NHS
Sheffield
Clinical Commissioning Group

# NHS Sheffield CCG Medicines Code 2017-2020

## A Guide to the Safe and Secure Handling of Medicines

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## 1. Introduction

The NHS Sheffield CCG Medicines Code makes available a good practice guide to the membership GP practices and other agencies commissioned by the CCG to provide primary care medical services across Sheffield. The code supports providers to have appropriate policies and procedures for the safe and secure prescribing, administration, storage and handling of medicines. This will enable them to comply with current legislation and the requirements of local risk management and clinical governance frameworks, with respect to the management of medicines.

This code is the first to be issued by NHS Sheffield Clinical Commissioning Group. It is based on the third issue of NHS Sheffield PCT's Medicines Code (2011), first issued August 2003. This has been extensively revised to reflect the new NHS structures and changes in legislation relating to medicines.

The relevant legislation concerning the safe and secure handling of medicines includes:

- The Medicines Act, 1968 partially repealed by:

  The Human Medicines Regulations, 2012 (SI 2012 /1916)
  http://www.legislation.gov.uk/uksi/2012/1916/contents/made

- The Misuse of Drugs Act, 1971

- The Misuse of Drugs Regulations, 2001

- The Health Act, 2006

- The Controlled Drugs (Supervision of Management and Use) Regulations, 2006

The code also considers the recommendations included in the following guidance:

- NMC The Code: standards for conduct, performance and ethics for nurses and midwives (2015)

- NMC Standards for medicines management (2007)

- Revised Duthie Report - The Safe and Secure Handling of Medicines: a team approach, 2005

- Patient Group Directions HSC2000/026

- NICE MPG2 Patient Group Directions, 2013

- A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England, 2006

- Guidelines issued by the GMC (General Medical Council) and BMA (British Medical Association)

- CQC Nigel's Surgery: Tips and mythbusters for GP practices (September 2016)

- NICE NG46 Controlled drugs: safe use and management, 2016

- Control of Substances Hazardous to Health (COSHH) Regulations, amended 2002

- Waste Regulations

## 2. Overall Principles and Control

All healthcare staff are accountable for properly discharging their duties and responsibilities in relation to medicines, including storage, handling, prescribing, and administration. Senior staff are responsible for ensuring that duties are only delegated to those with the appropriate knowledge and competence to carry out that duty.

The Medicines Code provides an overarching guidance for the use of medicines; however local procedures such as standard operating procedures (SOPs) or protocols are recommended. Further information to support development of these may be obtained from the Medicines Management Team and from the Medicines and Prescribing section on the CCG intranet:

http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/medicines-index.htm

**The categories of medicines covered within this Medicines Code include:**

- Controlled drugs, which includes those drugs controlled under The Misuse of Drugs Regulations 2001.

- All other medicines and medicinal products prepared for administration to patients, which are controlled under the Human Medicines Regulation 2012.

- All complementary medicines e.g. herbal or homeopathic medicines. These products are used for therapeutic purposes and require the same safeguards as other medicines.

- Other pharmaceutical preparations such as disinfectant, reagents and other preparations not used directly to treat patients that also require rigorous safeguards.

- Some substances designated as Medical Devices under the medical devices regulations but which are administered to patients as part of a medical or surgical procedure.

All medicines must be handled appropriately. Medicines which are part of a clinical trial must be handled in the same way but may be subject to more stringent requirements included within individual clinical trial protocols.

**Principles of Control**

An auditable trail for the procurement, ordering, delivery, storage, distribution, supply, administration and disposal of medicines should be established.

When a medicine changes hands there should be clear procedures on responsibilities, records and stock reconciliation.

An assigned person should be appointed with responsibility for ensuring the security of medicines. No other person should have access to medicine cupboards unless authorised to do so.

The keys to the medicine cupboard should be kept in a secure place, as decided by the assigned person. Access to the keys must be limited to those persons authorised by the assigned person.

Responsibility for the safe keeping of medicines rests with those who have means of access; records should be kept of all those having access.

All medicines must be kept locked away, and cupboards must be kept locked when not in use. Cabinets must meet the requirements set out within current British Standard(s).

Freezers and refrigerators used for the storage of medicines must have temperature monitoring.

Controlled stationary including order books and blank prescription forms should be kept in a locked cupboard.

**It is advised that samples of medicines and dressings are not accepted by primary care staff for use on patients.**

The loss of medicines, tampering or breach of security of the storage of medicines must be reported to the appropriate assigned person as soon as practicable.

Stocks of medicines should be used in rotation and expiry dates checked regularly to avoid waste.

All out-of-date stock medicines and any stock medicines no longer required should be disposed of appropriately in accordance with the healthcare waste management regulations.

Patients should be advised to return unused medicines to community pharmacies for safe destruction (note that community pharmacies cannot accept sharps returned from patients who are self-injecting).

Medicines prepared for use but not given must be disposed of; they must not be returned to their original container.

All medicines must be transferred or delivered in secure containers wherever possible. Appropriate documentation should be kept and signatures obtained.

Further details of control measures are included in relevant sections of this code.

## 3. Accountability

### 3.1 Responsibilities of Healthcare Professionals

All healthcare professionals are personally accountable for their practice according to their code of professional conduct or other code of ethics. They must be able to justify their decisions to their peers, and to any person or organisation, which may be affected by their actions, including individual patients, the public, their employers, and other health care professionals. Duties can be delegated but responsibility cannot be delegated.

Practitioners in training must be given every opportunity to become competent in medicines related activities under appropriate supervision. The supervising practitioner has responsibility for medicines procedures at such times.

#### 3.1.1 Authorised Prescribers

Medical doctors and other professionals who are authorised prescribers are responsible for prescribing medicines for patients. They must comply with current legislation and professional guidance.

They are responsible for prescribing in accordance with the marketing authorisation (product licence) or within their competence if prescribing off-licence, taking into account the patient's medical condition, allergic status and contraindications or cautions for use of a drug. Prescribers should prescribe within the scope of practice within their role.

### 3.2 Other Health Care Workers

Health care workers, who are not members of a professional body, e.g. health care assistants, may be involved in medicine administration in accordance with the directions of a prescriber.

All health care workers handling medicines for administration must be deemed competent to do so by the appropriate manager and must adhere to service protocols.

Protocols must define the competency assessment process, maintenance and reassessment of competency and specify the medicines involved. They must be authorised by the clinical governance lead.

### 3.3 Registered Pharmacists and Pharmacy Technicians

Pharmacists and pharmacy technicians in the Medicines Management Team support member GP practices in managing the safe, effective and economic use of medicines.
Registered pharmacists and registered pharmacy technicians are personally accountable for their professional practice and are expected to adhere to

standards defined by the General Pharmaceutical Council and within this Medicines Code.

### 3.3.1 Accountable Officer for Controlled Drugs

The Accountable Officer for Controlled Drugs post now sits with NHS England following the 2013 reorganisation of NHS commissioning. The changes are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2013. These take account of the establishment of CCGs and set out their obligations in respect of the safe management and use of controlled drugs.

The key change is that, unlike a PCT, a CCG is not a 'designated body' and therefore does not require the appointment and registration with the Care Quality Commission of an Accountable Officer for Controlled Drugs. It is instead a 'responsible body' and is required to co-operate with the Controlled Drugs Accountable Officer (CDAO) role at NHS England.

It is the CDAO at NHS England (covering Yorkshire and the Humber) who must ensure the safe use and management of controlled drugs in Sheffield and the CCG has a duty to co-operate with CDAO. Co-operation between the CCG and the CDAO was set out in the memorandum of understanding which came initially to the Quality Assurance Committee at the June 2013 meeting, and again (following updating) in December 2013.

The NHS England CDAO covering Yorkshire and the Humber has determined that Sheffield should continue to operate a Controlled Drugs Local Intelligence Network (CDLIN) and this is hosted by NHS Sheffield CCG.

## 4. Overview of Prescribing, Administration & Supply of Medicines

### 4.1 Independent Prescribing

Independent prescribers are responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required including prescribing appropriate treatment where necessary.

Doctors and dentists are independent prescribers. There are two types of independent nurse prescribers (see below). Pharmacist independent prescribers have been registered from January 2007; optometrists from June 2008; physiotherapists and chiropodists/podiatrists from August 2013 and therapeutic radiographers from February 2016.
For further information please refer to the CCG's non medical prescribing protocol.
http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/non-medical-prescribing.htm

**Community Practitioner Nurse Prescribers**

District nurses and health visitors (DNs/HVs) who have completed the appropriate training and are registered as a Community Practitioner Nurse Prescriber with the NMC may prescribe independently from a limited formulary of products designed to meet the needs of their patients (the Nurse Prescribers' Formulary (NPF) for Community Practitioners). This consists of appliances, dressings and some medicines, including Prescription Only Medicines specified in Schedule 3 of the POM Order. Details of the NPF can be found in the BNF and the Drug Tariff. All DNs and HVs receive training on prescribing from the NPF as part of their basic training.

Community practitioner nurse prescribers must not prescribe medicines, dressings or appliances for use outside of their licensed indications. The **only** exception to this is the prescribing of nystatin suspension off-label for neonates. Where community practitioner nurse prescribers are absolutely clear that the diagnosis is one of oral thrush, they may prescribe nystatin at the dose recommended in the British National Formulary for Children (BNFC).

**Nurse Independent Prescribers (NIPs)**

A nurse independent prescriber is:

- A nurse who is registered as a nurse, midwife or specialist community public health nurse.
- Has successfully completed an accredited training course and has recorded this with the NMC as a nurse independent prescriber.
- Has support from their employing organisation to take on an independent nurse prescribing role.

NIPs are able to prescribe any medicine for any medical condition, including all controlled drugs except diamorphine, dipipanone or cocaine for the treatment of addiction. NIPs may also prescribe medicines “off label” or those without a UK marketing authorisation (product licence). They must only ever prescribe within their own level of experience and competence, acting in accordance with the NMC’s “The code: professional standards of practice and behaviour for nurses and midwives”.

**Pharmacist Independent Prescribers (PIPs)**

A Pharmacist Independent Prescriber is:

- A registered pharmacist, whose name is held on the membership register of the General Pharmaceutical Council (GPhC), who has successfully completed an accredited course and has this recorded with the GPhC as a pharmacist independent prescriber.
- Has support from their employing organisation to take on an independent pharmacist prescribing role.

All registered pharmacists are able to train as a pharmacist independent prescriber. PIPs can prescribe any medicine for any medical condition, including all controlled drugs except diamorphine, dipipanone or cocaine for the treatment of addiction. PIPs may also prescribe medicines “off label” or those without a UK marketing authorisation (product licence).They must only ever prescribe within their own level of experience and competence and in accordance with the regulatory standards set by the GPhC.

## 4.2 Supplementary Prescribing

Supplementary prescribers take responsibility for implementing an agreed patient-specific clinical management plan, which has been agreed between the patient and the independent prescriber (doctor or dentist). There are no legal restrictions on the clinical conditions that may be treated under supplementary prescribing. However it is generally expected to be used for the management of chronic medical conditions and health needs.

There is no specific formulary or list of medicines for supplementary prescribing. Providing medicines are able to be prescribed by a doctor or dentist on the NHS, and that they are referred to in the patient's clinical management plan, supplementary prescribers are able to prescribe

- All General Sales List (GSL) medicines and all Pharmacy (P) medicines
- Appliances and devices that may be prescribed by GPs
- Foods and other borderline substances approved by the Advisory Committee on Borderline Substances

- All Prescription Only Medicines (POMs), including controlled drugs

- Medicines for use outside their licensed indications (i.e. “off label” prescribing), medicines without a UK marketing authorisation (“unlicensed” medicines), “black triangle” drugs and drugs marked “less suitable for prescribing” in the BNF.

There are currently three types of supplementary prescribers:

- Pharmacist supplementary prescribers
- Supplementary nurse prescribers
- Allied health professionals including physiotherapist, chiropodist, podiatrist, radiographer, optometrist and dietitian supplementary prescribers

### 4.3 Patient Group Directions

A Patient Group Direction (PGD) is a written instruction for the supply or administration of a licensed prescription only medicine to a group of patients who may not be individually identified before presentation for treatment (HSC 2000/026). It is not a form of prescribing and there is no specific training that health professionals must undertake, although individual PGDs may require certain competencies.

The majority of clinical care should still be provided on an individual, patient specific basis. PGDs should be reserved for those limited situations where there is an advantage for patient care without compromising patient safety.

More information on PGDs can be found in Chapter 16.

### 4.4 Patient Specific Directions

A patient specific direction is a “written direction” from an independent prescriber for a medicine or appliance to be supplied or administered to a named patient. This may be a simple instruction in the patient’s notes or against the patient’s kardex (if in a hospital, intermediate care facility or care home). Where a patient specific direction exists, there is no need for a PGD or a clinical management plan.

The BMA has issued guidance on Patient Group and Patient Specific Directions (2016)
https://www.bma.org.uk/advice/employment/gp-practices/service-provision/prescribing/patient-group-directions

## 4.5 Mixing of medicines

The Medicines and Healthcare products Regulatory Agency (MHRA) put in place changes to medicines regulations that enable mixing of medicines prior to administration in clinical practice. These changes became effective on 21 December 2009.

The changes enable:

- Doctors and dentists, who can already mix medicines themselves, to direct others to mix
- Nurse and pharmacist independent prescribers to mix medicines themselves and to direct others to mix
- Supplementary prescribers to mix medicines themselves and to direct others to mix, but only where that preparation forms part of the clinical management plan for an individual patient
- Nurse and pharmacist independent prescribers to prescribe unlicensed medicines for their patients, on the same basis as doctors and dentists (and supplementary prescribers if part of a clinical management plan).

The legal changes define mixing as “the combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient.”

These changes apply not only to palliative care, but to all clinical areas where the mixing of medicines prior to administration is accepted practice and supported by the employer’s policies for the delivery of healthcare.

For further information is available from DH Gateway ref:14330:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213885/dh_116360.pdf

## 5. Prescribing Medicines

See section 4 for an overview of prescribing, administration and supply of medicines.

### 5.1 Accountability

#### Non-Medical Prescribers

Non-medical prescribers remain accountable within their professional code of conduct or code of ethics.

Practice or service based non-medical prescribers may only issue prescriptions for patients registered with their own practice/service. CCG employed non-medical prescribers usually only issue prescriptions for patients registered with GP practices within the CCG, unless they have a contract to provide services otherwise. Non-medical prescribers should only prescribe for the visiting relatives of patients if they are temporarily registered with the practice concerned.

#### Medical Prescribers

Medical prescribers remain accountable to the GMC and must comply with their professional code of conduct.

Prescribing should be within the appropriate marketing authorisation (product licence) of the medicine. Where this is not the case, prescribing should be in accordance with evidence based practice or expert opinion.

Medical prescribers usually only issue NHS prescriptions for patients registered with GP practices within the CCG, unless they have a contract to provide services otherwise. Medical prescribers should only prescribe for the visiting relatives of patients if they are temporarily registered with the practice concerned.

### 5.2 Prescriptions

#### 5.2.1 Prescription Forms

Medical prescribers must prescribe for NHS patients using the standard FP10SS form (green). For prescribing by instalments including Schedule 2 controlled drugs and buprenorphine or diazepam by instalment, prescribers should use form FP10MDA-SS (blue).

Non-medical prescribers may prescribe on a standard FP10SS form (green) using the GP practice or service clinical computer system, provided this is set up to annotate the required prescriber details.

Nurse and pharmacist independent prescribers may also use the FP10 prescription forms, annotated with “Nurse Independent / Supplementary Prescriber” or “Pharmacist Independent / Supplementary Prescriber”.

Non-medical prescribers who work in more than one practice or service must have a separate prescription pad for each practice/service, with the correct information in the identification details area of the prescription form.

CCG employed prescribers who work across different practices can use one pad, but must complete the relevant practice number for the patient. If a CCG employed prescriber works for more than one employer, a separate pad would be required for each employer or setting.

### 5.2.2 Repeatable Prescribing Under NHS Repeat Dispensing Arrangements (RDA)

A repeatable prescription form allows items to be provided more than once. It must:

- state the number of times that items may be dispensed
- be generated by a computer
- be signed by a repeatable prescriber. It is also the clinical authority to supply a medicine in the format specified in the Regulations.
- Repeatable prescriptions may not be hand written

A batch issue is a form that is produced at the same time and has on it the same date as the repeatable prescription. The term ‘associated’ indicates that it is one of several batch issues that are linked to a repeatable prescription.

A batch issue must:

- be generated by a computer
- NOT be signed by a repeatable prescriber

The associated batch issues form a sequence of batch issues. The number on a batch issue indicates the number of times that the medicines or appliances ordered on the repeatable prescription can be dispensed. It will also have a number relating to its place in the sequence of batch issues.

See 5.2.6 for detailed information on RDA

### 5.2.3 Ordering & Recording Prescription Forms

Please see Appendix 2 for the procedure for ordering prescription pads.

### 5.2.4 Handling and Security of Prescription Forms

Prescription forms are controlled stationary and must be obtained, stored securely and issued only to the individual prescriber. It is advisable to hold only minimal stocks of prescription forms.

Single sheet prescription forms should be afforded the same security controls as prescription pads. It must be recognised that these forms are acceptable in handwritten form, so it is not advisable to leave the forms in printer trays when not in use or overnight. Prescribers are responsible for the security of these forms once issued to them, and should ensure they are securely locked away when not in use. Patients, temporary staff and visitors should never be left alone with prescription forms or allowed into secure areas where forms are stored. If there is concern over existing printer security, consideration should be given to fitting a security device to the printer to prevent theft of forms from the printer tray, or locating the printer in an area where patients do not have access.

The CCG (for CCG employed staff), practice or service and individual prescribers should keep a record of the serial numbers of prescriptions issued. The first and last serial numbers of each pad should be recorded. Blank prescriptions forms should *never* be pre-signed.

It is the responsibility of each prescriber to ensure the security of their prescription pads at all times. When on duty, the prescriptions must remain in the possession of the prescriber at all times. Prescriptions are less likely to be stolen from (locked) secure stationary cupboards than from desks, bags or cars. When not in use prescriptions should be kept in a locked drawer within the surgery or the home.

In the event of loss or suspected theft prescribers must report this immediately to NHS England Y&H office. The police should be contacted directly out of hours.

Employers must keep up to date lists of prescribers employed by them. Practices /services must notify the CCG immediately of any prescriber in their employment who is no longer carrying out prescribing duties. It is the responsibility of the employer:

- to ensure that no further prescription pads are ordered for a prescriber who has left employment or been suspended from prescribing duties;
- to recover, record and securely destroy all unused prescription forms issued to that prescriber relating to that employment.

### 5.2.5 Prescription Requirements

Refer to British National Formulary (BNF) for Guidance on Prescribing.
https://www.medicinescomplete.com/mc/bnf/current/PHP97234-guidance-on-prescribing.htm

- Prescriptions must be in indelible ink (this includes typewritten and computer generated and carbon copied) and once completed, must be signed in indelible ink by the practitioner giving the prescription.

- The prescription must include the name of the doctor or non-medical prescriber responsible for the prescription. For a non-medical prescriber this is the name of the non-medical prescriber who has signed the prescription.

- The prescription must include the name and address and the telephone number of the surgery /service for GPs and practice /service employed non-medical prescribers; for CCG employed staff the name and address of the CCG/organisation.

- The reference number (practice / service code) for the practice / service where the patient is registered.

- The CCG's unique code.

- A telephone contact number for the prescriber.

- For non-medical prescribers, a registration or PIN number as appropriate.

- The prescription must include the appropriate date.

- The prescription must include such particulars as to indicate whether the practitioner is a doctor or non-medical prescriber.

- The prescription must state the name of the patient (surname, forename and other initials); their address; and the age of the patient if under 12. It is also recommended that the age of the patient should be specified in those over 60 years and for those less than 5 years the age should be printed in years and months.

- The generic name of the medicine(s) on the prescription should be used except in the case of e.g. dressings, ostomy appliances or combinations of drugs where there is no generic name or where use of the generic name would result in confusion as to which product was required. Some preparations should be prescribed by brand when bio-availability differences in different product brands would cause a problem e.g. lithium. See Sheffield Formulary Appendix 6 for further information

- In general, names of drugs and preparations should be written in full. Unofficial abbreviations should not be used as they may be misinterpreted.

- The dose must be clearly stated. Prescribers should specify the dose by using mg (milligrams) or micrograms (written in full) and avoid the use of decimal points where possible.

- Particular care should be taken when prescribing paediatric doses.

- The quantity to be supplied must be clearly stated.

- The directions for use should be stated, i.e. timing, frequency of administration and route of administration.

- Any additional directions for use should be stated including supplementary warnings or advice.

- The directions “as required” or “as directed” should be avoided. If "as required" directions are used, the maximum dose of the medicines within a 24-hour period ideally must be stated on the prescription and the minimum interval between doses; the indication should be specified where appropriate.

- For topical preparations, the area to be covered should be specified.

- For hand written prescriptions, a line should be drawn under each item and a diagonal line should be drawn through the unused remaining blank area of the prescription. In the case of computer generated prescriptions there should be mechanisms in place to cancel out unused space on the prescription.

- Prescriptions, other than those for controlled drugs, should not be dispensed after the end of the period of six months from the appropriate date, unless it is a repeatable prescription. In this case it should not be dispensed for the first time after the end of that period and must be dispensed according to the directions contained on the prescription.

- Prescriptions for controlled drugs listed in schedule 2 or 3 of the Misuse of Drugs Regulations 1985 must be written in accordance with the requirements of those regulations (see section 17).

### 5.2.6 Repeat Dispensing Under NHS Repeat Dispensing Arrangements (RDA)

#### 5.2.6.1 Patient Selection

Repeat dispensing is a voluntary facility and not all patients will be suitable or wish to use repeat dispensing. Careful selection of the patient group is essential for the arrangements to work. Contact the CCG Medicines Management Team (MMT) to support patient selection and consent prior to setting up the scheme.

**What medicines or appliances can be prescribed as a part of the RDA?**

All medicines except scheduled 2 and 3 controlled drugs within the meaning of the Misuse of Drugs Act 1971 can be prescribed using the RDA. Appliances that can be prescribed on an FP10 can be prescribed as part of the RDA.

If changes are made to a current repeatable prescription then the prescriber will need to follow practice procedures to include:

- Removing the patient from the RDA until they are stable
- Cancelling the current repeatable prescription and issuing a new repeatable prescription and batch issues for the required medicines.
- Informing the pharmacist of the change to allow them to destroy the remaining batch issues and send the previous repeatable prescription to the BSA.

Patient safety is paramount. Consult the MMT for more information about clinical governance issues around managing minor medication changes in the RDA.

### 5.2.6.2 Repeat Dispensing – for prescribers

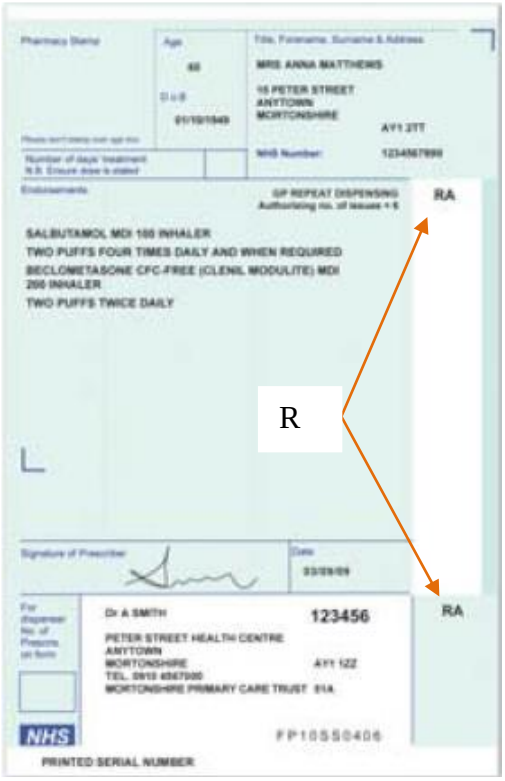
The following is a description of the repeat dispensing service, the specification of which is set out in the terms of service contained in the National Health Service (General Medical Services Contracts) Regulations 2004, with similar provisions for practitioners operating under PMS and other contracts. For further information, please refer to the relevant legislation. Use of the repeat dispensing arrangements is a matter for the prescriber's clinical judgement and mutual agreement between the prescriber, the patient and the dispensing pharmacist.

Where repeat dispensing is required, prescribers' software systems will need to produce a repeatable prescription on a FP10 and a further series of 'batch issues' (also printed on FP10s).

The repeatable prescription contains all the usual details i.e. name and address of patient, age, date of birth, prescriber details, signature and date. The prescriber is required to specify the number of issues they wish to permit from the prescription and, if appropriate, the dispensing interval (e.g. monthly, quarterly).

Whether to indicate a dispensing interval is at the clinical discretion of the prescriber. However, it is important to note that the specification of a dispensing interval by the prescriber will restrict the pharmacist as to when they can dispense. Not giving a dispensing interval allows the dispenser to use their professional judgment to dispense instalments at an appropriate time. This will allow leeway for unusual situations such as when the patient goes on holiday.

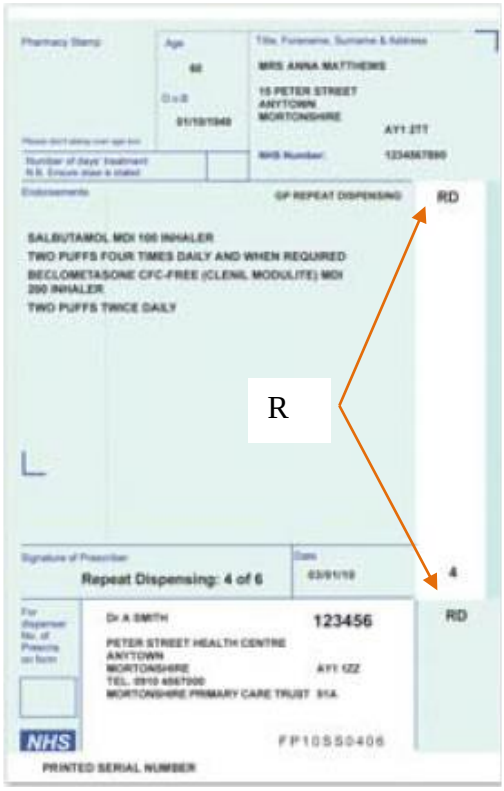
However, good practice expects both prescriber and dispenser to take account of the balance that needs to be struck between maximising patient convenience and the risk of oversupply and possible diversion because the intervals between instalments are too long or inadequately controlled.




The FP10 form is annotated “RA” so that the dispenser can distinguish when an FP10 is being used for repeat dispensing rather than as a normal single-event prescription. The prescriber must sign the repeatable prescription as this is the prescription authorisation. This is needed by the dispenser at each dispensing episode. The ‘batch issues’, however, are not signed by the prescriber as these are not prescriptions but are used for reimbursement purposes.

Batch issues are created by overwriting the prescriber signature box with the text “Repeat dispensing: [example] 6 of 12”. The date on which the repeats were authorised is printed on all batch issues. Further information on repeat dispensing forms is available on www.dh.gov.uk and

http://www.nhsbsa.nhs.uk/PrescriptionServices/1117.aspx




If change in medication is required, the patient must be issued with another prescription. If this is the case, or if the prescriber feels that a repeatable prescription they have issued is no longer appropriate, they should inform the patient and make every effort to contact the pharmacy. For this reason it is good practice for the prescriber to document which pharmacy the patient is using, if this information is known.

Current regulations do not allow for the provision of repeat dispensing services by dispensing doctors to their dispensing patients. They may, however, issue a repeatable prescription to a non-dispensing patient, to be dispensed by a pharmacist.

## 5.3 General Guidance on Prescribing

Prescribers should ensure:

- That national and local prescribing guidance is taken into account when choosing when it is appropriate to prescribe and in the selection of a product. Prescribers are asked to prescribe from the **Sheffield Formulary, including wound management products formulary** where possible.

- That they pay due regard to the cost-effective use of medication.

- That the record keeping is accurate and up to date.

- That the patient and their medication are reviewed on a regular basis that should be at least annual. Guidance on medication review is available in NICE NG5 Medicines Optimisation: https://www.nice.org.uk/guidance/ng5/chapter/1-Recommendations#/medication-review

The CCG supports a shared decision making approach to prescribing, where patients, their carers and clinicians, work together, in equal partnership, to make decisions and agree a care plan. Further information is available on the NHS England website and NICE Medicines Optimisation guideline:
https://www.england.nhs.uk/ourwork/pe/sdm/
https://www.nice.org.uk/guidance/ng5/chapter/1-Recommendations#patient-decision-aids-used-in-consultations-involving-medicines

It is strongly recommended that prescribers should avoid prescribing for themselves or close family members wherever possible, as judgement may be impaired and important clinical examination may be impossible.

### General Practitioners

Under NHS Pharmaceutical Services, general practitioners may prescribe all medicines other than those substances listed under Schedule 1 to the National Health Service (General Medical Services Contracts) Regulations 2004 (the “Blacklist”). This list can be found in part XVIIIA of the Drug Tariff. Drugs listed in Schedule 2 to the National Health Service (General Medical Services Contracts) Regulations 2004 may only be prescribed in certain circumstances. The prescription must be endorsed “SLS”. The list and circumstances for prescribing are listed within part XVIIIB of the Drug Tariff. General practitioners may only prescribe those dressings and appliances listed within the current edition of the Drug Tariff.
The Drug Tariff is available on-line at http://www.drugtariff.nhsbsa.nhs.uk/

In the transfer of prescribing from secondary care GPs must ensure that they are given appropriate information to take on the prescribing of the drugs for the patient under their care. The APG produces a traffic light system to indicate those drugs that are suitable to prescribe within primary care on a shared care basis (amber drugs). See section 5.11 on shared care.

GMC guidance: Good practice in prescribing and managing medicines and devices (2013)
http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

**Non-Medical Prescribers**

Non-medical prescribers can only prescribe for patients for whom they have clinical responsibility. Please see sections 5.1 and 5.2 for further guidance.

## 5.4 Documentation: Making a Record of the Prescription

All practice based prescribers are advised to make a record of the prescription in the patients' notes on the clinical computer system or Lloyd George notes as soon as possible and at least within 48 hours except for during weekends and bank holidays. For consultations outside the surgery or clinic, a record of the prescription should also be entered into the patient's notes, according to local risk management procedures.

The record should include a date, the name of the prescriber, the name of the item prescribed, the quantity prescribed, the dose, frequency, treatment duration and any other relevant details.

Prescribers not based at a GP practice should record the prescription according to their local procedures.

## 5.5 Communicating with the GP

All non-medical independent and supplementary prescribers need to ensure that the patient's clinical records at their GP practice are kept up to date. When a non-medical prescriber is not practice based, where appropriate, they must ensure that the GP has been informed of medicines that have been prescribed following the agreed procedure or service team policy for doing this. Such communication must normally take place within 48 hours, except during weekends and bank holidays, but the non-medical prescriber will need to use their clinical judgement in cases where the GP should be notified immediately.

City wide specialist and non-medical prescribers should ensure that they have a specific individual arrangement to document records and communicate with GP practices in agreement with their risk management procedures.

The GP must ensure the information is recorded within the patient's clinical record.

## 5.6 Prescribing situations not covered by the NHS

### 5.6.1 Interface between NHS & Private Treatment

- Patients are able to switch between private and NHS care at any time but should only be provided with an NHS prescription if the medication would usually be provided on the NHS.

- Primary care prescribers receiving requests following a private consultation should issue NHS prescriptions only if the primary care prescriber considers that the medication recommended is clinically necessary; the medicines would usually be provided on the NHS had the patient been assessed by an NHS service provider; and the primary care prescriber is willing to accept clinical responsibility for the prescribing decision recommended by another clinician. Where necessary primary care prescribers may wish to seek assurance that the treatment decision has been made in line with any relevant national guidance and the private clinician has the relevant expertise in their field of work. The following are examples of conditions where patients may choose to seek private diagnosis/care;

    - Transgender – NHSE has issued guidance to support prescribers if faced with requests from private on-line medical services, which can be extrapolated to include face to face clinics. The guidance includes advice on how to assess the expertise of the specialist and how the assessment and diagnosis has been made. The British Association of Gender Identity Specialists (BAGIS) can be contacted to enquire if the requesting clinician is registered and in which category.
    - ADHD - A diagnosis of ADHD should only be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD. A diagnosis should have been made in line with NICE guideline (NICE NG87, section 1.3). If there are concerns practices can contact SPA within SHSC to seek advice/support from local clinicians.

- Furthermore the CQC have a search facility on their website , which may provide further intelligence on whether private services are registered with the CQC.
- The primary care prescriber should not prescribe medication where the private consultation results in a by-passing of the usual CCG or NHS England criteria for treatment e.g. for IVF treatments.
- There is no obligation for the primary care prescriber to prescribe the recommended treatment where it is contrary to their normal clinical practice or to CCG guidelines / Sheffield Formulary. Advice may be sought from the medicines optimisation team where recommendations by private consultations are more expensive, but without good evidence that they are more effective, than those locally prescribed for the same

condition. This advice should be explained to the patient who retains the option of purchasing the more expensive drug via the private clinician.

- The private clinicians should prescribe privately for the patient where they continue to have the clinical responsibility and will personally determine the ongoing treatment unless shared care is agreed. The primary care prescriber should continue to provide NHS treatment for other conditions for which the private clinician does not take clinical responsibility.

- The principles of 'shared care' are the same as within the NHS when a primary care prescriber accepts clinical responsibility for prescribing a treatment and where the clinical responsibility is shared. Any prescribing should be in line with a locally agreed guideline.

### 5.6.2 Prescribing for patients travelling abroad

A detailed prescribing guideline for patients travelling abroad is available on the CCG intranet and from the Medicines Management Team. See section 17.4 for information regarding controlled drugs.

**Immunisations for travel abroad**

- Travel vaccines previously described in paragraph 27/Schedule of the GP Statement of Fees and Allowances may be provided at NHS expense. These include smallpox, typhoid, cholera, polio and infectious hepatitis (hepatitis A). This includes healthcare workers for example who will be at risk of occupational exposure to infectious disease e.g. VSO, etc.
- For all other travel vaccines a private prescription should be issued. (Exceptions include rabies immunisation to specific groups of people who are special risk due to their employment).

**Long Term and Prophylactic Medication Abroad**

- Regular medication for a pre-existing condition should be provided at NHS expense for journeys of up to 3 months duration. For periods over three months the patient should obtain further medication on a private prescription or from a doctor abroad. For intermittent medication, not more than 1 month's supply should be made at NHS expense.

- Medication should not be prescribed at NHS expense for conditions that MAY arise whilst travelling abroad e.g. travel sickness, diarrhoea.

- Emergency travel kits (containing items such as disposable needles, syringes, IV cannulae, plasma substitutes, etc.) should not be prescribed at the NHS expense.

- An 'executive letter' from the NHS encourages doctors to prescribe malaria chemoprophylaxis privately.

### 5.6.3 Borderline Substances and Dietary Products

- Prescribing of these products should comply with the recommendations of the Advisory Committee on Borderline Substances (ACBS) and prescriptions should be endorsed “ACBS”. Exceptions (at the prescriber's discretion) may follow recommendations from a dietitian or for a medical condition requiring nutritional support for a defined period of time e.g. following maxillo-facial surgery.

- Prescriptions should not be issued at NHS expense for dietary products outside the above uses, especially where they are used as an alternative to liquidising or purchasing appropriate food. Prescribers are advised to consult the Sheffield Formulary Malnutrition Care Pathway, available here: http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/prescribing-guidelines.htm

### 5.6.4 Single Vaccines for Measles, Mumps and Rubella

- The MMR vaccine is the most effective and safe means of ensuring protection against measles, mumps and rubella, and therefore is the only treatment the DH will provide on the NHS. It is a breach of the NHS GP terms of service to charge for supply or administering these vaccines to their NHS patients.

## 5.7 Checks on Prescribing Status

Prescriber status can be checked by contacting the relevant professional body by phone or via the internet.

For general medical practitioners contact the GMC on 0161 923 6602
http://www.gmc-uk.org/doctors/register/LRMP.asp
For nurses contact the NMC on 020 7333 9333
http://www.nmc-uk.org/search-the-register/
For pharmacists contact the GPhC on 020 3713 8000
http://www.pharmacyregulation.org/theregister/index.aspx
For allied health professionals contact the HCPC on 0300 500 6184
http://www.hcpc-uk.org/
For dentists contact the GDC on 020 7167 6000
http://www.gdc-uk.org/Pages/SearchRegisters.aspx

## 5.8 Electronic Transfer of Prescribing

The Electronic Prescription Service (EPS) allows a patient’s prescription to be sent electronically from their GP to a dispensing contractor. The patient may nominate a preferred pharmacy to which their prescriptions can be sent

automatically. The aim is also for dispensers to be able to submit reimbursement claims electronically to the appropriate authority.

Further details regarding EPS can be found at:
http://systems.hscic.gov.uk/eps

### 5.9 Repeat Prescribing Systems

Repeat prescribing has been defined as a partnership between the patient and prescriber that allows the prescriber to authorise a prescription so it can be repeatedly issued at agreed intervals, without the patient having to consult the prescriber at each issue. A repeat prescribing system offers many benefits to both practices and patients but also introduces risks. It is therefore essential that a practice's repeat prescribing system is underpinned by a robust procedure to ensure repeat prescription requests are dealt with efficiently and safely. The prescriber is responsible for any prescription they sign, including repeat prescriptions for medicines initiated by colleagues, so they must make sure that any repeat prescription signed is safe and appropriate.

Recommendations from the MMT on optimal repeat prescribing duration are here:
http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Optimal%20Repeat%20prescribing%20duration%20guidance.pdf

Further guidance on repeat prescribing is available from:
Repeat Prescribing in Primary Care PrescQIPP Bulletin 124 March 2016
https://www.prescqipp.info/repeat-prescriptions/send/258-repeat-prescriptions/2535-bulletin-124-repeat-prescribing

GMC guidance: Good practice in prescribing and managing medicines and devices (2013) Repeat prescribing and prescribing with repeats
http://www.gmc-uk.org/guidance/ethical_guidance/14325.asp

### 5.10 Medicines Reconciliation

There is a substantial body of evidence that shows when patients move between care providers the risk of miscommunication and unintended changes to medicines remain a significant problem. Medicines reconciliation is defined as 'the process of obtaining an up-to-date and accurate medication list that has been compared with the most recently available information and has documented any discrepancies, changes, deletions or additions resulting in a complete list of medications accurately communicated.'

Practices have a responsibility for ensuring the continuity of care, and minimising potential risk to a patient when they are being transferred from one care setting to another. They are expected to process information in relation to patient's medication including:

- When a patient is discharged following a hospital admission back into primary care;
- When a patient is admitted to hospital, or transferred to another care setting, whether this is planned or unplanned.

### 5.10.1 Discharge following a hospital admission or an out-patient appointment

There should be clear procedures within GP surgeries to make sure that information received about revised medication is updated to the patient's medical record. These procedures need to include:

- who has authority to make changes to medication as a result of discharge information
- what details need to be transcribed
- who has authority to transcribe discharge information
- time-limits within which information should be transcribed*
- training to be provided to staff undertaking this task
- patients identified as high priority for post discharge medicines review
- post discharge monitoring of drugs, where appropriate, when these are prescribed in primary care
- recording of specialist issued drugs on the clinical system**

*NICE medicines optimisation quality standard statement 5 (Medicines reconciliation in primary care): People discharged from a care setting have a reconciled list of their medicines in their GP record within 1 week of the GP practice receiving the information, and before a prescription or new supply of medicines is issued.
https://www.nice.org.uk/guidance/QS120/chapter/Quality-statement-5-Medicines-reconciliation-in-primary-care

**guidance is available from the Medicines Management Team:
http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Recording_SIDs_on_practice_clinical_systems.pdf

### 5.10.2 Transfer to another care setting

Practice computer systems can be configured to produce a minimum dataset for hospital admission, which can either be given to the patient, or faxed when necessary to a safe haven fax. However, the summary care record (SCR) is increasingly used by secondary care providers as part of the medicines reconciliation procedures on admission. The SCR consists of a core dataset of medication, allergies and adverse reactions. The enriched SCR has additional data, including significant medical history and reason for the medication, but requires specific patient consent. GPs are encouraged to discuss with patients the benefits of consenting to the enriched SCR to maximise its advantages.

Further information on SCRs is available from:
https://digital.nhs.uk/summary-care-records
http://www.intranet.sheffieldccg.nhs.uk/record-sharing.htm
http://www.intranet.sheffieldccg.nhs.uk/data-sharing.htm

### 5.11 Shared care

Following assessment and initial treatment in secondary care, the responsibility for on-going management may be transferred to primary care or shared care arrangements may be in place. The APG has endorsed the Principles of Shared Care and supporting shared care protocols and guidelines are available for some medicines. These are listed on the amber section of the traffic light drugs list.

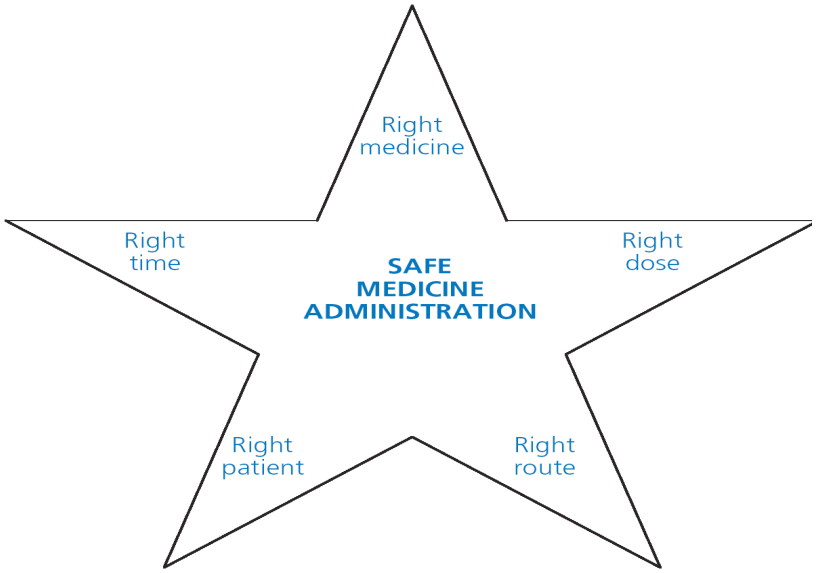
Clinicians are advised to refer to the GMC guidance: Good practice in prescribing and managing medicines and devices (2013) paras 35 to 43 for further information on shared care:
http://www.gmc-uk.org/guidance/ethical_guidance/14321.asp

Unlicensed medicines:
Where the medicines are unlicensed, or being used outside the terms of their UK licence (‘off label’), additional information is given in chapter 21 and in paras 67 to 74 of the GMC guidance: Good practice in prescribing and managing medicines and devices (2013)

http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp

## 6. Administration of Medicines

Definition: the activities undertaken when a medicines is administered, i.e. given by introduction into the body, or by external application, to a patient. This is a key activity in the medication use process and is the point at which there are many opportunities for error. Safe medicine administration involves the 5 rights: the right medication, in the right dose, to the right person, by the right route, at the right time.




A *non-parenteral medicine, dressing or appliance prescribed on the written directions of a doctor, dentist, non-medical prescriber or by an appropriate person working under a patient group direction (PGD) may be administered by:

- The patient
- A practitioner
- A relative/carer

* The legislation provides that no one may administer a parenteral prescription only medicine otherwise than to themselves unless they are a practitioner or acting in accordance with the directions of a practitioner. This restriction excludes a number of medicines for parenteral administration, which are exempt from this restriction when administered for the purpose of saving life in an emergency (listed in Appendix 1).

The prescriber must ensure that the person administering the medicine has sufficient information to enable the patient to derive the maximum benefit from it. The prescriber will need to use their judgement about the competence of the patient or carer to administer the medicine safely and according to instructions. This will include a consideration of whether:

1. The storage of medicines is safe and secure.

2. The patient understands the reason for taking/using the medicines and the consequences of not doing so.

Please also refer to the Sheffield T34 Syringe Driver Protocol if appropriate.

### 6.1 Administration of Medicines by any other staff

Staff other than nursing, medical staff and authorised practitioners, who are engaged in handling or administering specific medicines must be deemed competent to do so by the appropriate designated manager, must have undertaken the required training and must adhere to a local written and approved protocol. They must not be involved in the administration or checking of medicines, which are not defined within their local policy.

Patients who are able to self-administer medicines should be supported to do so. Patients who are unable to self-administer some or all of their medicines may have their medicines administered by their informal carer or a care support worker.

### 6.2 Administration by Care Providers

Care providers contracted with the local authority social services are able to support medicines administration to patients in their own homes where patients have authorised this during their care assessment. Home support workers are able to prompt and assist medicine administration depending on the level of support agreed. The service utilises medicine administration record (MAR) charts supplied by the patient's community pharmacy to record administration. For further details see the Sheffield City Council Medication Policy. Please note that the provision of MAR charts and monitored dose systems (e.g. NOMAD) from community pharmacy may be an unfunded service.

Care providers contracted with Sheffield CCG Continuing Health Care are similarly able to support medicines administration.

### 6.3 Administration of Vaccines

All health care practitioners participating in vaccines programmes, who are not independent prescribers, should be presented with either specific named prescriptions, patient specific directions or be covered by a patient group direction setting out the arrangements for administration. Health care assistants (HCAs) may administer vaccines provided that they have received training and assessed as competent. However, HCAs are not authorised under the medicines legislation to work under PGDs and require a patient specific direction to enable them to administer vaccines to a named individual.

Further information on travel vaccines is given under section 6.6.2 and on patient group directions in Chapter 16.

## 6.4 Verbal Orders to Administer from an Authorised Prescriber

The legislation does not specify that the directions of a prescriber need to be in writing in order to authorise administration. Nevertheless, it is good practice to ensure that whenever a prescription-only medicine is administered it has been authorised in writing by a practitioner before administration takes place.

Primary care prescribers are advised to comply with STH community services procedure regarding verbal instructions.

## 6.5 Single Use Medication

Medication presented in single use containers i.e. not containing a preservative, must be used for single use only. Never use single use containers for more than one patient. Partially used containers must be discarded.

Note: Best practice guidance for administration from multi-use vials i.e. containing a preservative is available on the Practice Resources pages on the intranet.

## 7. Supply of Medicines and Medicinal Products

All medicines supplied directly to patients must conform to the Medicines Labelling Regulations as well as European directives. This includes the name of the patient, date of issue and address of supplier. The expiry date of the medicine must be checked at the time of issue. All medicines should be supplied with a patient information leaflet.

### 7.1 Supply by Patient Group Direction

Prescription-only medicines may be supplied directly to patients without the need for a prescription under a Patient Group Direction. Please see section 16.

### 7.2 Medicines Act Exemptions

There are certain exemptions to the sale, supply or administration of medicinal products within the Medicines Act. These cover sale or supply by a doctor or dentist, as well as sale, supply or administration of certain medicinal products by groups of health professionals e.g. midwives, podiatrists, orthoptists. If you are unsure of the legality of supplying a medicinal product then please consult a pharmacist or the Head of Medicines Management.

### 7.3 Community Pharmacy

Pharmacies are licensed premises for the sale and supply of all General Sales List (GSL), Pharmacy (P), and Prescription-only medicines (POMs) when on a valid prescription.

### 7.4 Domiciliary setting

Medicines will be prescribed for individual patients by GPs or non-medical prescribers using the appropriate FP10 prescription form and dispensed by a community pharmacist (or a dispensing doctor).

Medicines prescribed on FP10 prescription forms must not be used for any other patient.

Emergency supplies of routine medicines during working hours may be made by a community pharmacist or dispensing doctor provided certain conditions are satisfied. Supply may be at the request of an independent or supplementary prescriber or at the request of the patient. Different conditions apply to each type of request. For further information see: http://www.rpharms.com/non-member/emergency-supply-qrg.pdf

Information on pharmacies with extended opening times (evenings and Sundays) is available from NHS 111. See chapter 22 for emergency supply out of hours
The community pharmacist has a responsibility under the Equality Act (2010) to make reasonable adjustments to their services and provide auxiliary aids where appropriate for people with disabilities.

The type and availability of aids to self-medication varies and a charge may be made, unless the patient qualifies under the Equality Act, as they are not covered by the current Drug Tariff. Special container, wing cap or screw cap bottles, which may be useful to aid self-medication, may be requested from the pharmacist if appropriate. Monitored dosage systems (MDS) are not always ideal because:

- They lead to errors if the dose is changed half way through supply
- There is wastage if they have to be refilled due to one change
- There are difficulties if a short course is added to the regime
- They cannot be used for soluble, dispersible or large tablets, or specific tablets and capsules, for example valproate.
- They have a short expiry date for "as required" medicines
- The tablets may become contaminated

The community pharmacist should be asked for help and advice as necessary.

### 7.5 Home Delivered Suppliers

The medicines management team has issued good practice guidance for items e.g. appliances, enteral feeds that are supplied directly to the patient's home from suppliers. GP practices are advised to follow this guidance to avoid over-ordering, wastage and inappropriate requests for items.

http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/new_page.htm

## 8. Transport and Receipt of Medicines

- Medicines should be transported in securely sealed or tamper evident containers.

- Items requiring refrigerated storage such as vaccines should be transported in validated medical grade cool boxes, according to Public Health England protocol for ordering handling and transporting vaccines.

- Staff in receipt of drugs must sign the appropriate notice to acknowledge receipt. Staff signing for deliveries must ensure that the delivery has not been tampered with or damaged in transit. Staff in receipt of drugs requiring refrigeration must ensure that cold chain requirements have been complied with during delivery and place the items immediately in the fridge.

- Drugs should be unpacked, checked against the order and stored appropriately as soon as possible after receipt.

- Staff unpacking orders must ensure that the delivery has not been tampered with and the contents of the delivery, the consignment notice and the order are correct.

- Any discrepancies must be reported immediately to the supplier.

- The delivery driver is responsible for safe delivery of the goods to the correct location. They are responsible for ensuring that a signature acknowledging receipt of the goods is obtained.

- Empty transit containers must be returned to the delivery driver for return to supplier, if applicable.

## 9. Storage and Safekeeping of Medicines

### 9.1 Storage in surgeries

- The authorised practitioner, as assigned by the practice or service, is responsible at all times for ensuring that systems for the safe and secure storage of medicines are followed to ensure that the quality of medicines and the security of medicines are maintained. The authorised practitioner is responsible for approving the design and location of medicine storage cupboards and for regularly monitoring storage.

- All internal medicines, disinfectants and reagents must be stored in locked cupboards, trolleys or other secure cabinets – all must be reserved solely for medicinal products. The only exception to this requirement is medicines for emergency use.

- The authorised practitioner should retain the keys for the lockable cupboards. Access to keys must be restricted to authorised personnel.

- Internal medicines must be stored separately from medicines for external use. Under no circumstances should medicines be transferred from one container to another, unless administered immediately, nor must they be taken out of their container and left loose. All medicines in transit must be stored in a sealed tamper evident container.

- Cupboards or refrigerators for the storage of medicines must be sited where they are convenient for staff, allow adequate space to permit surveillance and afford maximum security against unauthorised entry. Medicine cupboards should generally be sited in a clean utility room to which unauthorised persons do not have access. Cupboards must not be sited where they may be subject to higher than average humidity or temperature. Reagent cupboards must be sited in areas where testing is carried out.

- Medicines for clinical emergencies must be readily accessible and in a position to afford supervision to prevent unauthorised access. They must be in a tamper evident box and must not be in a locked cupboard.

- For storage of controlled drugs, see chapter 17.

### 9.2 Refrigerated Storage

- Medicines must not be stored together with food or pathological specimens, but in a separate lockable pharmaceutical fridge. Medicines requiring storage below room temperature will be marked “Store between 2° and 8°C”. Items requiring refrigerator storage must be placed in the designated medicines refrigerator immediately on receipt.

- The authorised practitioner is responsible for ensuring that the refrigerators used for storage of medicines contain continuous temperature monitoring devices with maximum and minimum temperatures that are recorded daily. They are responsible for ensuring that all staff who have access to the refrigerator are properly trained, and that items other than medicines are not placed in the medicine refrigerator.

- The service must have procedures in place detailing the monitoring and recording of refrigerator temperatures and action to be taken if the temperature goes out of range or in the event of refrigerator breakdown.

- Vaccine Storage

  **Do:**
  - keep all vaccines in their original packaging during storage
  - make checks at least once a week to:
    - rotate stock so that those with the shortest expiry date are moved to the front of the refrigerator and used first
    - remove any expired vaccines (ideally, there should be none) and discard in appropriate waste stream
  - mark clearly any vaccine returned to the fridge with the date and time of its return and place it at the front of the fridge so it is used first at the next session – this should only be done with vaccines that have remained in the cold chain.

  **Don't:**
  - stock pile vaccine (no more than four weeks' stock or as advised by ImmForm)

  For further details, refer to Public Health England protocol for ordering handling and transporting vaccines

### 9.3 Security of Medicines and Controlled Stationery

- When medicines are transported by staff it becomes the responsibility of that person to ensure safe custody as far as is practically possible.

- When a medicine is removed from its storage facility for use it must remain under the direct supervision of the person who has been delegated to use the product concerned. It is the responsibility of that person to ensure continued safe custody.

- Staff visiting patients outside the practice or service may need to carry medicines and other items in their car. These must be stored securely, out of sight, in the boot of the car. If the member of staff does not return to base before going off duty, they must ensure that drugs and other

equipment are stored securely in their home and not left in the vehicle overnight. Staff should be mindful of the effects of extremes of temperature on medicines and only carry the minimum amount necessary.

- Prescription pads are controlled stationery and their security is the responsibility of the individual prescriber. Prescription pads must be kept in a secure locked drawer or cupboard when stored on surgery premises, in accordance with the guidance in Appendix 2.

### 9.4 Storage in the Domiciliary Setting

- All medicines should be stored safely out of the sight and reach of children. Ideally they should be kept in a locked cupboard, drawer or container.

- Medicines should be stored in a cool place. Some medicines deteriorate if they are kept in warm damp places, so the bathroom or kitchen is not ideal.

- Medicines should be kept in the original container in which they are dispensed.

- The patient or carer should be encouraged to return expired or unwanted medicines to the community pharmacy or dispensing doctor.

- There are no special requirements for controlled drugs schedule 2 or 3 in a domiciliary setting. They should be treated as any other medicine.

## 10. Disposal of Unwanted Medicines

Practices and services should not maintain a stock of drugs that are not required. All unwanted drugs whether in or out of date should be placed in the appropriate clinical waste bin. There is a contract in place for waste collection from providers on a regular basis. Patients should be advised to return unused medicines to any community pharmacy or dispensing doctor for disposal. There is a contract in place for the collection of patient returned waste from community pharmacies which is also done on a regular basis. Out of date drugs are regarded as *pharmaceutical* waste and their disposal is the responsibility of the dispensing contractor. However, due to the low volume of these they are currently accepted for disposal through the regular collections.

Partly used drugs such as ampoules, drugs which have been refused or spat out, should be regarded as *clinical* waste and disposed of as such by the clinic or in the patient's home.

### 10.1 Disposal of Medicines by Community Clinics

Drugs should not be placed for disposal in a refuse bin. Only patient's own drugs can be returned to a community pharmacy for destruction.

The residual contents of opened live vaccine containers should be placed for disposal in a sharps bin with other clinical waste.

### 10.2 Disposal of Medicines by Care Homes

Medicines waste from patients within care homes with personal nursing care (formerly known as nursing homes) is classed under the Controlled Waste Regulations 1992 as *industrial* waste. These homes, therefore, should make their own arrangements to have such waste collected by an authorised person and delivered to an authorised facility for its safe disposal. Failure to do so could render the home to commit a number of offences under a range of legislation.

At former residential homes i.e. care homes with no personal nursing service, such medicines waste can be returned to the supplying pharmacy (although they can be returned to any community pharmacy). It is strongly recommended that homes record any returned medicines, listing the patient name, drug, strength and quantity.

### 10.3 Disposal of Patient's Own Medicine

Medicines obtained for a patient on a prescription are the property of the patient. If they are no longer required or the patient has died, the patient or patient's agent should be encouraged to dispose of them appropriately, returning them to a community pharmacy or dispensing doctor for safe disposal. Patients should be told not to dispose of medicines down the toilet

due to contamination of the environment, nor should they be disposed of in the dustbin.

### 10.4 Sharps Bins

Waste medicines and sharps generated by practice staff should be disposed of in sharps bins then disposed of in appropriate collecting bins and collected by an authorised person.

Waste medicines and sharps generated by practice staff in patients' homes should be disposed of in sharps bins and transported back to the surgery for safe disposal.

Waste medicines and sharps generated by self-caring patients in their own homes should be disposed of in sharps bins (Sharpsafe 1Litre available on FP10). Please note that arrangements for the disposal of these bins are currently under review.

### 10.5 Controlled Drugs

The disposal of controlled drugs belonging to patients is considered in Section 17.

## 11. Managing Errors or Incidents in the Use of Drugs

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care. It includes prevented patient safety incidents (known as 'near misses'). Patient safety incidents are not applicable to the use of medicines alone but medication errors account for approximately 10% of reports to the National Reporting and Learning System (NRLS).

**If a drug error occurs during medicine administration, medical advice must be sought immediately.**

In the event of any kind of medication error or near miss, the NHS England Y&H incident form must be completed. For services commissioned by the CCG, the incident should be reported to the CCG Quality Manager. The incident must be investigated by the practice /service and all appropriate actions implemented.

NHS England has launched a general practice e-form, developed specifically to make it quick and easy for all practice staff to report patient safety incidents to the NRLS.

GP practices are encouraged to also report incidents to the CCG so that lessons learned can be cascaded across member practices.

### Patient Safety NHS Improvement

Patient Safety has the leadership role for patient safety in the NHS and provides support to identify, understand and manage risks to the safety of patients, including routine review of patient safety incident reports sent to the NRLS. They alert the NHS to emerging patient safety risks through sharing of relevant safety information to providers, including information on how to reduce and avoid risk.

## 12. Adverse Reaction Reporting

If a patient suffers an unexpected reaction to a medicinal product, this should, where appropriate, be reported to the Commission on Human Medicines (CHM) / MHRA.

Medical, nursing, AHP and pharmacy practitioners should report a suspected adverse reaction to a medicinal product on the designated CHM/MHRA yellow card. This form can be found in the BNF, BNFC and NPF. Alternatively, all health professionals may send in reports on-line:
http://yellowcard.mhra.gov.uk/

Patients/carers/parents can also send reports to the MHRA if they suspect an adverse reaction has occurred using the online form.

Reporting should be carried out for prescribed drugs and vaccines and also for those medicines obtained by patients over the counter and for herbal medicines. The prompt reporting of adverse incidents should be carried out for **all** suspected adverse reactions to new drugs and vaccines under intense surveillance. To aid this distinction, drugs under intense surveillance are given the symbol of an inverted black triangle (▼). Reporting should also be undertaken for unlicensed drugs. For established products only report any serious reactions, even if these are well known, or unusual suspected reactions.

Guidance notes on reporting are available from the MHRA:
https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

Some products are classified as medical devices rather than medicines. Any adverse incident involving a medical device should also be reported using the yellow card. For enquiries to the MHRA regarding reporting adverse incidents involving medical devices telephone: 020 3080 7080

All health care professionals must also report the adverse reaction to the patient's GP, wherever possible, to ensure this is documented in the patient's clinical record.

## 13. Medicine Defect Reporting

A defect is present where the product as supplied by the manufacturer is not of the expected standard. Defects may involve inadequate or incorrect labelling, ineffective packaging, contamination or discoloration of the medicine and broken tablets etc.

When a defect is found or suspected in a medicine:

- Inform the pharmacy or supplier from where the medicines were obtained. They will advise and implement any necessary reporting, recording and investigation of the defect through the MHRA.

- Retain any remaining product and any associated products or equipment.

- If the product has been administered to a patient, inform the doctor responsible for the patient and record the defects in the patient's notes.

- Make a written report of the incident by completing a "significant event or critical incident form" as per NHS England incident reporting processes. Include detail of the specific batch number of the product.

Adverse incidents arising from the use of a medicinal product thought to be defective should be reported to the MHRA Defective Medicines Reporting Centre (DMRC). Please contact the CCG Medicines Management for advice, if necessary.

The Defective Medicines Report Centre, located at 151 Buckingham Palace Road, London, SW1W 9SZ. They can be contacted by emailing dmrc@mhra.gsi.gov.uk or by calling the hotline on 020 3080 6574.

The hotline phone is manned during office hours which are 08:45 to 16:45, Monday to Friday. Out of office hours, call the MHRA duty officer on 07795 641532.

Defective medicines can also be reported using the Yellow Card Scheme. A Yellow Card smartphone app has recently been launched; initially the app is focused on medicines safety information and is expected to be extended later to include reporting of defective medicines.
https://yellowcard.mhra.gov.uk/

### Counterfeit healthcare products

The MHRA ensures that the UK has systems in place to prevent counterfeit or fake healthcare products entering the supply chain. If counterfeit products become available, the MHRA seeks to detect counterfeits early and take action to protect the public.

Any person who suspects that a medicine may be a counterfeit product should report this to the MHRA via the Yellow Card scheme. Yellow Card counterfeit reports are investigated in accordance with the terms of the Human Medicines Regulations 2012 and Consumer Protection Act 1987, and associated legislation.
Further information about counterfeits can be found MHRA website, https://www.gov.uk/report-problem-medicine-medical-device

Also see - https://www.gov.uk/guidance/contact-mhra for update list of MHRA contact numbers

## 14. Drug Safety Messages and Recalls

All healthcare professionals are advised to register to receive regular Drug Safety Update Alerts issued by the MHRA[1] as these are not included in the Central Alerting System[2] (CAS) alerts.
https://www.gov.uk/drug-safety-update/email-signup
Any necessary recall of products is the responsibility of the licence holder. When defects represent a significant hazard to public health, the MHRA may issue a "drug alert" notification, which provides 4 classes of urgency for recall or caution in use.

Class 1 Action now
Class 2 Action within 48 hours except during weekends and bank holidays
Class 3 Action within 5 days
Class 4 Caution in use

Alerts, including the details of their intended recipients, will be sent via e-mail by the Central Alerting System to a designated person within NHS England Yorkshire and Humber. They will be responsible for the onward cascade of this information to the health professionals listed within the alert. This will include an arrangement for cascading messages out of hours.

Messages will be labelled as:

| | |
|---|---|
| Immediate | for cascade in 6 hours |
| Urgent | for cascade in 24 hours |
| Non-urgent | for cascade in 48 hours except during weekends and bank holidays |
| For information | not for cascade |

Nursing staff, community pharmacists, GP practices and walk in centres will be alerted to a product recall through the cascade process co-ordinated by NHS England Yorkshire and Humber.

NHS England: http://www.england.nhs.uk/ourwork/patientsafety/psa/

National Reporting & Learning System:
Email patientsafetyhelpdesk@nrls.nhs.uk

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[1] The MHRA: http://www.mhra.gov.uk

[2] The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. Alerts available on the CAS website include patient safety alerts, CMO messages, drug alerts, Dear Doctor letters and Medical Device Alerts.
https://www.cas.dh.gov.uk/Home.aspx

## 15. Control of Substances Hazardous to Health Regulations (COSHH)

The Control of Substances Hazardous to Health Regulations, known as COSHH, is UK legislation on chemical hazards at work[3]. The regulations came into force in 1989 with subsequent amendments.

Some medicines are, by their nature, hazardous. It is the responsibility of the practice manager within a GP practice or service manager to perform an assessment of hazard and risk for medicines held.

All staff should ensure that they are familiar with any local procedures for such substances.

[3] http://www.legislation.gov.uk/uksi/2002/2677/regulation/7/made

## 16. Patient Group Directions (PGDs)

The following practitioners can supply or administer medicines under PGDs:

- Paramedics
- Pharmacists
- Health visitors
- Midwives
- Nurses
- Opticians
- Podiatrists
- Physiotherapists
- Radiographers
- Dieticians
- Speech and language therapists
- Occupational therapists
- Orthoptists and prosthetists
- Dental hygienists and dental therapists

The practitioner must be authorised as a NAMED individual under a PGD. Health care assistants are not one of the groups that the medicines legislation allows to work under PGDs. If trained to administer vaccines, they must only do so under a patient specific direction from a prescriber. A practitioner working under a PGD cannot authorise another member of staff to administer or supply the medicine.

The MHRA has ruled that PGDs cannot be used as authorisation to administer vaccines that are being supplied as a private service by GP practices. This includes travel vaccines that are not available at NHS expense such as hepatitis B, meningitis ACWY, rabies and yellow fever. Administration of these vaccines must be under a patient specific direction.

### 16.1 Background

- A patient group direction (PGD) is a specific written instruction for the supply and administration of a named medicine in an identified clinical situation signed by a doctor (or if appropriate a dentist), and a senior pharmacist, and authorised by the primary care organisation. It applies to groups of patients who may not be individually identified before presenting for treatment. HSC 2000/026 states the requirements for all PGDs[1]. PGDs for NHS services cannot be authorised by the GP practice but need to be approved by NHS Sheffield CCG as detailed in 17.2.

- The majority of clinical care should still be provided on an individual, patient-specific basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where it offers an advantage for patient care (without compromising patient

safety), and where it is consistent with appropriate professional relationships and accountability.

## 16.2 Development and Approval of PGDs

- Personnel involved in the development of PGDs should refer to HSC 2000/026[1] for detailed guidance and also to the NICE guideline[2]. Useful resources are available on the national PGD website[3], including a database of PGDs.

- A PGD must be drawn up by a multidisciplinary group including a doctor (or dentist); a pharmacist; and representative(s) from the group of healthcare professionals expected to supply and administer medicines under the direction. PGDs may be developed locally or using national templates. The senior doctor (or dentist) and the senior pharmacist involved in the development of the direction must sign the PGD (by law). Members of the development group will be named within the direction. Each PGD should indicate to which professional groups it applies.

- The PGD will be submitted to the CCG's PGD Oversight Group, according to due process for approval within the organisation.

- The PGD Oversight Group will approve the PGD and it will be authorised on behalf of the CCG by the appointed person.

- PGDs to support the delivery of the national immunisation programme are the responsibility of NHS England Y&H and will be developed and approved in accordance with their procedures. Authorisation by the CCG is not required.

## 16.3 Record of PGDs

- The Clinical Audit and Effectiveness Team will keep a record of when the CCG's PGDs are due for review and will ensure that appropriate action is taken to contact those involved to conduct a review before this date.

- A database of approved CCG PGDs will be kept by the Clinical Audit and Effectiveness Team.

## 16.4 Distribution of New and Updated PGDs

- A copy of the PGD will be distributed to practice managers, service mangers and independent contractors as appropriate by the PGD Oversight Group.

- Approved PGDs are available on the CCG intranet under Medicines and Prescribing. This includes those issued by NHSE Y&H until a regional website is established.

### 16.5 Authorisation of Named Health Professionals

- When the PGD has been authorised for use, it is good practice for it to be 'adopted' by the provider organisation(s) if they have not been involved in developing and authorising the PGD. For example, when a PGD is developed and authorised by a CCG for use across GP practices, a process would need to be in place for each GP practice to adopt the PGD for use in their practice.

- Employers will be responsible for authorising practitioners to work according to the PGD. This is a legal requirement. By signing the authorisation form, the health professional and their employer are saying that the named individual is competent and qualified to operate in accordance with the PGD. The named health professional must have a separate authorisation form for each place they work if they have more than one employer.

- Employers are responsible to ensure that practitioners working according to a PGD are authorised and competent to do so.

- Locum practitioners working under the PGDs must be authorised by the GP practice or service.

- Practices may ask all GP partners to sign the authorisation form for each named individual or nominate a lead GP. They may also delegate this responsibility to an appropriate authorising manager.

- For community pharmacists the authorisation should be signed by the line manager or owner/contractor.

- Health professionals working under the PGD are advised to familiarise themselves with the PGD and understand the limits of the document, i.e. patients excluded from treatment, when to refer, when to seek further advice. It would be good practice for practice nurses to have a practice protocol or procedure to detail practice specific issues. All health professionals must practice according to their professional council guidance e.g. NMC, GPC.

- The health professional will keep the original or a copy of their authorisation form. The employer should also keep a list of authorised health professionals.

Health professionals who are eligible to work under a PGD require no additional formal qualification. However, health professionals have a professional responsibility to work within their competency and undertake

appropriate professional development, to work safely with PGDs as part of their professional practice. Employers should also ensure that appropriate training is available for health professionals using PGDs. However, individual health professionals are responsible and accountable for their decisions to supply and/or administer medicines using a PGD. The employer and the health professional have a responsibility to ensure that the health professional remains competent in working according to the PGD by keeping up to date with product changes, training and CPD.

## References


1. HSC 2000/026 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf
2. NICE MPG2 Patient Group Directions. August 2013. https://www.nice.org.uk/guidance/mpg2
3. Patient Group Directions website https://www.sps.nhs.uk/category/services/guidance-and-governance/patient-group-directions/

## 17. Controlled Drugs

Where the word ‘must’ has been used this signifies a legal requirement.

### 17.1 Legal Framework and Guidance

**The Misuse of Drugs Act 1971** – controls the import, export, production, supply, and possession of Controlled Drugs (CDs). All activities are prohibited unless the Act provides exception for it.

**The Misuse of Drugs Regulations 1985** – provides the exceptions for healthcare professionals (amongst others). Only activities specified in the regulations are therefore legal.

**The Misuse of Drugs Regulations 2001** – divides CDs into five schedules corresponding to their therapeutic usefulness and misuse potential.

**Schedule 1** (CD Licence) the most strictly controlled CDs of all. No recognised medicinal use* e.g. LSD. May only be possessed or used by persons with a Home Office licence for research or other special purpose.

**Schedule 2** (CD POM) In practical terms the most important of the five schedules. Includes opioids, the major stimulants such as amphetamine and lisdexamfetamine

**Schedule 3** (CD no register) Drugs which are not thought so likely to be misused as those in schedule 2, nor to be so harmful if they are misused. Includes temazepam, the barbiturates, buprenorphine and midazolam.

**Schedule 4** (CD Benz and CD Anab) Split into two parts: part 1 contains most of the benzodiazepines, zaleplon, zolpidem and zopiclone; and part 2 contains anabolic steroids and androgenic steroids together with the growth hormones.

**Schedule 5** (CD Inv) Contains preparations of certain CDs e.g. codeine, dihydrocodeine, which are exempt from full control when present in medicinal products of low strength.

A list of commonly encountered controlled drugs is available from the Home Office website at https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation.

**Misuse of Drugs (Substance Misuse) Regulations 1997** – Prohibits doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with these drugs for the treatment of organic disease or injury.

**Medicines Act 1968** – Sets out the requirements for a valid prescription. It also allows midwives to possess and administer diamorphine, morphine, pethidine or pentazocine.

**Health Act 2006, and The Controlled Drugs (Supervision of Management and Use) Regulations 2013** – Sets out minimum requirements for SOPs, responsibilities of CD accountable officers, the sharing of intelligence and the arrangements for power of entry and inspection of CD stocks and records.

**NICE Guidance NG46** - This guideline covers systems and processes for using and managing controlled drugs safely in all NHS settings except care homes. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs: https://www.nice.org.uk/guidance/ng46 **(NICE has produced guidance specifically aimed at care homes that includes recommendations on CDs** -https://www.nice.org.uk/guidance/sc1).

**The Safe Management of Controlled Drugs in Care Homes - NHS Yorkshire and Humber Commissioning Support -**
This good practice guidance (reviewed in April 2015) is based on documents that were previously issued by CQC (now withdrawn). Where necessary it has been updated in line with changes to the Regulations and the latest available guidance.
http://yhcs.org.uk/archive/wp-content/uploads/2014/12/Safe-management-of-CDs-in-Care-HomesYHCS-010415.pdf

## 17.2 Legal Requirements for Controlled Drugs

| Criteria | Schedule 2 | Schedule 3 | Schedule 4&5 |
|---|---|---|---|
| **Prescription Requirements** | Yes | Yes | No |
| **Safe custody requirements** | Yes, except some liquid preparations and secobarbital. | Yes except phenobarbital, mazindol, meprobamate, midazolam, pentazocine, phentermine, tramadol | No |
| **Destruction requirements** | Yes | No | No |
| **CD register requirements** | Yes | No | No |
| **Handwriting requirements** | No | No | No |
| **Emergency Supplies Allowed** | No | No, except phenobarbitone for epilepsy | Yes |
| **Repeat Dispensing Allowed on Prescription** | No | No | Yes (Sched 4 must be dispensed for the first time within 28 days of the appropriate date) |
| **Prescribers Address must be in the UK** | Yes | Yes | No |
| **Validity of Prescription** | 28 days | 28 days | 28 days (sch4)<br>6 months (sch 5 if POM) |
| **Private Prescriber Identifier No.** | Yes | Yes | Not required |
| **Private prescription form (FP10PCD) for community dispensing** | Yes | Yes | No |
| **Quantity on prescription (good practice, not legal requirement)** | 30 days | 30 days | 30 days (Sch4) |

Note: Schedule 4 and 5 (but not Schedule 3) controlled drugs can be prescribed on a repeat prescription. For Schedule 5 controlled drugs the first dispensing must be made within six months of the appropriate date. However, for Schedule 4 controlled drugs the first dispensing is only valid for 28 days after the appropriate date.

## 17.3 Possession of Controlled Drugs

The Act lays down the rules that a person may not legally have a controlled drug in their possession unless they are allowed to under regulations.

Schedule 2 controlled drugs may be possessed by:

- A medical practitioner (i.e. doctor, dentist, veterinary practitioner or veterinary surgeon)
- A pharmacist
- A sister or acting sister in charge of a ward or department of a hospital or nursing home or person in charge of a hospital or care home
- Several other categories and groups. (See Misuse of Drugs Regulations 2001 which can be accessed via the Home of UK Legislation website at http://www.legislation.gov.uk/ )

The supply of a controlled drug to a person is only lawful if the person supplying the drug and the person receiving are both authorised to possess controlled drugs.

Specified within these categories are “persons engaged in conveying the drug to a person who may lawfully have it in his possession”. This may include practice staff as long as their reason for possession is to convey the drug to an authorised person, e.g. doctor or pharmacist. Whenever possible the drugs should be obtained by the authorised person themselves.

The pharmacist must ascertain the role of anyone collecting a Schedule 2 controlled drug supplied against a prescription. It must be ascertained whether the person is the patient, the patient’s representative or a health care professional acting within their professional capacity as such. If a health care professional is collecting, their name and address must be obtained and if they are not known to the pharmacist, ID must be requested.

### 17.4 Patients Travelling Overseas

Travellers who are carrying controlled drugs out of or into the UK for their own personal use may need a personal licence if:

- they are travelling for 3 calendar months or more with controlled drugs listed under schedules 2, 3, 4 part I and 4 part II to the Misuse of Drugs Regulations 2001
- are carrying more than 3 months’ supply of controlled drugs listed under schedules 2, 3, 4 part I and 4 part II to the Misuse of Drugs Regulations

The application form for a personal licence can be found here:- https://www.gov.uk/government/publications/personal-import-export-licence-application-form

Any application must be made at least 10 working days before travel date.

The applicant will need to provide the following:

- a completed application form for a personal export/import licence

- a letter from the prescribing doctor or drug worker, which must confirm the patient's name, travel itinerary, names of prescribed controlled drugs, dosages and total amounts of each to be carried.

Patients travelling for less than 3 months and carrying less than 3 months' supply of prescribed controlled drugs listed under schedules 2, 3, 4 part I and 4 part II to the Misuse of Drugs Regulations 2001 will not need a personal import or export licence to enter or leave the United Kingdom. However, the Home Office advises that they should obtain a letter from their prescribing doctor or drug worker, which should confirm name, travel itinerary, names of prescribed controlled drugs, dosages and total amounts of each to be carried.

In either case, the personal licence or doctor's letter should be carried in hand luggage along with the drugs. But as amounts will vary travellers are advised to check with the carrier in advance of travel date that carrying the entire amount of medication in hand luggage is allowed.

### 17.4.1 Regulations in other countries

Other countries may have their own import regulations for controlled drugs and some, such as USA and those in the Middle East, prohibit the import of certain controlled drugs altogether; illegal import can incur heavy prison sentences. Patients should be advised to check with the embassy/consulate of their destination prior to making booking arrangements

## 17.5 Ordering Controlled Drugs

Since 30 November 2015 the use of standardised controlled drug requisition forms (FP10CDF) became mandatory when requesting Schedule 2 or 3 CDs from a community pharmacy for practice, service or GP bag stock. Note that this form must not be used when ordering from manufacturers, wholesalers or NHS hospital trusts. Note also that the requisition form is not required for Schedule 4 or 5 CDs.

Controlled drugs obtained must be entered in to the controlled drugs register within 24 hours of receipt as detailed in section 17.9.

To obtain a Schedule 2 or 3 controlled drug, a requisition (signed in ink by the authorised recipient) is necessary, on which **must** state:

- Signature of the recipient
- Name of the recipient
- Address of the recipient
- Profession or occupation
- Total quantity of drug
- Purpose of the requisition

The form is available for download from the NHS Business Services Authority (NHSBSA) website: http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/6-1387-Form_FP10CDF_v5_final.pdf.

Since the form needs to be signed in ink by the recipient it must be printed off although it can be completed electronically and saved.

If a messenger is sent to collect the controlled drug, they **must** carry a bearer's note, signed and dated by the practitioner, stating that they are authorised to collect the controlled drugs. This note must be retained by the supplier for at least two years.

A practitioner requiring a CD for practice use or stock, and unable to supply a requisition before delivery (e.g. for immediate unpredicted needs), may be supplied with that CD if they undertake to provide a requisition within 24 hours. Failure to do this is a criminal offence on part of the practitioner.

In exceptional circumstances, it may be necessary to obtain CDs from another practitioner, e.g. a colleague in the practice. All normal options must have been considered and be unavailable prior to undertaking this option. If this route is to be followed a requisition must be supplied and CDs must be booked out of one register and into another.

### 17.6 Invoices and Requisitions for Controlled Drugs

Although the original requisition on FP10CDF forms must be submitted to the NHS Business Services Authority Prescription Pricing Division (PPD) by the supplier, good practice recommends that the requestor should retain a copy for local records.

All invoices for CDs, including Schedules 4 and 5, must be kept for 2 years.

### 17.7 Controlled Drugs for the Emergency Bag versus Controlled Drugs for Individual Patients

It is important to distinguish between supplies of CDs prescribed for individual patients on a FP10, and supplies obtained for administration by GPs, for example, for their bag for use in emergencies. GPs **must not** use patient-specific prescriptions to "top-up" practice or personal stock, even if the practice stock was used for that patient initially.

### 17.8 Prescribing Controlled Drugs

#### 17.8.1 Prescription Requirements for Controlled Drugs

It is an offence for a practitioner to issue a prescription for a Schedule 2 or 3 controlled drug or for a pharmacist to dispense it, unless it is written in ink or is

otherwise indelible (e.g. typed or computer generated) and contains the following information:

- The full name and address of the patient (or “no fixed abode”), and the age of the patient where appropriate.
- The name of the preparation.
- The form of the preparation, even if only one form exists.
- The strength of the preparation, where appropriate.
- The dose to be taken. Note: “Take as directed” or “To be taken as required” is not legally acceptable; however, a dosage of “One to be taken as directed/ when required” is acceptable.
- Either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied e.g. for tablets, capsules, suppositories 10 (ten) would be acceptable.
- The address of the person issuing the prescription.

In addition it must:

- Be signed by the practitioner issuing it with their usual signature and dated by them (the date does not have to be hand written).
- Have written thereon, if issued by a dentist, the words “for dental treatment only”.

Note – Amendments to the Misuse of Drugs Regulations 2001, which came into force on 14th November 2005, removed the requirement for prescriptions for Schedule 2 and 3 CDs to be written in the prescriber’s own handwriting (other than signature).

Under no circumstances can a carbon copy or faxed prescription be accepted for a Schedule 2 or 3 controlled drug.

Where a prescription requires amending, the person who originally signed the prescription must amend it. If the prescribing doctor is not available, then the doctor on duty **must issue a completely new prescription**.

Note – Pharmacists are able to supply CDs against some prescriptions that have a technical error but where the prescriber’s intention is clear. The pharmacist must make the amendment to the prescription indelibly and clearly attributable to them.

All other guidance for issue of prescriptions given in chapter 5 must also be applied to prescriptions for controlled drugs.

Emergency supplies of Schedule 2 or 3 controlled drugs are not permitted either at the request of the patient or the practitioner. The only exception to this is phenobarbitone for the treatment of epilepsy. In other situations arrangements must be made to satisfy the legal requirements and ensure that the patient in need receives the medicines involved.

### 17.8.2 Substance Dependence Substitute Prescribing

For prescribing drugs listed in Schedule 2 of the Misuse of Drugs Regulations and buprenorphine or diazepam by instalment prescribing for the treatment of substance dependence, prescribers should use the appropriate FP10 MDA (blue) form. This form must not be used for any other purpose, including when the total quantity needs to be dispensed at one time. In this situation a normal FP10 must be used.

The prescribing of diamorphine, dipipanone and cocaine, for the treatment of addiction, requires a special licence.

Form FP10 (MDA) must specify the following details:

1. The instalment amount and the dose specified separately
2. The intervals to be observed between instalments; if necessary, instructions for supplies at weekends or bank holidays should be included
3. The total quantity of CD that will provide treatment for a period not exceeding 14 days
4. Clear supervision instructions, if intended.

Prescriptions which contain a direction that specified instalments of the total amount may be dispensed at stated intervals must not be dispensed otherwise than in accordance with the directions **unless** Home Office approved wording is included in the prescription:
*For supervised consumption*: “Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied”
*For unsupervised consumption*: “Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e., the instalment less the amount prescribed for the day(s) missed) may be supplied.”

### 17.8.3 Non-Medical Prescribers

Changes to the Misuse of Drugs Regulations 2001 relating to nurse and pharmacist independent prescribing of controlled drugs (*Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (Statutory Instrument 2012/973*)) came into force on 23 April 2012. Enabling them to prescribe any controlled drug listed in schedules 2-5 for any medical

condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction.

From 1 June 2015, physiotherapists who are annotated with the HCPC as independent prescribers have been able to prescribe from a limited list of seven controlled drugs by specified routes. Other non-medical prescribers are not able to prescribe controlled drugs except for patients within a clinical management plan.

### 17.8.4 Patient Group Directions (PGDs) and Controlled Drugs

Only certain controlled drugs are legally eligible to be included in a PGD, in accordance with The Misuse of Drugs Regulations (2001). See table below; for further information on PGDs refer to chapter 16.

**Controlled drugs that may be considered for inclusion in a PGD**

| Schedule | Controlled drugs that may be considered for inclusion in a PGD | Additional comments |
|---|---|---|
| Schedule 2 | Morphine<br>Diamorphine | Use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction) |
| Schedule 2 | Ketamine | |
| Schedule 3 | Midazolam | |
| Schedule 4 | All drugs, including benzodiazepines | Anabolic steroids and any injectable preparation used for treating addiction **must not** be included in a PGD |
| Schedule 5 | All drugs, including codeine | |

## 17.9 Controlled Drugs Registers

### 17.9.1 Requirements

Controlled drug registers are required to record the particulars of purchase and supply of all Schedule 1 and 2 controlled drugs.

Several criteria apply to controlled drug registers:

- The register should be present at the premises to which it relates and be available for inspection at any time.

- The register must consist of a bound book, or a computerised system.

- In the register (or separate part of the register used for each class of drug) a separate page must be used for each strength and form of individual drug. **The class, strength and form must be specified in the register at the head of each page. The name of the controlled drug, to which the entries relate, must also appear at the head of that page**. In the case of electronic registers, they must be capable of printing or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout.

- The entries must be made in chronological order, either on the day of receipt/supply or the following day, and in indelible ink or in a computerised form in which every entry is attributable and capable of being audited.

- Entries must not be cancelled, obliterated or altered in any way. Corrections must be by entry of a signed and dated note in the margin or at the bottom of the page.

- CD register entries must be made by a healthcare professional. However, another member of the healthcare team can check and countersign the register as appropriate.

- On reaching the end of a page in the register, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. As a matter of good practice this transfer may be witnessed.

- Once a register is full it must be retained for two years from the date of last entry.
- It is good practice but not a legal requirement that GPs keep a record of batch numbers of controlled drugs in the register.

Note – the definition of a CD register has been amended to include a computerised system. Electronic Controlled Drug registers must comply with best practice guidance. Current best practice guidance states that:

a) Registers may only be kept in computerised form if safeguards are incorporated into the software to ensure all of the following:
   - the author of each entry is identifiable;
   - entries cannot be altered at a later date;
   - a log of all data entered is kept and can be recalled for audit purposes.

b) Access control systems should be in place to minimise the risk of unauthorised or unnecessary access to the data in computerised registers.

c) Adequate backups must be made of computerised registers.

d) Arrangements should be made so that inspectors can examine computerised registers during a visit with minimum disruption.

An entry should be made for all controlled drugs received (except those returned by patients) and an entry made when controlled drugs are supplied to a patient or un-issued CDs are destroyed (see section 17.10). As several details require recording, it is important to ensure that the register has columns for all the details.

For controlled drugs **obtained** (note: does not include returns), the following headings must be used and the following information must be recorded in the CD register:

a) Date on which the supply was received
b) Name and address of person or firm from whom received
c) Quantity received

For controlled drugs **supplied from practice stock to GP bag** the following headings must be used and the following information must be recorded in the CD register:

a) Date on which the supply was made
b) Name and address of person to whom supplied
c) Particulars of the authority of the person who ordered the CD.
d) Quantity supplied

For controlled drugs **administered from practice stock to a patient** the following information must be recorded in the CD register:

a) Date on which the administration was made
b) Name and address of patient
c) Particulars of the prescriber
d) Quantity administered

### 17.9.2 Practice registers

If CDs are kept on the premises, a register must be kept for each premise (not just the main surgery). Entries should be made as detailed above (section 17.9.1).

Good practice - wherever possible, all register entries should be initialled by a witness other than the person making the entry.

### 17.9.3 Individual GP registers

In addition to the practice or service CD register, GPs require separate registers for any CDs held in their bag.

GPs are responsible for keeping their registers up to date. The GP should register the administration of CDs to a patient from their bag in their own CD register for their bag. Destruction of CDs from the GP's bag must also be recorded in their own CD Register.

If practice stock (CDs) is used to replenish a GP's bag then an order is not required, however the practice CD register should be completed as above (section 17.9.1) and witnessed by a person other than the one making the entry. This entry should indicate that the item is for the GP's bag. The GP should make the appropriate entries in their own CD register for their bag.

If no CDs are held centrally on practice or service premises then a personal register relating to the CDs held in each GP's bag only is required. However, when recording drugs received and supplied, it may be prudent to ensure that another senior member of the primary health care team initials the entry.

Good practice dictates that regular stock checks should be carried out, checking the balance of stocks against register entries. The frequency of these checks should be in line with a risk assessment and guidance from professional bodies.

## 17.10 Missing or Damaged Controlled Drugs

### Schedule 2 Drugs

These include morphine, diamorphine, fentanyl, oxycodone and methadone. If a discrepancy is identified, then check the controlled drug register for any errors or omissions in either the relevant "received" or the "supplied" section.

**If an error has been made in recording of drugs in or out, then a review of the procedures taken must be made as soon as is practicable.**
**If it is suspected that controlled drugs have been lost or stolen, or any patient harm has been caused, then contact the police and report to NHS England (Y&H) CD accountable officer immediately:**
england.yhcdao@nhs.net .

If controlled drugs are lost or stolen the quantity and description should be recorded as "lost or stolen" in the controlled drug register. A serious event of this nature should prompt a review and improvement of procedure for storage and/or handling; the CCG Medicines Management Team is able to advise

(contact the CCG controlled drugs lead via 0114 305 1667). If drugs are accidentally destroyed or damaged, then this should be recorded in the appropriate section of the register as soon as possible after the event in order to maintain an auditable trail.

**Schedule 3 Drugs**

These include temazepam, barbiturates, buprenorphine and pentazocine. These drugs do not need to be entered in the CD register, so discrepancies are harder to detect. However, any discrepancies that are noted should be dealt with in the same manner as described above (except entry in registers).

Although not a legal requirement it would be good practice to record Schedule 3 controlled drugs in a CD register with discrepancies dealt with as described above.

## 17.11 Storage of Schedule 2 and 3 Controlled Drugs

### 17.11.1 Storage in Practice

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 require that Schedule 2 CDs and some Schedule 3 CDs (e.g. temazepam and buprenorphine) must be stored in a CD cabinet.

The CD cabinet must comply with the requirements laid out in the Misuse of Drugs (Safe Custody) Regulations, including being fixed securely to a solid wall or floor with rawl or rag bolts. Suppliers of CD cabinets can confirm that a cupboard meets the legal requirements.

### 17.11.2 Storage in Doctor's Bag

A lockable bag must be used and kept locked when not in use. The keys must be retained by a person in lawful possession or by an individual authorised by them. A car does not constitute a locked receptacle.

Good practice:

- A combination lock may be a practical and convenient way to avoid problems with keys.
- Bags containing CDs should not be left in a vehicle for long periods or overnight.
- Stock levels held in doctor's bags should be kept to a minimum, and checked at least monthly for balance and expiry.
- When in the practice, the bag should be stored in a safe place away from patient areas.

## 17.12 Private Prescribing

When issuing private prescriptions, prescribers must comply with all legal requirements stated above. A GP may not charge for the issue of a private prescription to a NHS registered patient but may charge a non-registered

patient. All private prescriptions for Schedule 2 and 3 controlled drugs that will be dispensed in a community pharmacy or GP dispensing practice must be on a private controlled drug prescription FP10 (PCD). Requests for private prescription pads are made via NHS England:- england.yhcdao@nhs.net

### 17.13 Patient CD Returns

CDs that are no longer required should be returned to a community pharmacy for destruction and not accepted by the surgery.

### 17.14 CDs for Destruction

Please contact the CCG Medicines Management team (0114 305 1667) for guidance on who is able to witness destruction of expired CD practice or service stock and those held in the GP bag.

### 17.15 Standard Operating Procedures (SOPs) covering the Safe Management and Use of Controlled Drugs

All healthcare organisations must have and comply with an approved SOP for safe management and use of controlled drugs.

Each GP practice and service should have clear, written standard operating procedures (SOPs) in place that are known, understood and followed by practitioners and their staff. SOPs must cover the following:

- who has access to CDs
- where the CDs are stored
- ordering
- security in relation to storage and transportation of CDs
- disposal and destruction of CDs
- who to alert if complications arise
- record keeping requirements including maintenance of CD registers

The CD accountable officer is required to monitor CD prescribing undertaken by all prescribers whom NHS England has contracted or employed to provide services. Sheffield CCG currently undertakes this work on behalf of the CD Accountable Officer for Y&H.

## 18. Clinical Trials in Primary Care

Clinical trials must not be commenced until they have received approval through the Research Development Unit at Sheffield Health and Social Care NHSFT. This unit administers the management and research governance process on behalf of the CCG.

http://shsc.nhs.uk/service/research-development-unit/

The patient must give informed consent for the use of a trial medicine. The prescriber must consult any multidisciplinary team members involved in the patient's care before the treatment is carried out.

All clinical trial materials must be fully labelled and issued through a pharmacy, unless specified otherwise in the trial protocol.

At the end of a study, the prescriber may wish to continue to prescribe the trial medicines for the patients who have benefited in the study. The provision must be included in the original trial protocol and will be considered as part of the assessment process. For unlicensed medicines, it may be possible to continue using the medicine on a "named patient basis", according to due process.

For guidance on the process for approval of commercially sponsored and other trials, contact the Research Development Unit on 0114 2718438.

## 19. Continuing Professional Development for Non-Medical Prescribers

It is essential that all practitioners keep up to date with current practice. This involves continuing learning i.e. continuing professional development (CPD). CPD is an essential element in improving service quality on the delivery of health services.

All non medical prescribers have a professional responsibility to keep themselves abreast of clinical and professional developments to help ensure that their:

- Prescribing skills are kept up-to-date
- Prescribing skills extend as their prescribing role develops
- Management of conditions conforms to best practice and current evidence base.

The CCG has a process of self-certification. Non-medical prescribers will be asked to complete an annual self-certification form detailing their CPD and ongoing competence as a non-medical prescriber

## 20. The Conduct of Pharmaceutical Industry Representatives and Commercial Sponsorship

Please refer to NHS Sheffield CCG Commercial Sponsorship Policy and the Standards of Business Conduct and Conflicts of Interest Policy and Procedure

http://www.intranet.sheffieldccg.nhs.uk/policies.htm

## 21. The Use of Unlicensed Medicines

The policy includes:

- Drugs that do not have a marketing authorisation (formerly product licence) in the UK.

- Drugs that have a marketing authorisation in the UK but where the use of the drug falls outside the licence by reason of indication or method of use, e.g. amitriptyline in neuropathic pain. This is sometimes referred to as “off-label” use.

- Preparations of drugs where the drug is licensed in other forms e.g. spironolactone suspension.

- Drugs used in clinical trials are covered in separate policies.

The underlying principle of the UK and European legislation is that, subject to specified exemptions, no medical product may be placed on the market for sale, supply or offer for sale without an appropriate marketing authorisation (MA), formerly product licence (PL). Licensed medicines may be identified by the presence of a licence number prefixed by PL, MA, EMEA (European Medicines Evaluation Agency) or EU (European Union). The clinical indications are based on data submitted by the manufacturer as part of the licensing application. The Medicines Act allows for drugs without a marketing authorisation to be prescribed or licensed drugs used off-label when judged by the prescriber to be in the best interest of the patient, on the basis of available evidence.

The granting of a marketing authorisation for a drug ensures that the evidence of the safety and efficacy of the drug in relation to specified uses has been reviewed and accepted by an official, expert body. Licensed medicines must meet quality standards for manufacture and be accompanied by appropriate product information and labelling. Drugs or uses of drugs for which no UK marketing authorisation exists may be prescribed by medical practitioners, but liability for any harmful consequences rests with the prescriber and vicariously with the employing body.

Harm which arises as a result of a product defect, i.e. the product is not of the quality or safety expected, may rest with the manufacturer of the product, provided all reasonable steps have been taken by the prescriber and the pharmacy to ensure a product of appropriate quality and safety is supplied.

Drugs should be used in accordance with the marketing authorisation wherever possible. It is recognised, however that the treatment of individual patients and, in particular, paediatric prescribing may involve the unlicensed use of drugs. Prescribers must be aware of the use of drugs outside their marketing authorisation.

The use of unlicensed drugs should only take place where there is a supporting body of evidence or expert guidelines. Independent prescribers should consider this when agreeing to take over the prescribing of a drug without a MA or the use of an unlicensed drug for specialist indications from a hospital specialist. The specialist should give access to evidence which supports the use of the drug and information which enables the drug to be prescribed safely. Where this is felt to be outside the remit of the independent prescriber, they should consider whether such prescribing should continue to be undertaken by the appropriate practitioner within secondary or tertiary care services. The independent prescriber may not wish to continue such prescribing because of issues of liability.

Supplementary prescribers may prescribe medicines for use outside of their licensed indications as part of the clinical management plan. They may also prescribe unlicensed medicines that are part of a clinical trial and have a clinical trial certificate or exemption. The same considerations apply as for independent prescribers (see above).

Medicines used outside of the terms of their licence can be included in PGDs. The PGD should clearly state when the product is used outside of its licence and the reason for this. However, medicines that do not have a MA or PL cannot be supplied or administered under a PGD.

Where unlicensed drugs are used, patients should give informed consent to their use which should be recorded in their clinical notes. Patients have a right to receive information about all the treatment that they receive, including unlicensed therapy. Wherever possible, this should include written information in the form of patient information leaflets

All adverse reactions, which occur in patients treated with unlicensed drugs, should be reported to the Medicines Healthcare products Regulatory Agency (MHRA). This should be done in the same way as for licensed drugs.

Further information on the prescribing of unlicensed medicines is available from Drug Safety Update April 2009 on the MHRA website:
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990

The following references may also be useful:
GMC Prescribing guidance: Prescribing Unlicensed Medicines
GMC Hot Topic - Prescribing Unlicensed Medicines
MHRA Guidance on the Hierarchy for the use of Unlicensed Medicines (see Appendix 2) this provides guidance only and each case should be considered on its individual merit.
For use of medicines in children:
https://www.medicinescomplete.com/mc/bnfc/current/
Royal College of Paediatrics and Child Health unlicensed medicines statement
http://www.medicinesforchildren.org.uk/search-for-a-leaflet

## 22. Availability of Medicines Out of Hours

Medicines required by patients out of hours (OOH) can be obtained via a number of routes depending upon the circumstances.

NHS England Yorkshire and Humber holds a list of the names and addresses of pharmacy contractors, together with hours of business, who provide pharmaceutical services in the area. Out of hours services have been agreed via a locally commissioned service contract between NHS Sheffield CCG and Associated Chemist (Wicker) Ltd. Pharmaceutical services are available from this pharmacy on evenings, Sundays and Bank Holidays including Christmas Day, Boxing Day and New Years Day. In addition 100 hour pharmacies are open evenings and weekends and often provide an extended range of services. Information on the availability of services can be obtained from NHS England (Y&H), 111 and NHS Choices[4]

### 22.1 Out of hours access to controlled drugs

Controlled drugs, which are supplied or administered out of hours, may be provided from the GPs own stock of controlled drugs (see section 17). Prescriptions for controlled drugs from GP OOH services can be dispensed by the STHFT only when community pharmacies OOH services are closed. The prescriber will need to provide proof of identity on collection to take possession of the controlled drugs.
A process enabling the supply of a palliative care pack available through the GPOOH service has been developed. These packs contain the following:-

| Drug | Quantity |
|---|---|
| Diamorphine injection 5mg | 10 ampoules |
| Midazolam injection 10mg/2ml | 10 ampoules |
| Hyoscine butylbromide injection 20mg/ml | 10 Ampoules |
| Haloperidol injection 5mg | 10 Ampoules |
| Water for injection 10ml | 20 Ampoules |

[4] http://www.nhs.uk/service-search/Pharmacy/LocationSearch/10

## 23. Sheffield Formulary

The Sheffield Formulary contains guidance on the choice of drugs to be prescribed in primary care and includes the wound management formulary.

The Sheffield Formulary has been produced under the auspices of the Sheffield Area Prescribing Group (APG) and is designed to give clear concise guidance on drug selection. It contains a list of preferred choices for non-specialist drugs and products, which will be available in both primary and secondary care. The choice of preferred drugs has been made on the basis of evidence of clinical efficacy, safety, patient acceptability and cost-effectiveness. The contents reflect wide consultation within the city.

Appropriate funding will be made available for all drugs that receive positive NICE technology appraisal, however not all of these drugs will be specifically listed in this non-specialist, primary care formulary.

Whilst prescribers are expected to adhere to the guidance in the formulary, it is acknowledged that there may be occasions when prescribing outside the Sheffield Formulary will be necessary to address the need of individual patients.

Formulary chapters are regularly reviewed and the formulary is available on the NHS Sheffield CCG intranet sites:

http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/sheffield-formulary.htm

The Sheffield Formulary is supported by other resources including shared care protocols, prescribing guidelines and the Traffic Light Drugs list. These resources are available on the Medicines and Prescribing pages of the CCG intranet:

http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/medicines-index.htm

## 24. Consent to Treatment

It is a legal and ethical principle that consent must be obtained before starting treatment or physical investigation or providing personal care for the patient.

Wherever possible, the prescriber should discuss with the patient the medicines proposed to treat a patient. The discussion should be carried out in such a way that the patient is able to express agreement or disagreement with the proposed treatment. A concordant consultation with shared decision making is promoted by the CCG to enable the patient to get the most from their medicines. Further information on shared decision making is available from NHS England and NICE Medicines Optimisation guideline:
https://www.england.nhs.uk/ourwork/pe/sdm/
https://www.nice.org.uk/guidance/ng5/chapter/1-Recommendations#patient-decision-aids-used-in-consultations-involving-medicines

For consent to be valid, it must be given voluntarily by an appropriately informed person (the patient or, where relevant, someone with parental responsibility for the patient under the age of 18) who has the capacity to consent to the intervention in question.

Young people aged 16 and 17 are presumed, in law, to be able to consent to their own medical treatment. Younger children who understand fully what is involved in the proposed procedure (referred to as 'Frazer Guidelines') can also give consent, although ideally their parents will be involved.

The Mental Capacity Act came into force from 1st October 2007. This sets out how treatment decisions should be made for people of 16 years or older who do not have the capacity to make such decisions. For further information see:
http://www.dca.gov.uk/menincap/legis.htm#codeofpractice

There is no requirement for consent to be in writing.

Comprehensive guidance about consent can be obtained from the current DH reference guide:

https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

## 25. Glossary of Terms

**Administer**
To give a medicine by either introduction in to the body (e.g. orally or by injection) or by external application (e.g. cream or ointment).

**Commission on Human Medicines (CHM)**
Collects reports on adverse drug reactions via the “yellow card scheme”.

**Community Practitioner Nurse Prescriber**
Community Practitioner Nurse Prescribers are registered district nurses, health visitors or registered midwives who have successfully completed an accredited nurse prescribers’ training course and have recorded this with the Nursing and Midwifery Council (NMC). Community Practitioner Nurse Prescribers may prescribe from within the appropriate section of the Nurse Prescribers’ Formulary (NPF).

**Controlled Drug (CD)**
Controlled drug means a drug in Schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 1985 (as amended).

**Dietary Product**
A product included in the list of feeds in Appendix 2 of the BNF.

**Dispense**
To prepare a clinically appropriate medicine for a patient to self-administer or for administration by another. This function must be performed under the supervision of a pharmacist or dispensing doctor.

**Doctor/General Practitioner**
A doctor registered in the UK with the General Medical Council. A general practitioner is a doctor that treats people in the community that do not require specialist care.

**General Sales List Medicines (GSL)**
A licensed product on the general sales list that can, with reasonable safety, be sold or supplied otherwise than under the supervision of a pharmacist.

**Independent Prescriber**
A UK registered doctor; a dentist prescribing from the Dental Formulary; a nurse independent prescriber or pharmacist independent prescriber prescribing within their competence within the BNF; optometrist, podiatrist, physiotherapist and therapeutic radiographer independent prescribers for certain medicines.

**Medicine**
A substance, which may be administered for the purpose of diagnosis or for preventing or treating disease.

**Nurse Independent Prescriber (NIP)**
A registered nurse or registered midwife who has completed an approved course and has this recorded with the Nursing and Midwifery Council. Nurse independent prescribers may prescribe, within their competence, from the whole of the BNF including controlled drugs for specific indications.

**Pharmacist Independent Prescriber (PIP)**
A pharmacist who has completed an accredited training course and is registered as a pharmacist independent prescriber with the General Pharmaceutical Council (GPhC).

**Pharmacy Medicine (P)**
Any product which is not a prescription-only medicine (POM) or a general sale list medicine (GSL) is a pharmacy medicine. Pharmacy medicines must be supplied by or under the supervision of a pharmacist from a registered pharmacy but can be dispensed without prescription.

**Practitioner**
Practitioner is the term used to describe a doctor, registered nurse, pharmacist, dentist or other authorised healthcare professional.

**Prescribe**
To authorise in writing the supply or administration of a medicine.

**Prescription Only Medicine**
Medicines which may be sold or supplied from pharmacies in accordance with a prescription from a practitioner who is authorised to prescribe them.

**Prescription Pricing Division (PPD)**
Formerly known as the Prescription Pricing Authority (PPA). This is the part of the NHS Business Services Authority (NHSBSA) which inputs and provides data on prescriptions dispensed in NHS community pharmacies, by dispensing doctors and personal administration items.

**Supplementary Prescriber**
A registered nurse, midwife, pharmacist, podiatrist, chiropodist, dietitian, radiographer, optometrist or physiotherapist who has completed an accredited training course in supplementary prescribing and has this recorded with the Nursing and Midwifery Council, General Pharmaceutical Council, the Health & Care Professions Council or the General Optical Council.

**Supply**
To supply a medicine to a professional, patient or carer for administration.

## Appendix 1: Parenteral Administration – Exempt from Restriction

The following are medicines, given by parenteral administration, that are exempt from the Medicines Act restriction, when they are administered for the purpose of saving life in an emergency (see Chapter 7).

This list is not comprehensive but includes those products more likely to be available in primary care.

Adrenaline Injection 1 in 1000 (1mg in 1ml)

Atropine sulphate injection

Chlorphenamine injection

Glucagon injection

Glucose injection 50%

Hydrocortisone injection

Naloxone hydrochloride injection

## Appendix 2: Safe and Secure Handling of Prescription Forms

### Good Practice Guidance

### 1. Responsibility of the prescriber

Treat the prescription pad much as you would a chequebook so:

**DO**

- Keep the pad with you in your bag whilst out of the practice/service.
- Consider taking only one or two prescriptions out with you.
- Secure the pad in a locked drawer in your centre when not in use.
- Record the number of the first and last prescription in each pad, and the date on which they were used.
- Notify manager if any forms or the pad go astray.
- Return all unused prescriptions to your manager if you are leaving the employment of the practice or service.
- Only use your own prescription pad, and check it is yours before writing on it.

**DON'T**

- Pre-sign blank prescription forms.
- Leave the prescription pad in your car – 80% of GP pads that go missing are stolen from cars.
- Leave the pad unattended on your desk or at reception desks.
- Have more than one prescription pad in use at any one time.
- Let <u>any</u> other prescriber use your prescription pad.
- Use any other pad except your own.

### 2. Responsibility of the practice or service base

- Provide secure, lockable storage for prescription pads
- Ensure the provision of new prescription pads as required. See ordering process below.
- Minimise the risk of fraud by recording the serial number of the first prescription in each pad.
- Inform the CCG NMP administrator of details of non medical prescribers leaving the practice / service.
- Retrieve unused prescription pads from prescribers leaving the employment of the practice / service.
- Record and securely destroy all unused prescription forms issued to that prescriber relating to that employment.

### 3. Procedure for obtaining prescription pads

### 3.1 Non-medical prescribers (NMPs)

Following qualification the member of staff must visit the CCG NMP administrator bringing:

- Confirmation from professional body of registration as a prescriber
- ID badge/Smartcard
- Passport or other photo ID

During this visit they will also:

- Leave a specimen signature
- Complete the NMP competency declaration
- Discuss new role with CCG NMP lead (if available)

The NMP will then be

- Added to NMP database
- Registered as an authorised prescriber with NHSBSA Prescription Services

If prescription pads are required they can be ordered 7-10 days after registration. A maximum of two pads will be ordered. The member of staff will be informed when the pads are available and they will need to attend in person with associated identification (such as ID badge) in order to collect. The pads remain the property of the CCG. Prescription pads will be personalised with the prescribers' details and will be in pads of 50 forms serially numbered and produced on specially printed, anti-fraud paper.

Non-medical prescribers must ensure that any amendments/inclusions to the database are notified to the CCG within 48 hours (excluding weekends and bank holidays). The CCG NMP administrator will notify the NHSBSA Prescription Services of any changes to a non-medical prescriber's details e.g. change in practice or non-medical prescribers leaving.

### 3.2 Medical prescribers

Medical prescribers need to register and order prescription pads from Primary Care Support England.