudulently obtain prescriptions or medicines. Mechanisms should be in place to alert all prescribers, NMPs, pharmacies and GP dispensaries in the defined appropriate geographical area (Lincolnshire CCGs and neighbouring CCGs). Alerts are shared between other CCGs as appropriate. Suspected Drug User Alerts should also be circulated to the Optum Medicine Management and Optimisation Service and the Accountable Officer for Controlled Drugs.

18.7 Investigation

18.7.1 The Practice will investigate any loss or theft of prescription pads in line with their own incident reporting policy. Serious incidents are to be escalated and investigated in line with the NHSE Serious Incident Framework.

18.7.2 The CCG Quality Team is alerted to loss of prescription forms from the NHSE Contracting Team at Lincoln. The investigation findings should be shared with the CCG Quality Team. Where a report is anticipated but not forthcoming, the CCG Quality Team can offer support to facilitate the production and transmission of a report.

18.7.3 For further information on tackling fraud and managing security around Prescriptions including who to contact, see NHS Counter Fraud Authority (March 2018) The Management and control of prescription forms: a guide for prescribers and health organisations.

19. Implementation Strategy

19.1 Following approval, this policy will be posted on GP TeamNet (Lincs West CCG) and the CCG websites to aid dissemination.

19.2 Staff will be advised that this policy replaces all previous policies.

20. Audit / Monitoring / Review

20.1 The implementation of this policy will be audited by the practice (manager) through audit.

20.2 A random survey of relevant practitioner groups should be undertaken to assess whether the policy has been implemented / actioned. All monitoring and operational audits should be presented to the relevant organisational body for information and action as appropriate.

20.3 This policy should be reviewed in light of changes with local guidance, national guidance, national legislation and best practice.

21. Key References

- British National Formulary No 76 March 2019
- Medicines, Ethics and Practice Edition 43, July 2019
- Human Medicines Regulations 2012
- British standard specification for cupboards for the storage of medicines in healthcare premises, 1989:
<http://www.oxfordhealthformulary.nhs.uk/docs/British%20Standard%20BS2881for%20Medicine%20Cupboards.pdf>
- Counter Fraud Authority (2018) Management and control of prescription forms: A guide for prescribers and health organisations
- DH (2006) *Immunisation against infectious disease (The Green Book)* The Stationary Office. Accessed via <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>
- DH (2013) Environment and Sustainability Health Technical Memorandum 07-01: *Safe Management of Healthcare waste*
- Lincolnshire CCG Policy for the development and control of Patient Group Directions, Jan 2019
- Lincolnshire Joint Formulary www.lincolnshirejointformulary.nhs.uk
- Health Protection Agency (2012) *Vaccine incident guidance; actions to take in response to vaccine errors*
- MHRA (2014) The supply of unlicensed medicinal products (Specials) MHRA Guidance Note 14
- NICE (2013) Good practice guidance *Patient Group Directions*.
- National Prescribing Centre (2010) *Mixing of medicines prior to administration in clinical practice – responding to legislative changes* access via http://www.npc.nhs.uk/improving_safety/mixing_meds/ 11th August 2016.
- NHS England Leicestershire and Lincolnshire Area Team (2017) *Policy and Procedure for Maintaining the Vaccine Cold Chain*
- NPSA (2007) *Patient Safety Alert 19 Promoting safer management and administration of liquid medicines via oral and other enteral routes*
- NPSA (2007) *Patient Safety Alert 20 Promoting safer use of injectable medicines*
- Optum Controlled Drugs policy (2019)
- Optum Non Medical Prescriber policy (2019)

- PACE bulletin Vol 6 No 11. *Alternatives to prescribing unlicensed pharmaceutical specials*. September 2012.
- Public Health England (2014) '*Protocol for Ordering, Storing and Handling Vaccines*' accessed via <http://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>
- Public Health England (2014) '*ImmForm Helpsheet 18. Fridge failures and stock incidents*'
- Public Health England (2014) '*What to do if issues with vaccine storage management are identified during a Care Quality Commission inspection*'.
- Royal Pharmaceutical Society (2018) Professional guidance on the safe and secure handling of medicines.
- Royal Pharmaceutical Society (Jan 2019) Professional guidance on the administration of medicines in healthcare settings

Appendix 1

Security of prescription forms

Aide-memoire for prescribers

- Be aware that blank prescription forms in the wrong hands are like a blank cheque with an extremely high street value.
- Prescription form stock in possession of prescribers should always be stored securely when not in use.
- Prescribers should keep a record of the serial numbers of prescription forms issued to them. The first and last serial numbers of pads should be recorded.
- Prescribers should be encouraged to use prescription forms in number sequence order to aid tracking of usage, should a potential loss occur.
- To reduce the risk of misuse, blank prescriptions should never be pre-signed.
- Patients, temporary staff and visitors should never be left alone with prescription forms or allowed into secure areas where forms are stored.
- Prescribers on home visits should, before leaving the practice premises, record the serial numbers of any prescription forms/pads they are carrying. Only a small number of prescription forms should be taken on home visits – ideally between 6 and 10 – to minimise the potential loss.
- Prescribers on home visits/working in the community should take suitable precautions to prevent the loss or theft of prescription forms. Keep them out of sight when not in use and do not leave any prescription forms in vehicles overnight.
- Prescribers using the FP10PCD forms should exercise extra caution as there is greater potential for misuse of these forms.
- Blank or signed prescription forms should never be left at patients' homes, care homes or community pharmacies for GP or locum visits.
- Personalised forms which are no longer in use should be securely destroyed (e.g. by shredding) before being put into confidential waste, with appropriate records kept.
- Spoiled or cancelled prescription forms should be retained for audit purposes.
- Any suspected fraud incident involving prescriptions should be reported to either the Fraud and Corruption Reporting Line 0800 028 4060 or via the online reporting system at <https://cfa.nhs.uk/reportfraud>
- In the event of a loss or theft of prescription form stock, local procedures should be followed and the practice, the Lincoln Contracting team, Controlled Drugs Accountable Officer and the police should be notified as required. The incident should also be recorded on the practice's incident reporting system.