

Title	NHS Borders Code of Practice for the Control of Medicines (including Controlled Drugs SOP)
Document Type	Policy
Version Number	V6.0
CGQ & RDS ID Number	Clinical Governance & Quality Use only
Approval/Issue date	Jan 2023
Review date	Jan 2026
Owner/Responsible Person	Morrison R <u>Rhona.morrison@borders.scot.nhs.uk</u>
Developed by	Clark M – Jan 2019
Reviewed by	Morrison R; Scott S – July 2022; Fealy F – Aug 2022; ADTC – Sept 2022; Morrison R; Scott S; Thomson K – Nov 2022
Significant resource implications (financial/workload)	N/A
Approved by	NHS Borders Area Drug & Therapeutic Committee; Jan 2023
Health Inequality Impact Assessment (HIIA) (only statutory for policies)	November 2022

Uncontrolled when printed



NHS BORDERS - CODE OF PRACTICE FOR THE CONTROL OF MEDICINES

Update May 2021	The recommended review timescale to out-patient medicine administration regarding serial prescribing – updated.
Update July 2022	Reviewed and replaced with updates; Controlled Drugs Governance chapter replaced with the Controlled Drug updated SOP.
Update Nov 2022	Review and update transfer of CDs from ward to ward or theatre to ward p38- 39; Patient Controlled Analgesia (PCA) p47; and BGH Dispensing p75

Issued By: Borders General Hospital Pharmacy Department

Contents

INTRODUCTION
PATIENT INVOLVEMENT AND CONSENT
CHAPTER 1 - GENERAL MEDICINES ISSUES12
1.1 Purchasing medicines12
1.2 Clinical trials12
1.3 Patient's own medicines12
1.4 Multi-compartment compliance aids13
1.5 Cytotoxic chemotherapy13
1.6 Pharmacy services13
1.7 Medicines in wards and departments13
1.8 Unauthorised drugs or suspicious substances13
1.9 Assistant Practitioners14
CHAPTER 2 - CONTROLLED DRUGS IN SECONDARY CARE15
Standard Operating Procedures15
SAFER MANAGEMENT OF CONTROLLED DRUGS: A Guide to Good Practice in Secondary Care
(Scotland)16
2.1 Introduction
2.2 Legislation
2.2.1 Misuse of Drugs Act 197117
2.2.2 Misuse of Drugs Regulations17
2.2.3 Schedule 117
2.2.4 Schedule 217
2.2.5 Schedule 3
2.2.6 Schedule 4
2.2.7 Schedule 519
2.2.8 Misuse of Drugs (Safe Custody) Regulations 197319
2.2.9 Misuse of Drugs (Supply to Addicts) Regulations 199719
2.2.10 Health Act 2006/Health and Social Care Act 201219
2.2.11 Medicines Act 196819
2.2.12 Supply and administration of controlled drugs20
2.2.13 Supply and /or administration of controlled drugs under Patient Group Directions20
2.2.14 Midwife exemptions

2.3	Governance Arrangements	23
	2.3.1 Accountability and responsibility	23
	2.3.2 Standard Operating Procedures	23
	2.3.3 Additional Information	23
	2.3.4 General Principles	23
2.4	Management of CDs in wards, theatres, and departments	24
	2.4.1 Accountable individuals	24
	2.4.2 CD stocks	24
	2.4.3 Requisitioning of CDs	24
	2.4.4 Receipt of CDs	25
	2.4.5 Storage of CDs	26
	2.4.6 Responsibility for CD keys	27
	2.4.7 Missing CD keys	27
	2.4.8 Record-Keeping	27
	2.4.9 Records of Receipts	28
	2.4.10 Ward, theatre and department CD stock checks	29
	2.4.11 Archiving of CD records	29
	2.4.12 Prescribing for inpatients	30
	2.4.13 Prescribing for discharge patients	30
	2.4.14 Prescribing for outpatients	30
	2.4.15 Supplementary and Independent prescribers	31
	2.4.16 Administration	32
	2.4.17 Returning CDs to the pharmacy	34
	2.4.18 Records of CDs returned: Ward or Department	34
	2.4.19 Records of CDs returned: Pharmacy	35
	2.4.20 Discrepancies and diversion	35
2.5	Management of CDs – general processes and specific circumstances	36
	2.5.1 CD Stationery	36
	2.5.2 Definition of CD stationery	36
	2.5.3 Secure storage of CD stationery	36
	2.5.4 Supply of CD stationery	37
	2.5.5 Use of CD stationery	37
	2.5.6 Loss or theft of CD stationery	37

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 4 of 100

2.5.7 Movement/Distribution of CDs within and outside the hospital	8
2.5.8 Methods of transfer	8
2.5.9 Records of transfer	8
2.5.10 Messengers	8
2.5.11 Transfer of CDs from ward to ward or theatre to ward	8
2.5.12 Clinical trials	9
2.5.13 Labelling4	0
2.5.14 Disposal4	0
2.5.15 Clinical trial CDs returned by patients4	0
2.5.16 Management of CDs that are the patient's property4	0
2.5.17 Use of a patient's own CDs on the ward4	0
2.5.18 Out-of-hours supply4	1
2.5.19 Temporary/ward closure/relocation and transfer4	1
2.5.20 Relocation to different site4	2
2.5.21 CDs brought into hospital belonging to parents/carers4	2
2.5.22 Patients on prescribed methadone/buprenorphine (or other opiate substitution therapy OST) who are admitted or discharged from hospital4	2
2.5.23 CDs for midwives4	3
2.5.24 Supplies of CDs for home confinements4	3
2.5.25 Use of opiates by midwives for hospital births4	3
2.6 Procedures for Controlled Drugs in Hospitals4	4
2.6.1 Controlled drugs stock lists/wards, theatres and departments4	4
2.6.2 Issue of controlled drugs from the pharmacy4	4
2.6.3 Borrowing Schedule 2 and Schedule 3 controlled drugs between wards, theatres and departments4	4
2.6.4 Returning Schedule 2 controlled drugs and Schedule 3 controlled drugs with safe	
custody requirements to pharmacy from wards, theatres and departments4	
2.6.5 Security of controlled drug stationery4	
2.6.6 Dealing with discrepancies with controlled drugs in pharmacy department4	6
2.6.7 Action in the event of a breach of security involving controlled drugs4	
2.6.8 Patient Controlled Analgesia (PCA)4	
2.6.9 Suspicious substances4	8
2.7 Management of CDs in hospital pharmacies5	C
2.7.1 Accountability and responsibility5 NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 5 of 100	C

2.7.2 Security of CDs50
2.7.3 Ordering and receipt50
2.7.4 Receipt
2.7.5 Storage
2.7.6 Issuing of CDs to wards and departments51
2.7.7 Electronic systems
2.7.8 Labelling of CDs for Ward or Department use52
2.7.9 Liquid preparations
2.7.10 Computerised registers52
2.7.11 Checks of CD stocks held in the pharmacy52
2.7.12 Discrepancies53
2.7.13 Archiving of CD records53
2.7.14 Supply to outpatients and discharge patients53
2.7.15 Supply to external units or other health and social care bodies in exceptional circumstances
2.7.16 Destruction of stock CDs54
2.7.17 Destruction of CDs returned by patients54
2.7.18 Methods of disposal for CDs55
2.7.19 Pharmacy Staff training for management of CDs55
2.8 Additional governance arrangements for prescribing controlled drugs (non-medical prescribers)
2.8.1 Controlled drugs are only supplied or administered to patients on the authority of an independent prescriber (V300 NMC qualification) or pharmacist registered as an independent prescriber
2.8.2 Controlled drugs prescribed by independent prescriber are justified for the individual patient
2.8.3 Independent non-medical prescribers may prescribe controlled drugs
2.8.4 Controlled drugs are not prescribed for a period beyond their clinical need
2.8.5 Records of prescribing of controlled drugs facilitates monitoring of the quantity and frequency of prescribing of controlled drugs in general and for individual patients, and adherence to the Clinical Management Plan or Personal Core Formulary
2.9 Staff training for management of CDs
2.10 Glossary of Terms
CHAPTER 3 – ORDERING
3.1 Out of Hours

CHAPTER 4 – STORAGE AND SECURITY	62
4.1 Hospitals/Health Centres/other departments	62
4.2 Medicines security and keys	62
4.3 Medication in the home	63
4.4 Transport of medication by community staff	63
4.5 Security of prescription pads	63
4.5.1 Prescription Fraud	64
4.6 Cold chain	64
4.7 Falsified Medicine's Directive	65
CHAPTER 5 – PRESCRIBING	66
5.1 Authority to Prescribe	66
5.1.1 Non-Medical Prescribing (NMP)	66
5.1.2 NMP prescribing in pregnancy	66
5.1.3 Pharmacist Amendments	67
5.1.4 Prescribing for Children	67
5.1.5 Prescribing Unlicensed Medicines/Outside Licensed Indications	67
5.2 In-Patients	68
5.2.1 Medicines Reconciliation	68
5.2.2 Red wrist bands	68
5.2.3 Use of the Medicine Chart	68
5.2.4 Verbal Instruction	70
5.3 Patient group directions (PGDs)	71
5.4 Patient specific directions (PSDs)	71
5.5 Medicines act exemptions	72
5.6 Patients' relatives	72
5.7 Out-patients Clinics (BGH and Outreach)	72
5.8 Emergency department (ED) & Borders Urgent Care Centre (BUCCs), BGH	73
5.8.1 Medicines Required in ED or BUCCs, BGH	73
5.8.2 Medicines Required at Discharge	73
5.8 Prescribing of medicines in hospital-discharge medications	73
5.8.1 Medicines reconciliation	73
5.8.2 Discharge Supply	73
5.8.3 Short Notice Discharge – Community Hospitals	74

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 7 of 100

5.8.4 Doctors Own Prescribing	74
CHAPTER 6 – DISPENSING	75
6.1 Borders General Hospital	75
CHAPTER 7 – ADMINISTRATION AND RECORDING OF MEDICINAL PRODUCTS	76
7.1 Single practitioner administration	76
7.1.1 Weight-related dose	77
7.1.2 IV administration	77
7.2 Administration	78
7.2.1 Controlled Drugs	79
7.3 Covert Administration of Medication	80
7.4 Administration of Parenteral Medicines	80
7.4.1 Intravenous (IV) cytotoxic chemotherapy	80
7.4.2 Parenteral nutrition	80
CHAPTER 8 – INTRAVENOUS ADMINISTRATION	81
8.1 Prescriber's Responsibility	81
8.2 Responsibility for Administration	81
8.3 Pharmacy Service Responsibility	83
8.4 Dosage Calculations by the Intravenous Route	83
8.5 Authority to Prepare IV Additives	83
8.6 Other Parenteral Routes	84
8.7 Infusion Pumps and Drivers	84
8.8 Prescribing Process and Documentation of Medicines to be added to Intravenous In Fluids	
8.9 Labelling and Checking of Medicines added to Intravenous Infusion Fluids	85
8.10 IV Safety Checks	85
8.11 Records	85
8.12 Subcutaneous Infusions	86
CHAPTER 9 – LOCAL PROCEDURES AND GUIDANCE	87
APPENDIX 1 – RECEIPT OF CDs	88
APPENDIX 2 – GUIDE FOR RECEIVING CDs INTO CABINET	91
APPENDIX 3 – MISSING CD KEYS	93
APPENDIX 4 – CD CHECKOMNICELL	94
APPENDIX 5 – FORM FOR THE REMOVAL OF SUSPICOUS SUBSTANCES	96

APPENDIX 6 – DEALING WITH CD DISCREPANCIES	97
APPENDIX 7 - STUDENT NURSE MEDICINE ADMINISTRATION – A GUIDE	99
BIBLIOGRAPHY	100

INTRODUCTION

This Code of Practice lays down guidance for all staff who may be involved in the prescribing, supply and administration of medicines.

For the purpose of this code a medicine is defined as a substance that is introduced into the body, or externally applied to the body, for the purpose of:

- treating disease
- preventing disease
- diagnosing disease
- ascertaining the existence, degree or extent of a physiological condition
- contraception
- inducing anaesthesia, or
- otherwise preventing or interfering with the normal operation of a physiological function

and includes all licensed medicines, unlicensed medicines, medicines used off label, contrast media, medical gases, medicines licensed as medical devices, wound products, stoma bags, catheters, aromatherapy oils (policy in section 10), herbal medicines and other complementary medicines.

The Code of Practice for the Control of Medicines document should be read in conjunction with the policies/documents included in section 10.

The Code provides broad guidelines and some procedures. Detailed local procedures may be necessary in specific areas; refer to section 10.

Managers/Heads of Department are responsible for ensuring staff follow the guidelines laid down in the Code. Each individual member of staff must ensure that they comply with the code and with their respective professional guidelines.

The code has been mapped to appropriate local and national legislation/guidance such as the *NMC Guide for Medicines Management*.

The bibliography at the end of this document includes references used to compile this Code of Practice and can be used as extra reading for staff involved with use of medicines.

PATIENT INVOLVEMENT AND CONSENT

All staff should appreciate the importance of involving the patient in their treatment as much as possible. This includes ensuring that informed consent to treatment has been given, either by the patient or the parents (if the patient is under 12 years). Consent should be informed, i.e. the person should have an adequate understanding of their condition and proposed treatment to enable them to make an informed decision.

If the patient is unable to give consent due to diminished capacity, use of the *Adults* with *Incapacity Act* is mandatory by law in non-emergency situations.

Emergency medication may need to be prescribed and administered without consent in certain circumstances; this is covered under 'Common Law'.

Special provisions apply under the Mental Health (Care and Treatment) (Scotland) Act 2003, in relation to treatment for mental disorder. Advice should be sought from the Psychiatric Liaison Service or other appropriate staff from the mental health service in these circumstances.

In certain cases the consent must be written, e.g. for participation in clinical trials.

It is important that the patient (or carer/parents if appropriate) receives adequate information about their medicines prior to discharge unless their care plan deems it inappropriate.

The patient should know as a minimum:

- why the medicine is being prescribed and its purpose
- how and when to take it
- how long it is to be taken for
- what side-effects they may experience

When advising patients on medicines related matters appropriate medicines information can be provided in leaflet form. This must be in addition to, and not instead of, fully explaining the medication to the patient during the consultation.

Medicines information leaflets may be provided in large print/brail/electronically and the use of a translator should also be considered if required.

Patients should be encouraged to assume greater responsibility for taking their medicines in preparation for their discharge. Self-medication should be encouraged wherever appropriate and local procedures agreed with medical, nursing and pharmacy staff.

The information in this Code can be made available:

- In large print
- On audio tape or CD
- In Braille and Community languages
- We accept requests on tape and in alternative formats.

CHAPTER 1 - GENERAL MEDICINES ISSUES

1.1 Purchasing medicines

 Medicines may only be purchased on behalf of NHS Borders by a pharmacist acting in accordance with laid down procedures. Samples or clinical trial material must not be left on NHS Borders premises without being taken to the Borders General Hospital Pharmacy Department for issue.

1.2 Clinical trials

- 1. No clinical trial may commence until approval has been given by the Research Ethics Committee and NHS Borders Research Governance Committee.
- 2. All medicinal supplies (including placebos) must be issued through the pharmacy department.
- 3. A full protocol and code breaks must be held by the trial organiser and the pharmacy (if hospital based).
- 4. NHS staff must not knowingly administer or supply trial material if informed consent has not been given. It is the responsibility of the trial organiser to ensure informed consent has been obtained (There are some mechanisms by which drugs in trials may be given where informed consent is not possible i.e. patient unconscious, these mechanisms must be stipulated within the trial protocol).

1.3 Patient's own medicines

- Patients should be encouraged to bring their own medicines into hospital with them to aid identification of current treatment and to continue using within the Patient's Own Drug (POD) dispensing system. Patient's own medicines must go with the patient if they are transferred. Patient's own medicines will be assessed, according to procedure and continue to be used, if appropriate.
- 2. Medicines no longer appropriate should be disposed of via the usual route for disposal/return of medicines.
- 3. Some patients will be taking complementary medicines, eg. herbal or supplements. The prescriber should assess whether to prescribe these products according to their competence and using current peer reviewed literature as a basis for sound decision making. If they are prescribed then they should be treated as a medicine under this Code of Practice. Not all of these products may be available to be provided whilst in hospital, so it may be necessary for patients to continue taking their own complementary medicines whilst an inpatient.
- 4. When managing patients' own controlled drugs please refer to the information in section 3 and the Policy for the Management of Controlled Drugs in Secondary Care.
- 5. Patients' own Controlled Drugs must be entered into the ward/department CD Register and stored in the CD cupboard. Where patient's own CDs have been approved for reuse, standard operating procedures must be followed and use must be in accordance with Patients Own Drug Guidance. When the patient is discharged the drugs should either be returned to the patient or to pharmacy for destruction, either action should be clearly

recorded and witnessed in the CD Register.

1.4 Multi-compartment compliance aids

- 1. Guidance on the use of multi-compartment compliance aids is available on the NHS Borders intranet.
- 2. Patients who are using a multi-compartment compliance aid (e.g. MTS, Dossett, Nomad, Venalink) when admitted to hospital must have this recorded in their notes as part of their drug history/admission details. Admission checklists should include a prompt for identifying those patients who will require a multi-compartment compliance aid at the point of discharge. Patients may be referred to a community pharmacy for assessment for supply of a multi-compartment compliance aid. If a patient has formal Carers in place, the care provider may carry out an assessment to determine the most appropriate medicines management support to provide.
- 3. Discharge arrangements should ensure that a system is set up for a multicompartment compliance aid to be refilled in the community and that the pharmacy filling the aids is informed regarding changes in medication. Staff will ensure that patients are assessed for their suitability to use multi-compartment compliance aids. This assessment should be carried out during initial prescribing, at the point of any changes in condition, and on discharge or transfer from hospital.

1.5 Cytotoxic chemotherapy

- Cytotoxic chemotherapy must only be prescribed and administered within the local policies Guidelines for Handling Cytotoxic Drugs (BGH Pharmacy) and the national guidelines CEL 30 (2012), Revised Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy (SACT) by appropriately trained staff.
- 2. Intrathecal cytotoxic chemotherapy is the subject of specific local policies and procedures Policy for Intrathecal Chemotherapy BGH and may only be prescribed, dispensed and administered by trained and authorised staff on the register held within BGH pharmacy.

1.6 Pharmacy services

1. The pharmacy department is responsible for procurement, storage, dispensing, labelling and distribution of medicines for NHS Borders. It is also responsible for ensuring the quality of medicines supplied. Pharmacists also play a role in providing advice and information on all aspects of the use of medicines.

1.7 Medicines in wards and departments

- 1. The staff member in charge of a ward or department which holds medicines is responsible for safety and security of those medicines.
- 2. Topical Medicines from Stock: These are single patient use items. Nursing staff taking a topical prep from stock must label it with an addressograph for the intended patient (or wait and order for the patient from pharmacy).

1.8 Unauthorised drugs or suspicious substances

1. If patients are found to be in possession of drugs or substances which may be illegal or for the purposes of abuse follow the Procedure for Dealing with unauthorised drugs or other

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 13 of 100

suspicious substances found in NHS Hospital premises.

1.9 Assistant Practitioners

- Assistant practitioners must undergo the approved vocational qualification and competency assessment prior to undertaking any role in medicines administration or management.
- 3. Assistant Practitioners will participate in the administration and recording of oral, topical, medicinal products, at the appropriate level for their training, as outlined in the local standard operating procedure (SOP) documents. This will be following delegation and preparation by the registered nurse/midwife.
- 4. Assistant Practitioners may second check controlled drugs. This excludes high strength doses as labelled by pharmacy 'high dose' and sent to ward in red bags. Assistant Practitioners involved in checking, preparing and administering medication by the intravenous route should witness the whole process from preparation to administration.

5. Assistant Practitioners may independently second check:

- drug calculations
- administration of medicines &controlled drugs
- second signatory in Controlled Drug Record Books
- controlled drugs stock checks
- verbal orders
- 'pre-pack' medicines issued by a registered nurse/ midwife for patients taking home

This specifically EXCLUDES:

- Medicines that require blood investigations/ interpretation
- Doses that are weight related
- Infusions requiring specific on-going monitoring of the patient
- Patients with more than one concurrent infusion
- Medications identified for bolus infusion as high risk (identified in IV study day)

Assistant Practitioners may administer/undertake:

- subcutaneous fluids
- PEG feeds and medication where this is defined on a clear agreed care plan.
- blood glucose monitoring and stable diabetic insulin injections where delegated by a registered Nurse/midwife.
- prophylactic low molecular weight s/c heparins such as Dalteparin where it is prescribed in the pre-printed section of the medicines chart only.
- routine vaccines under patient specific directions or prescription.
- Enema and suppositories
- Vaginal pessaries
- Receiving medications on wards/ ensuring medications follow transferred/moved patients
- 6. Assistant Practitioners skills may be developed in specific areas, where this is appropriate the Area Drugs and Therapeutics Committee must be formally approached to agree exceptions to this policy. This will include single vial dilution, where the full vial is administered but excludes part doses.

CHAPTER 2 - CONTROLLED DRUGS IN SECONDARY CARE

NHS Borders has adopted the guidance issued by the Scottish Government in February 2008 (CEL 7 (2008)) Safer Management of Controlled Drugs: A Guide to Good Practice in Secondary Care (Scotland) (appendix 1)) as policy.

This will apply to all secondary care settings including community hospitals. Community hospitals should be considered as for all other wards and departments and not as a separate entity as detailed in some parts of the guidance.

Standard Operating Procedures

- 1. Staff handling controlled drugs will work within the framework of the guidance. To achieve this staff are required to follow NHS Borders standard operating procedures (SOPs) to meet the standards of practice outlined in the guidance.
- 2. SOPs to support the main elements within the policy will be drafted centrally in consultation with staff from across NHS Borders.
- 3. NHS Borders SOPs may be adapted for local use as long as the adapted SOP complies with the detail of the guidance. Such changes must be agreed with the Controlled Drug Governance Team. Copies of locally adapted SOPs must be lodged with Controlled Drug Accountable Officer.
- 4. All SOPs must be authorised by the Controlled Drug Controlled Drug Accountable Officer for NHS Borders (contact details below) or someone delegated by her to carry this out.
- 5. Where SOPs for a particular activity are not available these may be drawn up locally but must be authorised by the Controlled Drug Accountable Officer, alternatively where activities are not frequently carried out, staff must follow the detail within the guidance.
- 6. Copies of SOPs will be made available on the NHS Borders intranet, once completed.

SAFER MANAGEMENT OF CONTROLLED DRUGS: A Guide to Good Practice in Secondary Care (Scotland)¹

2.1 Introduction

- 1. The fourth report of the Shipman Inquiry, "The Regulation of Controlled Drugs in the Community"² made recommendations to strengthen and improve systems for the use and management of controlled drugs for human use. The UK Government's response to the fourth report, "Safer Management of Controlled Drugs"³ agreed that the systems should be improved and strengthened and set out a programme of work to address the shortcomings identified by the Inquiry. This has included amendments to the Misuse of Drugs Regulations 2001 and new governance arrangements introduced in the Health Act 2006 and Regulations made under the Act the Controlled Drugs (Supervision of Management and Use) Regulations 2013⁴.
- 2. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It aims to set out robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of CDs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them.
- 3. In recent years, developments have taken place to modernise working practices. For example, the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, e.g. Operating Department Practitioners. This guidance seeks to clarify how these developments fit within the existing legal framework for controlled drugs. It builds on and augments the advice provided in *The Safe and Secure Handling of Medicines: A team approach (the Revised Duthie Report*) and readers are encouraged to refer to the *Revised Duthie Report* for guidance on more general aspects of medicines management⁵.
- 4. In this document the term "should" has been used for recommendations that relate to good practice and "must" for those governed by legal requirements. Recommendations have also been inserted that "may" be followed as matters of good practice, if they are relevant to local circumstances. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasion find gaps or points which fit uneasily with their situation. In such cases the principles listed in Chapter 4 (of CEL 7 (2008)) will provide a basis for policy formulation.
- 5. Legislation relating to Controlled Drugs is reserved. The Scottish Government is therefore not in a position to answer specific individual queries relating to the management of

¹ <u>https://www.sehd.scot.nhs.uk/mels/CEL2008_07.pdf</u> (Accessed 05 September 2022)

² <u>https://webarchive.nationalarchives.gov.uk/ukgwa/20090808160142/http://www.the-shipman-inquiry.org.uk/fourthreport.asp</u> (Accessed: 05 September 2022)

³ <u>https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http://www.dh.gov.uk/assetRoot/04/09/79/06/04097906.pdf</u> (Accessed: 05 September 2022)

⁴ <u>https://www.legislation.gov.uk/uksi/2013/373/contents/made</u> (Accessed: 05 September 2022)

⁵ <u>https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines</u> (Accessed 05 September 2022)

NHS Borders Code of Practice for the Control of Medicines; Updated July 2022 Review July 2024 Page 16 of 100

controlled drugs. Healthcare professionals should in the first instance contact their Health Board's Accountable Officer for Controlled Drugs.

6. This guidance is based on "Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)" published by the Department of Health in October 2007, which was developed following widespread consultation with key stakeholders chaired by the Royal Pharmaceutical Society of Great Britain. In Scotland, at the request of the Chief Pharmaceutical Officer, a working group from the Directors of Pharmacy Group reviewed and developed the guidance for the Scottish healthcare system.

2.2 Legislation

2.2.1 Misuse of Drugs Act 1971

 The legislation relating to Controlled Drugs is reserved and the Misuse of Drugs Act (MDA) 1971 and its associated Regulations provide the statutory framework for the control and regulation of CDs. The primary purpose of the MDA is to prevent misuse of CDs. The Act makes it unlawful to possess or supply a CD unless an exception or exemption applies. (Additional statutory measures for the use and management of CDs are laid down in the Health Act 2006 and its associated Regulations).

2.2.2 Misuse of Drugs Regulations

1. The Misuse of Drugs Regulations (MDR) enables certain classes of persons to possess, produce, supply, prescribe or administer CDs in the practice of their professions. The MDR classify the drugs in five schedules according to the different level of control required. Schedule 1 CDs contains the most strictly controlled, whereas Schedule 5 CDs are subject to a much lower level of control. For practical purposes, healthcare staff need to be aware of the current Regulations. The MDR are periodically amended and revised and can be found at www.legislation.gov.uk

2.2.3 Schedule 1

1. Includes hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research and other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners, for example, doctors, dentists and veterinary surgeons and pharmacists may not lawfully possess Schedule 1 CDs except under a license from the Home Office.

2.2.4 Schedule 2

 Includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine. Schedule 2 drugs (except secobarbital) are subject to safe custody requirements under The Misuse of Drugs (Safe Custody) Regulations 1973. They must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe⁶, which

⁶ See part 2.4.5.2 for details of suitability of locked receptacles; also refer to *The Misuse of Drugs (Safe Custody) Regulations 1973* and British Standard 2881:1989

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 17 of 100

can only be opened by the person in lawful possession of the CD or a person authorised by them. These drugs may be manufactured or compounded by a license holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

- 2. A pharmacist may supply Schedule 2 CDs to a patient only on the authority of a prescription in the required form issued by an appropriate practitioner. Not all prescribers can currently prescribe CDs but the position may change in the future.
- 3. Schedule 2 CDs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 CDs.
- 4. There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 CDs and this register must comply with the requirements of the Misuse of Drugs Regulations 2001, as amended. As a matter of good practice, wards and departments should also keep a register for Schedule 2 CDs. Midwives must keep a register for the Schedule 2 CDs that they are allowed to carry.
- 5. The destruction of unused or unwanted Schedule 2 CD stock must only take place in the presence of an appropriately authorised person. A license is required to import or export Schedule 2 CDs.

2.2.5 Schedule 3

- 1. Includes tramadol, gabapentin and pregabalin plus a small number of minor stimulant and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused. With some exceptions, Schedule 3 CDs are exempt from the safe custody requirements and can be stored on the open dispensary shelf.
- 2. The exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment. There is no legal requirement to record transactions involving Schedule 3 CDs in a CD register.
- 3. Invoices must be kept for two years.
- 4. The requirements for destruction do not apply unless the CDs are manufactured by the individual.
- 5. Schedule 3 CDs are subject to full import and export control.

2.2.6 Schedule 4

- 1. Is split into two parts:-
 - Part 1 (CD benzodiazepines) contains most of the benzodiazepines, plus other substances including the 'Z' drugs (zaleplon, zolpidem, zopiclone), fencamfamin and mesocarb.
 - Part 2 (CD anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoceptor stimulant) and growth hormones (5 polypeptide hormones).
- 2. There is no restriction on the possession of Schedule 4 Part 2 drugs when it is part of a medicinal product. However, possession of a CD from Schedule 4 Part 1 is an offence without the authority of a prescription in the required form. Possession by practitioners and pharmacists acting in their professional capacities is authorised.

- 3. Drugs in Schedule 4, Part 1 are subject to full import and export control. A Home Office license is required for the importation and exportation of substances in Part 2 unless the substance is in the form of a medicinal product and is for administration to a person to themselves.
- 4. All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers.
- 5. Prescription writing requirements for Schedule 4 CDs do not apply, except those requirements laid out in the *Medicines Act 1968*. CD registers do not need to be kept for Schedule 4 CDs although records should be kept if such CDs are compounded, or if a licensed person imports or exports the CDs (see regulation 22 of the *Misuse of Drugs Regulations 2001*).

2.2.7 Schedule 5

- 1. Includes preparations of certain low strength CDs which are exempt from full control when present in medicinal products, as their risk of misuse is reduced.
- 2. There is no restriction on the import, export, possession, administration or destruction of Schedule 5 CDs and the *Safe Custody Regulations* do not apply. (Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession).
- 3. A practitioner or pharmacist acting in his/her capacity as such, or a person holding an appropriate license, may manufacture or compound any CD in Schedule 5.
- 4. Invoices must be retained for a minimum of two years.

2.2.8 Misuse of Drugs (Safe Custody) Regulations 1973

1. The regulations impose controls on the storage of CDs and the degree of control depends on the premises where the CDs are being stored. All Schedule 2 and 3 CDs should be stored securely in a cabinet or safe, locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet.

2.2.9 Misuse of Drugs (Supply to Addicts) Regulations 1997

1. These regulations prohibit practitioners 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 if the drugs are being used for the treatment of organic disease or injury.

2.2.10 Health Act 2006/Health and Social Care Act 2012

 The Controlled Drugs (Supervision of Management and Use) Regulations 2006, made under the Health Act, came into effect in Scotland on 1 March 2007. The regulations set out requirements for certain NHS and independent organisations for the safe management and use of CDs. As a consequence of the Health and Social Care Act passing in 2012, The Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the 2013 Regulations") came into force in England and Scotland on 1 April 2013.

2.2.11 Medicines Act 1968

1. The *Medicines Act* and regulations made under the Act govern the sale, supply and NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page **19** of **100**

administration of medicines. It also allows certain exemptions from the general restrictions for e.g. midwives. A number of healthcare professionals are permitted to supply and/or administer medicines in accordance with Patient Group Directions (PGDs).

2. More information about the *Medicines Act* and PGDs can be found on the website of the *Medicines and Healthcare products Regulatory Agency (MHRA)*⁷

2.2.12 Supply and administration of controlled drugs

- 1. There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be:
 - Prescribed by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary non-medical prescriber as a part of a patient specific clinical management plan.
 - Supplied and administered by a midwife.
 - Supplied and administered under Patient Group Directions.
 - Certain restrictions apply to each of these routes of supply.

2.2.13 Supply and /or administration of controlled drugs under Patient Group $Directions^{8}$

- A Patient Group Direction (PGD) allows a range of specified health care professionals, who may not be prescribers in their own right, to supply and/or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have signed it.
- Named nurses, paramedics and other specified health professionals can supply and administer certain CDs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment No. 3) Regulations 2003⁹ The limited circumstances are:
 - Registered nurses (but no other healthcare practitioners) in accident and emergency departments and coronary care units in hospitals can supply or administer diamorphine for the treatment of cardiac pain in accordance with a PGD.
 - Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 CD in accordance with a PGD, except:-
 - the anabolic steroids in Schedule 4, part 2;
 - injectable formulations for the purpose of treating a person who is addicted to a drug.

⁷ <u>https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</u> (Accessed 05 September 2022)

⁸ <u>https://webarchive.nationalarchives.gov.uk/ukgwa/20130126151508/http://www.homeoffice.gov.uk/about-us/corporate-publications-strategy/home-office-circulars/circulars-2003/049-2003/ (Accessed 05 September 2022)</u>

⁹ <u>https://www.legislation.gov.uk/uksi/2003/2429/contents/made</u> (Accessed 05 September 2022)

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 20 of 100

2.2.14 Midwife exemptions¹⁰

- 1. Registered midwives may administer parenteral a number of specified CDs in the course of their professional practice. These are:
 - Diamorphine
 - Morphine
 - Pentazocine lactate
 - Pethidine hydrochloride

¹⁰ <u>https://www.legislation.gov.uk/uksi/1997/1830/contents</u> (Accessed 05 September 2022)

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 21 of 100

Table 1 Summary of legal requirements that apply to Controlled Drugs in Schedules 2,3, 4 and 5 of the Misuse of Drugs Regulations 2001

Schedule (as	Schedule 2	Schedule 3	Schedule 4	Schedule 4	Schedule 5
outlined in	examples include:	examples include:	(Part 1)	(Part 2)	examples include:
Misuse of	diamorphine,	buprenorphine,	examples include:	examples include:	low strength
Drugs	morphine,	temazepam,	benzodiazepines,	anabolic and	opioids such as
Regulations	methadone,	midazolam,	zopiclone, Sativex	androgenic	codeine, pholcodine and
2001)	oxycodone, pethidine,	gabapentin, pregabalin,		steroids, clenbuterol, growth	morphine
2001)	ketamine,	tramadol		hormones	10mg/5ml oral
	amphetamines				solution
					('Oramorph'
Designation	CD Lic POM	CD No Reg POM	CD Benz POM	CD Anab POM	CD Inv P or CD
					Inv POM
Prescription	YES	YES	NO	NO	NO
writing					
requirements					
(applicable to					
outpatient and					
discharge					
prescriptions)					
Prescription	28 days after	28 days after	28 days after	28 days after	6 months
valid for	appropriate	appropriate	appropriate	appropriate	
	date	date	date	date	
Safe custody	YES	YES	NO	NO	NO
	except	with certain			
	quinalbarbitone	exemptions (see			
		MEP 45, July			
		2022, 3.6.9, pg.			
		116-117)			
Requisitions	YES	YES	NO	NO	NO
necessary?					
Records to be	YES	NO	NO	NO	NO
kept in CD					
register					
Emergency	NO	NO	YES	YES	YES
supplies		with exception			
allowed?		of			
		phenobarbitone			
		when			
		prescribing			
		indication is			
		epilepsy			
Maximum	30 days as good	30 days as good	30 days as good	30 days as good	N/A
duration that	practice	practice	practice	practice	
may be					
prescribed					
•	1	I	I		

Table adapted from Medicines, Ethics and Practice

* Prescriptions for Schedule 2 and 3 CDs may be typed or computer generated but must be signed by the prescriber¹¹ Further information can be found in Medicines, Ethics and Practice Guide (MEP) and in the British National Formulary (BNF).

¹¹ <u>https://www.legislation.gov.uk/uksi/2005/2864/made</u> (Accessed 05 September 2022)

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 22 of 100

2.3 Governance Arrangements

2.3.1 Accountability and responsibility

- At local level, Controlled Drug Accountable Officers in designated bodies (see Controlled Drugs (Supervision of Management and Use) Regulations 2006) must ensure the safe management and use of controlled drugs within their organisation. In Scotland, NHS Boards, the State Hospitals Board for Scotland, the National Waiting Times Centre Board, the Scottish Ambulance Service, and independent hospitals (including hospices) are designated bodies.
- Full guidance on the new governance arrangements including monitoring and inspection arrangements for controlled drugs can be found in HDL (2007) 12 dated 14 February 2007¹².
- 3. Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Controlled Drug Accountable Officer for the organisation that is receiving the service (once the CDs have been received responsibility for them passes to the receiving organisation). In setting up and reviewing these governance arrangements, the Controlled Drug Accountable Officer will want to pay particular attention to and prioritise key areas of risk which will include the interface with other health and social care providers.

2.3.2 Standard Operating Procedures

Full guidance on the development of standard operating procedures can be found in CEL (2007)14 dated 17 October 2007^{13}

2.3.3 Additional Information

- A comprehensive list of drugs included in Schedules 1-5 is given in the 2001 Misuse of Drug Regulations and can be accessed at <u>https://www.legislation.gov.uk</u>
- 2. See also Home Office, available at https://www.gov.uk/government/organisations/home-office

2.3.4 General Principles

- 1. There are a number of overarching principles that guide the use of medicines in general and CDs in particular. They underpin and inform the decisions that are made about the safe management of CDs within the current legal framework. The following principles should apply in relation to the management of CDs:
 - Patients have timely access to the medicines prescribed for them.
 - Organisations and individuals comply with the current legal requirements for CDs.
 - Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.
 - Patients are adequately informed about their treatment.

¹² <u>https://www.scot.nhs.uk/sehd/mels/HDL2007</u> 12.pdf (Accessed 05 September 2022)

¹³ <u>https://www.scot.nhs.uk/sehd/mels/CEL2007_14.pdf</u> (Accessed 05 September 2022)

NHS Borders Code of Practice for the Control of Medicines; Updated July 2022 Review July 2024 Page 23 of 100

- CDs are used and managed safely and securely.
- There is a clear audit trail for the movement and use of CDs.
- The use of CDs is audited and action is taken if necessary.
- CDs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of CDs.
- Local procedures and protocols are designed to be as clear and accurate as possible and do not impose an intolerable administrative burden.
- The stock levels and preparations of CDs held in wards and departments match what is routinely used in that clinical area.
- Healthcare staff have access to up-to-date information about CD legislation and official (e.g. Home Office) guidance.
- Healthcare staff in the organisation work to standard operating procedures, approved by the Controlled Drug Controlled Drug Accountable Officer.
- Healthcare and appropriate ancillary staff receive adequate training and are competent in the management of CDs (appropriate to their sphere of activity and level of responsibility).
- Access to CDs is restricted to appropriate, designated and legally authorised personnel.

2.4 Management of CDs in wards, theatres, and departments

2.4.1 Accountable individuals

- 1. The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of a ward, theatre or department is responsible for the safe and appropriate management of CDs in that area.
- 2. The registered nurse, midwife or ODP in charge can delegate control of access (i.e. keyholding) to the CD cabinet to another, such as a registered nurse or ODP.
- 3. However, legal responsibility remains with the registered nurse, midwife or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

2.4.2 CD stocks

- 1. There must be a list, and a minimum stock level, of the CDs to be held in each ward, theatre or department as stock items. The contents of the list must reflect current patterns of usage of CDs in the ward, theatre or department and must be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines and the registered nurse, midwife or ODP in charge.
- 2. The list must be modified if practices change and must be subject to annual review.

2.4.3 Requisitioning of CDs

- 1. The registered nurse, midwife, or ODP in charge of a ward, theatre or department, is responsible for the requisitioning of CDs for use in that area.
- 2. The registered nurse, midwife or ODP in charge can delegate the task of preparing a requisition to another registered nurse or midwife. However, legal responsibility remains with the registered nurse, midwife, or ODP in charge.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 24 of 100

- 3. Stock orders must be written on a Controlled Drug Order Book with duplicate pages and must be signed by an authorised signatory - that is a registered nurse, midwife, or ODP. Non stock CDs must be ordered in the ward controlled drug order book and the medicine chart of the patient the CD is required for must be sent to Pharmacy with the CD order book.
- 4. The registered nurse, midwife, or ODP in charge of a ward, theatre or department, is responsible for ensuring access to ordering stationery is restricted to those staff authorised to order CDs.
- 5. Orders must contain the following:
 - Name of hospital
 - Ward / Department
 - Drug name, form, strength, ampoule size if more than one available
 - Total quantity
 - Signature and printed name of registered nurse, midwife or operating department practitioner authorised to order controlled drugs for that ward/department.
 - Date
- 6. On occasion it may be necessary for registered pharmacy staff to alter the quantity, strength or formulation supplied. Where this happens the change must be altered, signed and dated by the registered member of pharmacy staff on both copies on the requisition. Omnicell cabinets will automatically generate orders for CD stock items. The stock list and the stock levels are agreed between the ward pharmacist and the charge nurse of the ward. When the reorder level is triggered an order is automatically generated and this will be received in pharmacy for processing. See above 3.5.3 #3 for ordering of non-stock controlled drugs. The charge nurse should discuss with the ward Pharmacist if there is a requirement for the CD Stock lists/levels to be adapted.
- 7. The person who accepts CDs for transit/delivery from the pharmacy must sign for receipt. This may be on separate documentation kept for this purpose.

2.4.4 Receipt of CDs

- When CDs are delivered to a ward, theatre or department they must be handed to a registered nurse, midwife, or ODP or Healthcare support workers (HCSW) that has completed the CD training module. On no account should CDs be left unattended. Messengers must identify the registered nurse or midwife by checking their identity badge. As a matter of good practice, where practical, the receiving person should not be the same person who ordered the CDs.
- The person permitted to receive CDs must sign for receipt of the sealed delivery package confirming that it was received intact. The package must be held in a secure place, or under direct surveillance, as defined in SOP Receiving Controlled Drugs:-Receiving Controlled Drugs –SOP-CD020 at APPENDIX 1
- 3. As soon as possible after delivery the registered nurse, midwife or ODP in charge must:
 - Check the CDs against the order form including the number ordered and received. If this is correct then the duplicate sheet in the CD order book must be signed in the "received by" section. Any tamper-evident seals on packs of medicines must be left intact when they are received from pharmacy. This will simplify and speed up routine

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page **25** of **100**

checks. A seal must only be broken when the pack is required for administration. Place the CDs in the appropriate CD cabinet. For wards with Omnicell cabinets stock drugs must be received into the cabinet following this process: See the guide below:-

Guide for Receiving CDs into Omnicell Cabinet – <u>at APPENDIX 2</u>

- Non stock controlled drugs should be entered into the ward register as below as there will not be a storage bin allocated for that drug in the Omnicell cabinet.
- Enter the CDs into the CD register, update the running balance and check that the balance tallies with the quantity that is physically present.
- 4. Receipt of CDs and updating of the CD record book (register) must be witnessed by a second competent person. This may be a HCSW that has completed the CD training module. If, when the tamper evident seal is broken the contents do not match the expected amount stated on the pack, the person in charge must contact the pharmacy department immediately. Make appropriate records in the CD Register and all necessary action taken to resolve the discrepancy must be documented.

2.4.5 Storage of CDs

- 1. The Misuse of Drugs (Safe Custody) Regulations 1973 covers the safe custody of CDs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store CDs.
- 2. Ward, theatre and department CD cabinets should conform to the British Standard reference BS2881¹⁴. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See <u>www.soldsecure.com</u>) should be used. Omnicell cabinets meet the required security standards.
- 3. All CDs must be stored in a locked receptacle which can only be opened by a person who can lawfully be in possession, such as a pharmacist or the registered nurse, midwife or ODP in charge, or a person working under their authority.
- 4. In certain circumstances, for example when CD discharge medicines are sent to the ward several hours before the patient leaves the medicines should be stored in the CD cabinet until the patient is ready to be discharged. These medicines must be segregated from the ward CD stock; there is not a requirement to document the quantities in the CD ward register. The cabinet should be dedicated to the storage of CDs.
- 5. General measures for the storage of CDs include the following:-
 - Cabinets must be kept locked when not in use
 - The lock must not be common to any other lock in the hospital
 - Keys must only be available to authorised members of staff and at any time the key holder must be readily identifiable
 - No other medicines or items should normally be stored in the CD cabinet except an item which has been agreed to by the Accountable Officer.
 - CDs must be locked away when not in use.

¹⁴ BS2881:1989 is the standard relating to the storage of medicines in healthcare premises. Officially titled *"Specification for cupboards for the storage of medicines in health care premises"* the act was published in July 1989 and covers both medicines cabinets and controlled drugs cabinets.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 26 of 100

There must be local SOPs (see below 3.5.7) for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.

2.4.6 Responsibility for CD keys

- 1. The registered nurse, midwife or ODP in charge is responsible for the CD key. The CD key must be kept separately from all other drug cupboard/ward keys. Key holding may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the registered nurse, midwife or ODP in charge.
- 2. On occasion, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).
- 3. The CD key should be returned to the nurse, midwife or ODP in charge immediately after use by another registered member of staff. If this is not practical, the registered nurse, midwife or ODP in charge must at all times know who has the CD key.
- 4. There must be a local SOP (see below) for storage of spare CD keys. This procedure must ensure that they are secure at all times and can only be accessed by authorised staff (see below 3.5.7).

2.4.7 Missing CD keys

- 1. If the CD keys cannot be found then urgent efforts must be made to locate the keys e.g. by contacting nursing, midwifery or ODP staff who have just gone off duty.
- 2. If the keys cannot be located, a SOP (see below) is in place to ensure that the senior registered nurse or midwife or the duty nurse or midwife manager is informed as soon as possible and the duty pharmacist as soon as appropriate. The SOP specifies the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded. A Datix must be completed even if the keys are subsequently found.
- 3. If the keys cannot be found then the hospital management and the police must be informed as soon as possible, within 48 hours. The SOP below is in place for recording and handling of incidents regarding lost CD keys:-

Missing CD keys – <u>SOP-CD023 at APPENDIX 3</u>

2.4.8 Record-Keeping

- 1. Each ward, theatre or department that holds stocks of CDs must keep a record of CDs received and administered in the CD Record Book (register) for wards that have Omnicell this information will all be documented in the online Omnicell register.
- 2. The registered nurse, midwife or ODP in charge is responsible for keeping this CD Record Book up to date and in good order.
- 3. The CD Record Book must be bound (not loose-leaf) with sequentially numbered pages and it must have separate pages for each drug, each form and each strength, so that a running balance can be kept easily. Entries must be made in chronological order, in ink or be otherwise indelible.
- 4. All entries must be signed witnessed by a registered nurse, midwife or ODP and must be witnessed preferably by a second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 27 of 100

registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained competent person. This may be a HCSW that has completed the CD training module.

- 5. Patients own controlled drugs which are being used or stored must be entered in the Patients Own Controlled Drug Register or at the back of the non-stock register (for wards with Omnicell cabinets) on a dedicated page, and each transaction must be recorded.
- 6. On reaching the end of a page in the CD record book, the balance must be transferred to another page. The new page number must be added to the bottom of the finished page and the index updated. This transfer must be witnessed.
- 7. If a mistake is made it must be bracketed in such a way that the original entry is still clearly legible. This must be signed, dated and witnessed by a second registered nurse, midwife, ODP or other registered professional or by an appropriately trained competent person. The witness must also sign the correction. See example below:-

NAME FORM AND PREPERATION OF STRENGTHMORPHINE SULPHATE Injection 10mg

AMO	UNT OBTAINED				AMOUNT (S)	ADMINISTERED			
Amount	Date Received	Serial No. Of Requisition	Date	Time	Patient's Name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
10 amps	24/04/22	SN:12			Received from Pharmacy				10 amps
			6/3/22	8.00am	Jenny Hill (syringe driver) *(6 ml remaining stopped and discarded SJ/BS)	1vial	S Jones	B Smith	9 amps

*error 4 mls remaining SJ/BS

2.4.9 Records of Receipts

- 1. A record must be kept of all CDs that are received or administered.
- 2. For CDs received, the following details must be recorded on the appropriate page in the CD Record Book:
 - Date of entry.
 - The serial number of requisition (CD order).
 - Quantity received.
 - Form (name, formulation and strength) in which received.
 - Name/signature of nurse/authorised person making entry.
 - Name/signature of witness.
 - Balance in stock.

For wards with Omnicell cabinets all of the above will be recorded in the online Omnicell register - **Guide for Receiving CDs into Omnicell Cabinet** – <u>at APPENDIX 2</u>

3. After every administration, the stock balance of an individual preparation must be confirmed to be correct and the balance recorded in the CD Record Book. The entry must be signed and dated. Omnicell cabinets will require both the staff member issuing the controlled drug and a witness to confirm that the physical balance matches the Omnicell balance.

2.4.10 Ward, theatre and department CD stock checks

- The stock balance of all CDs entered in the CD record book must be checked and reconciled with the contents of the cabinet at least once daily on days that the ward, theatre or department is open, at a change of shift, by a registered nurse, midwife or ODP from each shift. HCSWs who have completed the CD training module may act as a witness. In addition, stock checks must be carried out every three months by pharmacy staff. For wards with Omnicell cabinets a cycle count must be completed daily on 'touched' items and a full cycle count completed weekly. See guide below:-CD Check Omnicell – at APPENDIX 4
- The registered nurse, midwife or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward, theatre or department.
- 3. Where possible the staff undertaking this check should be rotated periodically. The stock check must take account of the following points:-
 - The balance in the CD record book must be checked against the contents of the CD cabinet, not the reverse, to ensure all balances are checked.
 - It is not necessary to open packs with intact tamper-evident seals for stock checking purposes, e.g. manufacturer's complete sealed packs.
 - Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks must be carried out. The balance must be confirmed to be correct on completion of a bottle.
 - In the event of a spillage, a second person must verify that it has occurred, and countersign the CD record book and Datix the incident so that any trends may be identified.
- 4. A record indicating that this reconciliation check has been carried out and confirming the stock is correct must be kept. This record must include as a minimum the date and time of the reconciliation check, and be signed by the registered nurse, midwife or ODP and the witness.
- Any discrepancy which cannot be accounted for by error or omission must be reported to the charge nurse and the ward pharmacist. If the discrepancy cannot be resolved it must be reported to the controlled drug team (<u>controlleddrugsteam@borders.scot.nhs.uk</u>, or ph: 01896 827711) and the police as soon as possible, within 48 hours.

2.4.11 Archiving of CD records

1. CD records, including documents designed to track and/or monitor CD usage, must be stored for two years from the date of the last entry or seven years if they contain details of CD destruction. The Omnicell CD register will show the last 6 months of data. However

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page **29** of **100**

Omnicell will automatically retain data so if you require to view data beyond the 6 month period then contact the Omnicell helpdesk <u>Omnicell@borders.scot.nhs.uk</u>

2.4.12 Prescribing for inpatients

- CDs can be prescribed on the inpatient medicines chart or other approved prescription charts including electronic records in line with local policies and procedures. CDs may only be prescribed by a suitably qualified practitioner who is recognised and authorised by the organisation to undertake this function.
- 2. The written requirements for CDs on these charts are the same as for other medicines:-
 - Medicine name and form
 - Route
 - Dose
 - Frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs if applicable)
 - Start date
 - Finish date where appropriate
 - Signature of prescriber
 - The patient's name, CHI number and allergy status must also be written on the chart.

2.4.13 Prescribing for discharge patients

 Prescriptions for CDs for patients who are going home (discharge medicines) must be written on locally-approved prescription forms for dispensing by the hospital pharmacy. <u>http://intranet/resource.asp?uid=22318</u>

These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a CD prescription.

- Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on these prescription forms for in-patients so far as this is necessary for the purposes of his employment as defined in the Medical Act 1983. Further guidance is available from the GMC.
- 3. Up to a maximum of 30 days' supply should be prescribed, as a matter of good practice. However, routine practice is to prescribe and supply 7-14 days.

There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where a prescriber considers it clinically appropriate to supply more than a 30-day quantity and this does not pose an unacceptable risk to patient safety, the patient's notes should be annotated to that effect. Prescribers who prescribe more than a 30-day supply must be prepared to justify their decision.

2.4.14 Prescribing for outpatients

 CD prescriptions for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (regulation 15). The prescription must be written on a Hospital Based Prescription (HBP5) form and endorsed "BGH to supply" if the hospital pharmacy is to dispense, or no endorsement if a community pharmacy is to dispense and should contain the same information as above.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page **30** of **100**

- 2. A prescription for Schedule 2 and 3 CDs must contain the following details written so as to be indelible, i.e. written by hand, typed or computer-generated:-
 - The patient's full name, address and, where appropriate, age.
 - The name and form of the drug, even if only one form exists.
 - The strength of the preparation, where appropriate.
 - The dose to be taken.
 - The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures.

In addition the patient's CHI number must be included on the prescription.

- 3. The prescription must be signed by the prescriber with his/her usual signature, in his/her own handwriting and dated by him/her (the date does not have to be handwritten). 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 their signature).
- 4. CD prescriptions may be computer-generated. Only the signature has to be in the prescriber's own handwriting. The prescriber is also required to sign any manual changes. If an electronic solution exists, local polices should describe how this operates within the supply system.
- 5. If the prescription is prepared by someone other than the prescriber then that person must be a registered healthcare professional.
- 6. The use of pre-printed sticky labels on prescriptions is good practice to ensure that all required details are included in a legible form, and to reduce transcription errors. However, if they are used, such sticky labels should be non-peelable and tamper evident (so that it is obvious if an attempt has been made to remove them), and they must be fixed to all duplicate copies of the prescription. Prescribers must sign across the sticky label and prescription (so that the signature is not entirely on the label). This is a further safeguard to ensure sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescriber signed for.
- 7. Sticky labels must not be used on CD prescriptions to be dispensed in the community. The scanning systems in use at Practitioner Services Division cannot process such prescriptions.

2.4.15 Supplementary and Independent prescribers

- Regulations were amended in 2005 to permit a supplementary prescriber, when acting under and in accordance with the terms of an agreed individual Clinical Management Plan (CMP), and supported by additional governance arrangements, to prescribe and administer and/or supply or direct any person to administer any CD provided that the CD is included in the CMP. Independent prescribers may prescribe any controlled drugs within their competency.
- 2. Good practice requires that there is a separation of duties. If the prescriber is a pharmacist, then they must not also dispense the controlled drug unless a second pharmacist, who is in a position to check that it is appropriate for the patient, checks it. If the prescriber is a nurse, they must not also administer the controlled drug, unless a second nurse who is in a

position to check that it is appropriate for the patient, checks it.

2.4.16 Administration

- 1. The administration of CDs must comply with all local policies and procedures for the administration of medicines. Nurses and midwives must follow Nursing and Midwifery Council standards and guidance.
- 2. The administration of CDs within secondary care should be done via two-person administration process; this process must include a registered nurse, midwife or ODP. HCSW's that have completed the CD training module may act as a witness. Any departure from the double checks process should be considered exceptional and carries with it a specific risk assessment to support this practice.
- 3. For the administration of CDs, one practitioner should be a registered nurse, midwife, doctor or ODP. HCSW's that have completed the CD training module may act as a witness. Both staff members must be present during the whole of the administration procedure or, in the case of an infusion or patient-controlled analgesia device, for the set-up and start. They must both witness:-
 - The preparation of the CDs to be administered.
 - The CD being administered to the patient.
 - The destruction of any surplus drug (e.g. part of an ampoule infusion not required).
- 4. A record must be made in the ward, theatre or department CD Record Book when a CD is removed from the CD or Omnicell cabinet for administration or destruction.
- 5. In theatres, the practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, must be avoided. An amount must be issued to the anaesthetist for a specific patient and any surplus drug must be destroyed and witnessed. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "2.5mg given and 2.5mg discarded "
- 6. Injectables must be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- 7. For CDs administered the following details must be recorded in the register:-
 - Date and time when dose administered.
 - Name of patient.
 - Quantity administered and discarded if appropriate.
 - Form (name, formulation and strength) in which administered.
 - Full signature of nurse/authorised person who administered the dose.
 - Full signature of witness (where there is a second person witnessing administration).
 - Balance in stock.

For wards with Omnicell cabinets all the above details will be recorded on the online register by selecting the patient from the ward list then selecting the CD required from the drugs list.

If part of a vial is administered to the patient, the registered nurse, midwife or registered practitioner should record the amount given and the amount discarded e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "2.5mg given and 2.5mg discarded".

The remainder of the vial should be discarded by a registered nurse and a suitable witness in a yellow blue lidded sharps bin. The contents of a Vernagel sachet should be placed in the sharps bin and the remaining contents of the vial/ampoule/syringe driver then emptied on top of the Vernagel powder in the sharps bin. This will then make the controlled drugs irretrievable as per legal requirement.

7. When an infusion containing a controlled drug is discontinued before all the solution has been infused then this should be recorded in the ward controlled drug register. (Either next to or below the original entry) please see example below:-

AMC	UNT OBTAINI	ED	AMOUNT (S) ADMINISTERED						
Amount	Date Received	Serial No. Of Requisition	Date	Time	Patient's Name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
			6/3/22	8.00 am		1 vial	S Jones	B Smith	6 VIALS

NAME, FORM, STRENGTH Morphine Sulphate Injection 10mg/ml

The partial dose disposed of column on the prescription/Administration chart for continuous infusion chart should be completed to record details of what is being discarded. This should be signed by if possible 2 registered nurses or a registered nurse and an Assistant Practitioner/HCSW or a student nurse/midwife at appropriate stage of training.

Section 2 - Preparation details - Syringe Size

Date	Time	Drug Name	Dose	Batch (Exp date)	Partial dose disposed of	Prepared and checked by:
6/03/22	8.00am	Morphine sulphate	10mg	xxxxxxxxx	6ml SJ/ BS	SJ/BS

The remaining contents of the infusion must be disposed of by two registered nurses in a yellow blue lidded sharps bin. The contents of a Vernagel sachet should be placed in the sharps bin and the remaining contents of the syringe driver then emptied on top of the Vernagel powder in the sharps bin. This will then make the controlled drugs irretrievable as per legal requirement.

For community nurses disposing of partial doses of syringe drivers they should follow the same process. If possible a second witness Registered nurse/Assistant Practitioner/HCSW or a student nurse/midwife at appropriate stage of training should sign to say that they have witnessed the disposal.

8. Individual doses of CDs which have been prepared but not administered must be destroyed by a registered nurse midwife or registered health professional on the ward or department in the presence of a witness and the reason documented in the CD Record Book. If the CD has been issued from an **Omnicell cabinet** it should be entered as 'waste drugs' on Omnicell and this will require the nurse to enter the reason for the drug not being administered therefore meaning the Omnicell register is updated and accurate. It must also be documented on the medicine chart that it has not been administered. Unused vials should be discarded in a yellow blue lidded sharps bin registered nurse midwife or registered health professional on the ward or department in the presence of a witness. The contents of a Vernagel sachet should be placed in the sharps bin and the remaining contents of the syringe driver then emptied on top of the Vernagel powder in the sharps bin. This will then make the controlled drugs irretrievable as per legal requirement.

2.4.17 Returning CDs to the pharmacy

- 1. Any CD's which are expired or patient's own CD's no longer required on the wards must be collected by Pharmacy (Pharmacist/Pharmacy technician) and **not** returned to Pharmacy by ward staff. To request for Pharmacy staff to uplift CD's from the ward telephone Pharmacy dispensary ext 26610 or liaise with your ward pharmacy technician who will then arrange for this to be done.
- 2. Unused CD stock from wards or departments may be returned to the pharmacy for reissue by the pharmacy, provided it was initially issued by BGH pharmacy and has at all times been under the control of that hospital. The pharmacy department be contacted to collect the CD's and then must carry out a risk assessment of returned CDs to ensure they are fit for re-use.
- 3. The CDs must be transferred to the pharmacy in a safe and secure way.

2.4.18 Records of CDs returned: Ward or Department

- 1. The ward or department must keep a record of drugs returned to the pharmacy in the CD record book. The entry must be made on the relevant page of the CD record book and must show:-
 - Date
 - Reason for return
 - Names and signatures of the registered nurse, midwife or ODP responsible and a relevant pharmacy staff
 - Quantity removed
 - Name, form and strength of drug
 - Balance remaining
- 2. There must be a fully auditable trail of the CD movement back to the pharmacy and the

pharmacy register.

2.4.19 Records of CDs returned: Pharmacy

- 1. The following details must be recorded when CDs are returned to the pharmacy:-
 - Date
 - Name, form, strength and quantity of drug returned
 - Reason for return
 - Name of the practitioner and pharmacy technician/pharmacist

2.4.20 Discrepancies and diversion

- 1. The balances in the CD record books must always tally with the amounts of CDs in the cabinet. If they do not, the discrepancy must be reported to the charge nurse who will lead the investigation.
- 2. The process for reporting and investigating discrepancies reporting and investigation is listed below. In the first instance the following must be carefully checked:-
 - Check arithmetic since last correct balance and confirm when stock check/correct balance was recorded to allow a time frame to be defined.
 - Check all controlled drug stocks with a second person (include date expired stock, dispensed medicines not yet collected and exclude patient returns)
 - Check other register sections of same drug class for erroneous entries
 - Sense-check register (correct pack sizes, patterns of entry for potential missing entries, and unusual quantities)
 - Check diary and contact all members of staff who have worked in the clinical area during the relevant period to verify any supplies made that have not been entered
 - All requisitions received have been entered into the correct page of the register. For wards with Omnicell the online register can be accessed by those with authority using the following link <u>http://intranet/microsites/index.asp?siteid=5&uid=9</u> ☑
 - All CDs administered have been entered into the CD record book/Omnicell(Medicine charts of patients who have been prescribed the drug may have to be compared to entries on Omnicell or in the CD ward register)
 - Items have not been accidentally put into the wrong place in the cabinet.
- 3. If the error or omission is traced, the registered nurse, midwife or ODP in charge should make an entry in the CD Record Book clearly stating the reason for the entry and the corrected balance. This entry must be witnessed by a second nurse, midwife, ODP, pharmacist, pharmacy technician or doctor. Both persons must sign the CD Record Book. Please see example below:

NAME, FORM, STRENGTH Oxycodone M/R tablets 10mg

AMOUNT OBTAINED			AMOUNT ADMINISTERED							
Amount	Date Received	Serial no. Of requisition	Date	Time	Patient's name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE	
56	24/02/22	SN:12			Receíved from pharmacy				66	
			06/03/22	8.00am	William Scott	*(2 tabs) *entered in error SJ/BS	S Jones	B Smith	*(64) *error SJ/BS	
						1 tab			63	

- In wards with Omnicell cabinets, see guide below: Guide for Dealing with CD Discrepancies <u>at APPENDIX 7</u>
- 5. If no errors or omissions are detected then a Datix must be completed, the ward pharmacist must be contacted the time and date that the pharmacist is contacted must be noted in register. If the discrepancy cannot be resolved it must be reported to the Controlled drug team and the police as soon as possible, within 48 hours.

2.5Management of CDs – general processes and specific circumstances

2.5.1 CD Stationery

 The registered nurse, or midwife in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of CDs for use in that area and for ensuring that all CD stationery used to order, return or distribute CDs is stored securely and that access to the stationery is restricted to those staff authorised to order CDs.

2.5.2 Definition of CD stationery

- 1. CD stationery includes:-
 - CD requisition books.
 - CD record books.
 - CD prescription
 - Omnicell records

2.5.3 Secure storage of CD stationery

- 1. CD stationery which is kept in wards, theatres or departments must be kept in a locked cupboard/Omnicell cabinet or a locked drawer to which access is restricted.
- 2. Stocks of CD stationery held in pharmacy departments must be kept in a secure area that is locked when there is no one present.

2.5.4 Supply of CD stationery

- 1. CD stationery must be issued from the pharmacy against a written requisition signed by a registered nurse or midwife or ODP
- 2. A record must be kept of the supply of CD stationery. It should include:-
 - Date
 - Ward/department
 - Name of person ordering the stationery
 - Type of stationery issued
 - Quantity
 - The serial numbers of the stationery
 - Signature of the member of pharmacy staff making the supply
 - Name of the registered nurse or midwife receiving the stationary

Any unused stationery returned to pharmacy must be recorded as a return, with the details above, in the supply record.

2.5.5 Use of CD stationery

- 1. Only one CD Order Book per ward or department should be in use.
- 2. When a new CD Record Book is started, the balance of CDs in stock must be written into the new book immediately by a registered nurse, midwife or ODP. This transfer should be witnessed.
- 3. All CDs must be transferred to the new CD Record Book at the same time. This may be carried out by a registered nurse/midwife/ODP. This transfer must be witnessed by a registered/student nurse/midwife/ODP or authorised member of staff e.g. pharmacist or pharmacy technician.
- 4. When transferring the physical balance and the CD Record Book balance must be checked. The balance in the old CD Record Book should be made 'zero' stating the date and the quantity transferred to the new CD Record Book. This must be signed by both members of staff. Any part used pages in the old CD Record Book should be ruled off.
- 5. The new CD Record Book should have an entry on the appropriately titled page stating the balance that was transferred and the page of old CD Record Book from which the information was transferred. This must be signed by both members of staff.
- 6. The front page of the old CD Record Book should be dated to show when the CDs were transferred and the book closed.
- 7. The front cover of the new CD Record Book should be dated to show when the book came into use.
- 8. Completed ward requisition books and CD record books must be retained securely in the ward or department for a minimum of two years from the date of closure.

2.5.6 Loss or theft of CD stationery

1. Loss or theft of any CD stationery which may be used to order CDs must be reported immediately to Pharmacy, and as soon as possible, within 48 hours, to the Accountable Officer and the police.

2.5.7 Movement/Distribution of CDs within and outside the hospital

- 1. Movement/distribution of CDs is likely to involve the following situations:-
 - Collection by ward staff from the pharmacy collection by porters from the pharmacy
 - Delivery by pharmacy staff to wards, departments, theatres
 - Collection by patient or representative for outpatient items only
 - Delivery by hospital porter/driver/blood bikes
 - Delivery by commercial courier (for example, taxi out-of-hours)

2.5.8 Methods of transfer

- 1. CDs must be transferred or conveyed in a secure, sealed, tamper-evident container.
- 2. CDs may not be transported in pneumatic tubes, or posted.

2.5.9 Records of transfer

1. At each point where a CD moves from the authorised possession of one person to another, a signature for receipt must be obtained. The transit forms will be filed in Pharmacy.

2.5.10 Messengers

- 1. The person who conveys the CD acts as a messenger, that is to say they carries a sealed or tamper-evident container and is responsible for delivering the container intact.
- 2. The person acting as the messenger must:-
 - Ensure destination is known.
 - Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
 - Have a valid ID badge.
- 3. CDs must only be handed to members of staff who are wearing valid ID badges.
- 4. CDs should be transported using NHS transport whenever possible. Where a commercial courier or taxi driver is responsible for conveying a CD they should be asked to show their valid company ID.
- 5. Taxi drivers or commercial couriers should not be made aware that CDs are being transported as this may increase the potential for diversion or may discourage taxi drivers from carrying CDs. As a matter of good practice the taxi driver identity number should be recorded. Contract taxi companies should be informed that taxi driver proof of identity will be routinely requested.

2.5.11 Transfer of CDs from ward to ward or theatre to ward

The three situations in which this is most likely to arise are:-

- 1. When a patient is receiving a CD by means of PCA pump infusion.
 - When a patient is transferred to another clinical area with controlled drugs such as PCA infusion, the current administration and monitoring chart must be transferred with him/her.
 - The registered nurse/midwife/ODP in theatre/ITU must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to ensure that the record is accurate when the patient is handed over, and that the quantity remaining is correct.

- The registered nurse/midwife/OPD in the clinical area to which the patient is transferred to must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to confirm that the record is accurate
- The local procedure for PCA must be followed at all times.

2. When a patient is receiving a CD by means of syringe pump or infusion (not PCA).

- When a patient is transferred to another clinical area with controlled drugs such as infusions, syringe drivers or patches, the current administration and monitoring chart must be transferred with him/her.
- The registered nurse/midwife/ODP in the clinical area the patient leaves must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to ensure that the record is accurate when the patient is handed over, and that the quantity remaining is correct.
- The registered nurse/midwife/OPD in the clinical area to which the patient is transferred to must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to confirm that the record is accurate

3. When a patient has his/her own CDs. (See below for the process)

- The nurse/midwife/OPD from the ward the patient is leaving from must check the balance of the controlled drug matches the balance in the ward CD register (patient's own section). The balance should also be checked and signed by a witness (registered nurse/Assistant Practitioner/or a student at the appropriate stage of training or a HCSW that has completed the CD training.
- An entry must then be recorded in the ward register signing the controlled drug out and documenting which ward the patient has been transferred to. Balance remaining will be zero.
- The nurse from the ward the patient is being leaving from should then take the ward CD register and the controlled drug to the ward the patient is being transferred to.
- A nurse from the receiving ward should check the balance of the CD against the balance recorded in the CD register from the previous ward.
- The CD should then be entered into the CD ward register of the receiving ward by a registered nurse and the entry must be counter signed by the nurse that had transferred the CD/patient.
- 4. When a CD has been dispensed on a "named-patient" basis. (The process in these circumstances should be the same as when a patient has his/her own CD's see above (2).
 - Patients' own CDs must be transferred from ward to ward with the patient in line with procedures for transferring all other medicines and properties belonging to that patient.

2.5.12 Clinical trials

1. The procedures for the use of CDs in clinical trials must comply with the Misuse of Drugs Regulations and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and MHRA guidance on clinical trials.

- 2. All clinical trial CDs must be stored segregated from stock CDs in the CD cabinet. They do not necessarily need to be stored in a separate CD cabinet. A separate page in the register must be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.
- 3. If a discrepancy is identified then it must be reported on the internal incident reporting Datix system in accordance with local procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed and also the clinical trials pharmacist for the hospital site and the Accountable Officer.
- 4. For double blind trials in which only one arm involves a CD, pharmacy staff may be unaware which packs contain CDs. In this situation, all supplies must be treated as CDs until the end of trial.
- 5. For trials involving the use of Schedule 1 CDs, a license from the Home Office must be obtained before the item is received into stock or supplied. The license should normally be held by the lead pharmacist for the hospital site and/or the Accountable Officer. A copy must be kept with the trial protocol.

2.5.13 Labelling

1. All clinical trial CDs must be labelled and dispensed in accordance with the specific trial protocol in addition to the MDR requirements.

2.5.14 Disposal

1. The clinical trial protocol must stipulate requirements for disposal of CDs. Clinical trial CDs must be destroyed in the same way as other CDs (see Chapter 8 Destruction of CDs in pharmacies). However, this destruction may need to be carried out following the monitoring instructions with the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

2.5.15 Clinical trial CDs returned by patients

 The clinical trial protocol must stipulate requirements for handling of CDs returned by patients. The pharmacy must establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records must be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimized.

2.5.16 Management of CDs that are the patient's property

1. The procedure for the management of CDs that are the patient's property must follow the general procedure regarding safe receipt, storage, recording and administration. Consent to use patients own controlled drugs should also be obtained (This should include destruction).

2.5.17 Use of a patient's own CDs on the ward

- 1. Patient's own CDs (i.e. CDs brought into hospital by the patient on admission) must be recorded in the ward's Patient's Own CD Record Book and stored in the CD cabinet.
- 2. It may be appropriate to use a patient's own CDs whilst they are in hospital. On such NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page **40** of **100**

occasions the drugs must be stored in the CD cabinet and checked for suitability according to the local procedure for patients own drugs to ensure that they are fit for purpose.

- 3. If patients' own CDs are no longer required for use, they should be designated for destruction following consent by the patient or the patient's representative. Pharmacy should be contacted to uplift the controlled drugs or destroy on the ward where appropriate. The removal/destruction should be recorded in the patient's own CD register and witnessed by a registered nurse.
- 4. Storage of CD discharge prescriptions do not require to be recorded in the Patient's Own CD Record Book unless the patient is remaining on the ward overnight.
- 5. Patient's own medicines including CDs must never be used to treat other patients.

2.5.18 Out-of-hours supply

- 1. The nurse, midwife or ODP in charge is responsible for ensuring that adequate stocks of controlled drugs are available to ensure that doses are not missed or delayed. There must be a system in place to ensure that adequate supplies of required medicines are ordered during the pharmacy opening hours.
- If supplies of CDs are required when the pharmacy is closed: in the first instance if another ward stocks the CD then see below section 3.7.3 for process when borrowing from wards. If the CD is not available, then contact the telephone exchange who will then contact the on-call pharmacist for advice/supply.

2.5.19 Temporary/ward closure/relocation and transfer

- 1. For the management of CDs during short and long term ward, department and theatre closures and transfers. The procedure must ensure the security of the CDs and should be auditable.
- 2. The process must include:-
 - A provision for a risk assessment to be carried out. The risk assessment must consider the likelihood of detection of an intruder, the deterrents in place, and the particular medicines being stored.
 - Arrangements for removal and temporary storage of CDs by the pharmacy, if appropriate.
 - Arrangements for return of CDs to the pharmacy for re-use, if appropriate.
 - Arrangements for transfer of CDs and Controlled Drug Record Book, if appropriate.
 - Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but CDs and Controlled Drug Record Book are left in place.
 - Specification of the entries required in the in particular when ward staff transfer but CDs and Controlled Drug Record Books are left in place.
 - Specification of the entries required in the Controlled Drug Record Book.
 - Arrangements for secure storage of current (i.e. in use) CD stationery during closure.
 - Arrangements for return of stocks, including reconciliation with list of CDs removed, if appropriate.
 - Arrangements for restocking, if appropriate.

2.5.20 Relocation to different site

- 1. If controlled drugs are required to be moved then a stock check must be completed by a registered nurse from the original location and a member of the pharmacy team.
- 2. The controlled drugs are packed into bag/box and sealed as appropriate.
- 3. The sealed bag/box must be transported by a member of staff to the next location.
- 4. Documentation must be verified and a stock check must be undertaken at the new location
- 5. Any discrepancies must be notified to the pharmacy department and Accountable Officer and investigated.

2.5.21 CDs brought into hospital belonging to parents/carers

- Parents/carers who are substance users may bring CDs prescribed and supplied for their own use on to hospital premises. There needs to be a local procedure that addresses this. For example, in neonatal units, women who no longer require medical or nursing care, and who are transferred to the transitional care area while their babies remain in hospital may have difficulties travelling to their community pharmacy to collect their methadone.
- 2. The required daily dose may be dispensed from the ward under the following circumstances:-
 - the woman has genuine difficulty in accessing the community pharmacist
 - the arrangement lasts no longer than seven days
 - there are written comprehensive and clear procedures in place to be followed by the midwife or nurse who provides the daily dose
- 3. Where there are concerns about potential diversion, staff should be alerted that this may be a possibility and, if appropriate, reference should be made to the appropriate child protection services.

2.5.22 Patients on prescribed methadone/buprenorphine (or other opiate substitution therapy OST) who are admitted or discharged from hospital

- Patients who are receiving prescribed methadone/buprenorphine for opiate dependence in the community may be dispensed installments between daily to on a weekly basis by their pharmacist. Consumption of the dose may be supervised by the pharmacist. Frequency of dispensing takes into account the individual patient's dose, stability and personal circumstances.
- 2. If a patient on an OST programme is admitted to hospital, it is essential that hospital and community colleagues work together to ensure that the supply arrangements are modified appropriately during the period of the hospital stay and at discharge.
- 3. On admission (individual dealing with patient's admission) contact the prescriber, Borders Addiction Service and the community pharmacist to confirm that the patient is prescribed OST, and to inform them of the admission. Obtain the following information:-
 - Current dose.
 - If on supervised or daily pick-ups.
 - When last dose was dispensed / supervised.
 - Number of days' supply given (if not daily dispensing).
- 4. Advise the community pharmacist that no further supplies should be given and ask the prescriber to cancel or suspend the prescription, as appropriate. Remove any of the

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 42 of 100

medicine that is in the patient's possession for use during the hospital stay if suitable, or destruction if not suitable.

- 5. Document all of these details in the healthcare record. Maintain a record of the methadone in the CD register.
- 6. On discharge (person dealing with patient's discharge)Contact the prescriber in the community to inform him/her of the agreed discharge date and time, confirm the current dose and when the last dose will be administered before discharge.
- 7. Confirm that the usual prescriber in the community will make the necessary arrangements with the community pharmacist to provide a new prescription or re-instate the suspended prescription.
- 8. Make sure that suitable arrangements have been made to allow the patient to collect the next due dose following discharge.
- 9. Administer the daily dose on the ward before the patient is discharged, unless alternative arrangements have been made.
- 10. Inform the patient of the arrangements for the next dose.
- 11. Do not return any unused supplies that were brought in on admission, and donor provide a discharge supply unless a single dose is required until the regular arrangement in the community is put in place.

2.5.23 CDs for midwives

1. A registered midwife may possess, administer and supply diamorphine, morphine, in his/her own right so far as is necessary for the practice of his/her profession.

2.5.24 Supplies of CDs for home confinements

1. In NHS Borders, if during a home confinement controlled drugs are required during the labour then they must be prescribed and administered at the Borders general hospital. Currently controlled drugs are not administered during home confinements.

2.5.25 Use of opiates by midwives for hospital births

- 1. Procedures for ordering, receipt, storage and disposal of controlled drugs for use by midwives within the hospital must be the same as those for all wards, theatres and departments (see above
- 2. Midwives may administer diamorphine or morphine, without a prescription written by a registered prescriber, or a Patient Group Direction, provided it is part of their professional practice.
- 3. There should be a protocol agreed by the multi-professional team for the administration of diamorphine or morphine, during labour. Opiates required for the relief of pain out with labour should be prescribed by a registered prescriber.
- 4. Administration must be recorded on the woman's prescription and administration record, in the maternity record and in the controlled drug register.

2.6 Procedures for Controlled Drugs in Hospitals

2.6.1 Controlled drugs stock lists/wards, theatres and departments

- 1. The charge nurse and the responsible pharmacist must agree a stock list for all medicines, including controlled drugs, that reflects the needs of the patient group in each clinical area, and is in line with agreed formularies.
- 2. Staff need to be trained and competent to handle and administer all the medicines that are routinely stocked in the clinical area.
- 3. The stock list must contain a list of the names and forms of all medicines required, and the minimum stock level that must be held.
- 4. The stock list must be reviewed and updated regularly, at least once every year.
- 5. Medicines that are not on the agreed stock list must only be prescribed and ordered if there are staff available in the clinical area that are trained and competent to handle and administer them.
- 6. Patients must be encouraged to bring their own medicines for use during the hospital stay.
- 7. Medicines that are not included in the agreed stock list, or where the patient's own supply is not available or suitable, must be obtained timeously, so that doses are not missed or delayed.

2.6.2 Issue of controlled drugs from the pharmacy

- 1. Controlled drugs must be issued from the pharmacy in a tamper evident package, clearly labelled with the destination, and accompanied the Controlled Drug Order formbook containing a note of what has been supplied. For CD's ordered by Omnicell cabinets a copy of Omnicell order should be sent with the CD's.
- 2. Tamper evident packaging and a note of what has been supplied are not required when medicines are collected by the patient (outpatients only).
- 3. The messenger or porter who collects the completed order from the pharmacy must sign for receipt of the sealed package.
- 4. The signature of any person that collects a controlled drug from the pharmacy must be recorded on the transit form and their details recorded on the dispensary log book.

2.6.3 Borrowing Schedule 2 and Schedule 3 controlled drugs between wards, theatres and departments

- 1. Schedule 2 and Schedule 3 controlled drugs may only be borrowed between wards, theatres and departments when the pharmacy is closed unless under emergency situations, and following consultation with the on-call pharmacist.
- 2. Controlled drugs may be borrowed under the following circumstances the charge nurses agree the ward, theatre or department that holds the stock is nearby to the borrowing ward, theatre or department only a small number of doses are required, if there are a large number of doses required then contact the telephone exchange who will inform the on call pharmacist who can arrange for it to be supplied.
- 3. The dose must be transferred at the time it is required.
- 4. Stock must not be transferred between controlled drug registers where recording is required. The register of the ward, theatre or department from which the dose is being

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 44 of 100

taken from must be used to record administration details.

- 5. The charge nurse of the ward, theatre or department from which the dose is being transferred from must check the prescription chart and must sign the register to confirm that the dose has been issued. This should be countersigned by a nurse from the ward the patient is being transferred to.
- 6. Two registered nurses from the ward, theatre or department to which the dose is being transferred must complete the procedure for administration of controlled drugs.

2.6.4 Returning Schedule 2 controlled drugs and Schedule 3 controlled drugs with safe custody requirements to pharmacy from wards, theatres and departments

- 1. When there are expired schedule 2 controlled drugs/schedule 3 controlled drugs which require safe custody or controlled drugs not on the agreed stock list that are no longer required for the individual patient, pharmacy must be notified and they will arrange to come and uplift the controlled drugs to return to pharmacy. If they are suitable for reuse they will be returned into pharmacy stock and the cost will be credited back to the ward.
- 2. Controlled drugs must **never** be returned to the pharmacy in the pharmacy delivery box or in pharmacy Envopaks. Pharmacy must be contacted to arrange for them to be uplifted by pharmacy staff to arrange return or disposal of controlled drugs no longer required.
- 3. An itemised list containing the name, strength and form of the medicine, and the quantity being returned, must accompany all schedule 2 controlled drugs and schedule3 controlled drugs with safe custody requirements, returned to the pharmacy. All items being returned must be listed on the controlled drugs form and this must be signed by the pharmacist/pharmacy technician and charge nurse. The top 2 copies of the page must accompany the controlled drugs being returned, and the other copy must be retained in the ward, theatre or department.
- 4. All controlled drugs brought into hospital by patients remain their own property. They should be returned to the patient at discharge if they are still prescribed. If not then pharmacy should be contacted to uplift them to be returned to pharmacy to be destroyed.
- 5. The consent of the patient, or the patient's representative should be obtained where possible when CD's are to be destroyed.

2.6.5 Security of controlled drug stationery

- 1. Controlled stationery including any stationery, which, in the wrong hands, could be used to obtain medicines fraudulently.
- 2. The following items are examples of controlled stationery and must be received and held securely:-
 - Controlled drug register
 - Controlled drug order book
 - HBP prescription forms (Hospital Out-patient)
 - Hospital discharge prescription form
- 3. The person receiving controlled stationery in the ward, theatre or department is responsible for its security.
- 4. The issuing authority for controlled drug stationery must keep a record of receipt and issue. The date issued and the identity of the person requesting and issuing must be

recorded.

- 5. Unused Controlled Drug Order books and prescription forms must be returned to the issuer, who must record receipt.
- 6. Records of the receipt and issue of controlled stationery must be retained for two years.
- 7. Only one Controlled Drug Order book should be held on a ward at any time, except when otherwise agreed locally with the site lead pharmacist to meet exceptional circumstances, for example some community hospitals.
- 8. Outpatient clinics/departments requiring HBP prescription forms should only be supplied with small amounts i.e.: maximum of 2 pads each time to ensure robust audit trail.
- 9. Controlled Drug registers that are being replaced should have part-used pages ruled off.
- 10. Loss or theft of any controlled stationery must be reported immediately to the charge nurse or department manager, who is responsible for investigating and reporting the incident in accordance with the procedure for incidents. The Accountable Officer must be informed.
- 11. Controlled Drug registers must be retained securely for two years from date of last entry or seven years if containing details of CD destructions.
- 12. Controlled Drug Order books must be retained securely for two years from date of last entry.

2.6.6 Dealing with discrepancies with controlled drugs in pharmacy department

- 1. If a member of staff becomes aware of a controlled drug discrepancy, they must ensure that it is reported and investigated immediately as follows:-
 - Access the Pharmacy online register and print off showing the relevant time frame.
 - Print off record from ascribe (log view) on recent issues/receipts.
 - Check other register sections of same drug class for erroneous entries.
 - Compare online Omnicell register to ascribe records to check that they correspond.
 - Check orders have all been entered by checking delivery notes / invoices / stock orders for discrepancies.
 - Check diary and contact all members of staff who have worked in the clinical area during the relevant period to verify any supplies made that have not been entered.
- 2. If the discrepancy can be resolved at any of the above steps, a note should be entered on Omnicell to indicate the reason for the discrepancy.
- 3. Any discrepancy which cannot be resolved must be notified to the dispensary manager/pharmacy management and to the controlled drugs team. A note should be entered on the drug file on Omnicell to indicate that a discrepancy is currently under investigation and the time and date that it was reported should be indicated.
- 4. Key must be returned immediately.

2.6.7 Action in the event of a breach of security involving controlled drugs

- Theft of controlled drugs is a serious criminal offence under the Medicines Act 1968, the Misuse of Drugs Act 1971 and other legislation and will be dealt with accordingly by the NHS Board Accountable Officer, professional and regulatory bodies and the police.
- 2. A breach of security includes any deviation from the procedures that causes actual or potential loss or theft of medicines. Examples of such incidents include:-

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 46 of 100

- Controlled drugs are found to be missing
- Controlled stationery is found to be missing
- A key for the area's controlled drug cabinet is found to be missing
- Controlled drugs belonging to ward / department stock are found to be missing
- Patients own controlled drugs are found to be missing
- An unauthorised person has access to controlled drugs or controlled drug stationery
- 3. Any person who discovers a breach of security is responsible for reporting it immediately to the charge nurse or line manager. All concerns will be treated in the strictest confidence regardless of whether the subsequent review substantiates these concerns. All investigations must be carried out in a discrete manner.
- 4. All breaches of security that cause actual or potential loss or theft of controlled drugs must be investigated and the appropriate corrective and preventive action taken. If medicines have been misappropriated police charges may be brought.
- 5. The charge nurse must take reasonable steps to ensure that controlled drugs are in fact missing, for example check administration records; cupboards not normally used for storage of controlled drugs and pharmacy delivery records.
- 6. If the charge nurse is unable to satisfy him/herself that all medicines can be accounted for, they must report suspicions to the relevant manager immediately.
- 7. Where a manager has been informed of suspected or actual theft of medicines, they must inform relevant professional leads including the controlled drugs team/Pharmacy.
- 8. Should the result of the preliminary review identify any evidence of actual theft, the Controlled drugs team and police should be contacted immediately. Any evidence should be retained pending police investigation.
- 9. Staff should be familiar with and refer to the local Fraud Policy in all cases of suspected or actual theft of medicines.
- 10. The Controlled drugs team/Accountable Officer must be informed of any incident or concern relating to controlled drugs.

2.6.8 Patient Controlled Analgesia (PCA)

- 1. Controlled drugs for administration via a PCA device should be prescribed stating the drug concentration, bolus dose, lock out time and rate of background infusion, inappropriate.
- 2. All PCA infusions must be prepared in theatre/ITU or labour ward.
- 3. Two registered practitioners that have been trained and assessed as competent must be present during the set up and start of the device. One must prepare the controlled drug to be administered and attach the device to the patient; the other must check each step. They must both verify the programme against the written prescription and must sign the administration record chart, as a record of this check. Both practitioners are equally accountable for the process.
- 4. Preparation of subsequent PCA infusions for patients residing in ward areas will be prepared as above (both practitioners will sign prescription chart), with only ONE of the registered practitioners transferring and attaching the PCA infusion to the correct patient in the ward area. This practitioner will sign the infusion chart on the ward, taking responsibility for the administration. CONTINUING PCA IS THE ONLY SITUATION WHERE SINGLE NURSE ADMINISTRATION OF CONTROLLED DRUGS IS PERMITTED.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 47 of 100

- 5. The following details should be recorded in the Controlled Drug Register and the syringe chart:-
 - Date and time when PCA commenced
 - Name of patient
 - Quantity in syringe
 - Form (name, formulation and strength) in which administered
 - Name/signature of practitioners who set up the PCA
 - Name of the prescriber
 - Balance in stock
- 6. The issue of the CD will be recorded on the online register but not the details of the syringe so it is essential that all the details are recorded on the syringe chart.
- 7. When the PCA is discontinued, the time, date and the residual amount of drug in milligrams should be recorded on the PCA chart together with the signatures of the two practitioners involved. The residual controlled drug must be disposed of and are cord made on the Prescription chart.
- 8. The local procedure for PCA must be followed at all times

2.6.9 Suspicious substances

- The NHS does not permit the use, possession or supply of illegal substances on its premises. For the purposes of this procedure, a substance is suspicious if the person in possession cannot reasonably explain why they have it, or there is any doubt about its nature. This includes Novel Psychoactive Substances (NPS) or "Legal Highs" as these may contain CDs.
- 2. Schedule 1 CD include the hallucinogenic drugs, for example, LSD, ecstasy, cannabis. The class of persons who may lawfully possess them is strictly limited, and does not include pharmacists or other clinicians, except under licence granted by the Home Office.
- 3. A nurse may only take possession of a Schedule 1 CD for the purpose of handing it to a police officer, or to a person authorised to destroy it. The nurse is not authorised to supply, therefore it is illegal for the nurse to return it to the patient or patient representative.
- 4. A pharmacist is authorised to take possession of a Schedule 1 CD in order to destroy it, or to hand it to a police officer or to another person authorised to destroy it.
- 5. When a member of staff takes possession of a suspicious substance, it is important that all actions related to the taking into safe custody or destruction of such substances are fully and correctly documented and witnessed. Also, accurate records maybe required for evidence if matters proceed to a court case.
- 6. If a patient is found in possession of a suspicious substance, the nurse or other member of staff should inform the patient that the substance is to be removed for destruction. Unless large quantities of drugs are involved, the main aim is to ensure that the drugs are handled and destroyed in a safe and legal manner.
- 7. Where large quantities of unauthorised drugs or other substances are found on a patient's person, the police should always be informed and fully assisted in their enquiries. It is recommended that in these circumstances the local police station is contacted directly. They may attend the ward and initiate enquiries. In these circumstances, public interest overrides that of confidentiality.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 48 of 100

- 8. Discovery in the hospital setting of quantities of unauthorised drugs consistent with the patient's own personal use rarely leads to successful prosecution. Furthermore, a heavy handed response can compromise patient care and cause considerable disruption of ward routines and the waste of much time and effort. The police are aware of this and do not wish to compromise patient care and recognise that the delicacy of the circumstances demands a balanced and sensitive approach. Therefore, the decision to contact the police or dispose lawfully of the substance should be taken jointly by the lead nurse/midwife in conjunction with the consultant or senior doctor with clinical responsibility for the patient.
- 9. If the patient refuses to hand over the suspicious substance, the police should be informed and they will remove the suspicious substance when they attend in these circumstances.
- 10. The member of staff finding the substance should immediately inform the nurse in charge/lead midwife or manager in charge of the ward or department.
- 11. The nurse in charge/lead midwife or manager in charge of the ward or department should contact the site lead nurse/manager and the consultant or senior doctor in charge of the patient and request their attendance.
- 12. The person finding the suspicious substance, the nurse in charge/lead midwife or department manager and the site lead nurse/manager should complete Part A of the form 'The removal and destruction of suspicious substances':-

Form for the Removal of Suspicious Substances –at APPENDIX 6

- 13. An entry should also be made in a separate page in the back of the ward/department CD register, headed "Suspicious Substances" stating 'received one sealed bag of suspicious substance from patient, CHI number', witnessed and signed by two registered nurses.
- 14. Where it is agreed by the site lead nurse/manager and the patient's consultant or senior doctor that the quantity of the substance found is consistent with patient's own personal use, then the ward pharmacist/technician should be requested to attend to remove the substance. In this case, Parts B and C of the form 'The removal and destruction of suspicious substances' (see link below for form) should be completed as indicated, by the site lead nurse/manager, consultant/senior doctor, pharmacist/technician and witness. If the patient objects to this course of action, the local police must be contacted.
- 15. The suspicious substance and form must be stored securely in the CD cabinet until a pharmacist can attend. The pharmacist/technician should return the substance to the hospital Pharmacy and document the receipt of it in the patient's own register in the suspicious substances register. All destructions should be undertaken using a denaturing kit by pharmacy technician/suitably trained staff member and the authorised witness.
- 16. One copy of the form should be filed in the patient's medical notes and one copy retained by the pharmacy department in a designated folder for 2 years.
- 17. Where either the site lead nurse/manager or the consultant or senior doctor in charge, or both, consider that the quantity of the substance found is greater than is consistent with the patient's own personal use the local police must be alerted.
- 18. Contact the police (Edinburgh Service Centre on '101' or previously agreed contact number for relevant site) to arrange for the substance to be collected by a police officer.
- 19. The suspicious substance and form should be stored securely in the CD cabinet until police officers can attend.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 49 of 100

- 20. When the police attend, ward and pharmacy staff should cooperate fully. In some cases, the police may not need to know the identity of the patient. However, if this information is required it should be disclosed by the site lead nurse/manager or consultant. In the investigation of an alleged criminal offence, confidentiality is unlikely to be a sufficient defense in law against disclosure.
- 21. Each case will be treated on its own merits and it is therefore not possible to indicate the precise action the police will take. However, the patient will never be questioned or removed from the ward or department if it is considered by the consultant or senior doctor in charge to be inappropriate on clinical grounds.
- 22. Following enquiries, the police will remove the suspicious substance directly from the ward. Part D of the form 'The removal and destruction of suspicious substances' (see link below for form) should be signed by the police officer and the nurse/midwife or pharmacist witnessing the transfer. One copy should be given to the police, one copy retained by controlled drugs governance officer in a designated folder for 2 years and one copy filed in the patient's medical records.

2.7 Management of CDs in hospital pharmacies

2.7.1 Accountability and responsibility

 The Accountable officer for the hospital is responsible for the safe and appropriate management of CDs in the pharmacy. Day-to-day management of CDs (for example, receipt into an issue from dispensary stock) in the pharmacy will normally be delegated to a suitably-trained, competent registered pharmacy technician or pharmacist. However, legal responsibility for CDs remains with the lead pharmacist for the hospital.

2.7.2 Security of CDs

- 1. The pharmacy must have SOPs covering each of the aspects of the safe management of CDs such as ordering, receipt, record-keeping etc.
- SOPs must be kept up-to-date, reflecting current legal and good practice requirements for CDs, and there must be a system of document control to ensure that the correct version is used.
- 3. SOPs must be approved by the Accountable Officer or by the person to whom they has delegated this task. The AO is accountable for all the systems for the safe management of CDs.

2.7.3 Ordering and receipt

1. Ordering of CDs from wholesalers and manufacturers and receipt of CDs must follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

2.7.4 Receipt

- 1. There must be a local procedure for the receipt of CDs into the pharmacy department.
- 2. The procedure must ensure the security of CDs and should be auditable. It must include:

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 50 of 100

- who may sign for receipt.
- how the goods must be checked (e.g. matching of the details on the delivery note to the goods) and appropriate stock control documentation completed.
- an instruction that any tamper-evident seals on packs must be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- an instruction that if, when the tamper-evident seal is broken the contents do not match the expected amount stated on the pack, the pharmacy must contact the supplier.
- the action to be taken if the item received is incorrect.
- arrangements for storage of incorrect items for return.
- specifications of the entry required in the register, including who may make the register entry and whether a witness is required.
- 3. Receipt must be recorded immediately, and no later than 24 hours after receipt. ASOP is required defining the procedure for safe storage and records of stock when receipt is not recorded immediately. The balance in stock must be checked and recorded as correct by the person making the entry.
- 4. The stock must be put away into the appropriate section of the CD cabinet promptly.

2.7.5 Storage

1. Pharmacy CD cabinets must comply with the Misuse of Drugs (Safe Custody)Regulations. A risk assessment must be undertaken to determine whether additional security arrangements are required, for example when the pharmacy is unmanned.

2.7.6 Issuing of CDs to wards and departments

- 1. There must be a local procedure for the issuing of CDs to wards and departments.
- 2. The procedure must ensure the security of the CDs and must be auditable. It must include:-
 - the procedure for checking that the requisition is valid and complete the mechanism for correcting an incomplete or inaccurate requisition.
 - specifications of the details required on labels (see below).
 - specification of entry required in the register, including who may make the register entry.
 - whether a check by a second person is required. The decision as to whether a check by a second person is required or not must be made following a risk assessment.
 - arrangements for the transfer of the CDs to the ward or department.

2.7.7 Electronic systems

Where electronic systems for the requisitioning of CDs are introduced, safeguards in the software must be put in place to ensure that:-

- only individuals who are authorised to requisition CDs from the pharmacy can do so.
- entries cannot be altered at a later date.
- a log of all data entered is kept and can be recalled for audit purposes.

2.7.8 Labelling of CDs for Ward or Department use

- 1. There must be a SOP for labelling CDs issued from the pharmacy. The CD pack must clearly state:-
 - Drug name, form and strength.
 - Quantity.
 - Store in CD cabinet.
 - Expiry date if dispensed from bulk. (NB: certain preparations have a reduced expiration date once opened, e.g., oral methadone solution).
 - Keep out of reach and sight of children.
 - Address of the pharmacy.
 - The batch number of a product that has been dispensed from bulk.
- 2. Each container must be labelled individually.

2.7.9 Liquid preparations

- 1. Discrepancies can arise with liquid CDs as a result of e.g. manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted.
- 2. Stock balances of liquid medicines should be checked by visual inspection but periodic volume checks must be carried out. The balance must be confirmed to be correct on completion of a bottle.
- 3. In the event of a spillage, a second person must verify that it has occurred, and countersign the CD record book. If a ward has **Omnicell** cabinets then the balance should be amended to show the new balance and a description of the spillage added to account for the discrepancy. A Datix entry must be made.

2.7.10 Computerised registers

- 1. Entries in computerised registers must be attributable and auditable.
- 2. If the CD register is held in computerised form, the following safeguards in the software must be put in place to ensure that:-
 - the author of each entry is identifiable.
 - entries cannot be altered at a later date.
 - all entries are attributable to the individual making the entry.
 - a log of all data entered is kept and can be recalled for audit purposes.
 - adequate backups are made.
 - systems are in place to minimise the risk of unauthorised access to the data.

2.7.11 Checks of CD stocks held in the pharmacy

1. All CDs in the pharmacy must be checked periodically e.g. every week by a pharmacist/technician with an ATO as the witness. CDs that are awaiting destruction should be segregated from in-date stock. A separate register for out-of-date stock from Pharmacy stock and ward returned out of date stock should be kept. Each CD to be destroyed should be allocated a serial number which corresponds with the entry in the expired drugs register. Once serial number/quantity and details where the CD has been returned from has been documented the CD's awaiting destruction placed in the

designated 'expired ward stock/pharmacy stock' area in the CD safe.

- A pharmacist or suitably trained technician must check ward controlled drug registers and reconcile stock at least once every 4 months. The pharmacist must complete the ward stock check form recording any discrepancies found. A copy of the form should be provided to the charge nurse. The original should be returned to Pharmacy and filed.
- 3. If any discrepancies that cannot be resolved are found in the stock of controlled drugs, pharmacy technician must act immediately by completing a Datix report, informing the charge nurse, the ward pharmacist, and the controlled drugs team. The charge nurse and/or controlled drugs team may inform the police if appropriate.

2.7.12 Discrepancies

- 1. The balance recorded in the register and/or, where relevant, the electronic register/pharmacy stock control system, must be reconciled against the stock of every product in the CD cabinet. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate misuse.
- 2. There must be a careful check of transactions from the Omnicell register and in the stock control system to trace an error or omission.
- 3. If an error is traced then a register entry must be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and a second person who checks the whole process.
- 4. If no errors or omissions are detected then the discrepancy must be reported to the Accountable officer for the hospital. If the discrepancy cannot be resolved it must be reported to the controlled drugs team and the police as soon as possible, within 48 hours.

2.7.13 Archiving of CD records

- 1. Every requisition, order or private prescription on which a CD is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made.
- 2. The time periods for archiving CD documentation are:-
 - TWO YEARS for requisitions
 - TWO YEARS FROM LAST ENTRY for controlled drug record books
 - SEVEN YEARS FROM LAST ENTRY DETAILING CD DESTRUCTION for controlled drug record books

2.7.14 Supply to outpatients and discharge patients

- 1. Persons asked to supply CDs on prescription must establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.
- 2. When outpatient prescriptions are being given directly to patients or their representatives, the patients or their representatives may be asked to provide evidence of identity when collecting Schedule 2 CDs. The requirement allows discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 53 of 100

- 3. The following information must be recorded in the dispensary log book for Schedule 2 CDs supplied on prescription:-
 - whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient;
 - if the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address;
 - if the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory); and
 - whether evidence of identity was provided by the person collecting the drug.
- 4. The patient's date of birth may be used as a second check if necessary.

2.7.15 Supply to external units or other health and social care bodies in exceptional circumstances

1. A hospital pharmacy can no longer supply controlled drugs to an external organisation unless for a named individual and not routine practice.

2.7.16 Destruction of stock CDs

- 1. Any pharmacy held stock of obsolete, expired or unwanted Schedule 2 & 3 CDs must be recorded in a timely manner. Destruction can only take place in the presence of a person authorised by the Accountable Officer.
- 2. Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, must be kept segregated from other CDs in the designated 'expired ward stock/pharmacy stock' area in the CD safe.
- 3. When stock Schedule 2 CDs are destroyed, the following details must be entered into the CD register:-
 - Drug name
 - Drug form
 - Drug strength
 - Quantity of drug being destroyed
 - Date of destruction
 - Signature of the authorised person in whose presence the drug was destroyed
 - Signature of the person carrying out the destruction

2.7.17 Destruction of CDs returned by patients

- 1. CDs that have been prescribed for, and dispensed to, a named patient and returned to the pharmacy by the ward pharmacist/technician must be recorded in the patient's own returns register.
- 2. Each CD that is returned must be allocated a serial number which corresponds with the serial number next to the entry documenting the return in the patient's own register returns register.
- 3. The record of CDs returned must be made on a designated page in the CD register. The following details must be recorded:-
 - Serial number

- Date of return of the CDs
- Name, quantity, strength and form of the CDs
- Role of the person who returned the CDs (if known)
- Name and signature of the person who received the CDs
- Patient's name and address (if known)
- Comments, for example, expiry date, name of patient and ward
- 4. The destruction should be clearly recorded in the patient's own returns register and the date of destruction should be recorded, The serial numbers of the items destroyed must be entered and this should be entered and signed by the authorised witness and signed by the Pharmacy technician/suitably trained Pharmacy staff member who had witnessed the destruction.

example: 23/07/23 Entries SN:25 to SN:58 destroyed by CDGO NHS Borders Shelley Scott/Jane Smith

5. Destruction of CDs should occur with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment but be no less then every three months.

2.7.18 Methods of disposal for CDs

1. The SOP for disposal of CDs must be followed.

2.7.19 Pharmacy Staff training for management of CDs

1. Pharmacy staff must receive appropriate training on local SOPs for CDs when they first become involved in prescribing, supplying, administering or disposing of CDs Pharmacy staff must be informed and, if necessary, receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

2.8 Additional governance arrangements for prescribing controlled drugs (non-medical prescribers)

2.8.1 Controlled drugs are only supplied or administered to patients on the authority of an independent prescriber (V300 NMC qualification) or pharmacist registered as an independent prescriber

- The practitioner who dispenses a prescription for a controlled drug written by an independent prescriber, or who administers a controlled drug from stock that has been prescribed is able to check that the prescriber is a registered prescriber within NHS Borders.
- 2. There is justification that, in general, independent prescriber needs to be able to prescribe controlled drugs in his/her area of practice.
- 3. Only controlled drugs included in the Clinical Management Plan (for supplementary prescribers) or in the Personal Core Formulary agreed with the employer (for nurse independent prescribers) are prescribed by non-medical prescribers. The Clinical

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 55 of 100

Management Plan or the Personal Core Formulary specifies the name of each controlled drug, the medical condition, and the dose range for which it will be prescribed.

2.8.2 Controlled drugs prescribed by independent prescriber are justified for the individual patient

- 1. Controlled drugs are prescribed, dispensed or supplied, and administered by separate practitioners wherever possible.
- 2. A nurse independent prescriber or nurse supplementary prescriber does not supply a controlled drug that they have prescribed, to the patient, carer or other health professional who administers it. In primary care, the prescription for the controlled drug is dispensed for the individual patient by a pharmacist.
- 3. In circumstances where an independent prescriber or supplementary prescriber is responsible for administering a controlled drug that they has prescribed, and that has been dispensed for the individual patient by a pharmacist, a suitably competent second person checks that the accuracy of the medicine administered. A suitably competent person in this situation is a person who can check that the correct medicine, and the correct quantity or dose is supplied or administered to the correct patient.
- 4. Where a supplementary prescriber is responsible for administering a controlled drug that they have prescribed, and that is administered from stock, a suitably competent second person checks that the accuracy of the medicine administered. A suitably competent person in this situation is a person who can check that the correct medicine, and the correct quantity or dose is supplied or administered to the correct patient.
- 5. Where an independent prescriber is responsible for administering a controlled drug that they has prescribed, and that is administered from stock, a suitably competent second person checks that the medicine administered is correct for the patient. A suitably competent second person in this situation is a person with sufficient knowledge of the medicine, and of the patient to whom it is being supplied or administered, to be able to intervene when the medicine is not appropriate.
- 6. In circumstances where a pharmacist supplementary or independent prescriber is responsible for dispensing a controlled drug that they has prescribed, a suitably competent second person checks the accuracy of the dispensed medicine. A suitably competent person in this situation is a person who can check that the correct medicine of the required quality, the correct dose, and the correct route have been selected for administration to the correct patient.
- 7. If a non-medical prescriber prescribes a new dose of a controlled drug that has already been dispensed for the individual patient, the unused medicine is returned to the pharmacist and a new supply is dispensed.

2.8.3 Independent non-medical prescribers may prescribe controlled drugs

1. A nurse independent prescriber (V300 NMC qualification) or a pharmacist independent prescriber can prescribe any medicines within their competency and for which they are prepared to accept legal responsibility, including 'off-label' medicines, unlicensed medicines and any controlled drug specified in Schedule 2, 3, 4 or 5, except diamorphine, cocaine and dipipanone for the treatment of addiction

 Prescribing must be in line with the NHS Borders Joint Formulary and/or the East Region Formulary in addition to local protocols. Nurse independent prescribers must list the controlled drugs in their Personal Core Formulary, which must have been agreed by management and the service.

2.8.4 Controlled drugs are not prescribed for a period beyond their clinical need

1. The review date and referral criteria for a Clinical Management Plan that includes a controlled drug is agreed to take account of the clinical need of the patient for the controlled drug.

2.8.5 Records of prescribing of controlled drugs facilitates monitoring of the quantity and frequency of prescribing of controlled drugs in general and for individual patients, and adherence to the Clinical Management Plan or Personal Core Formulary

- 1. Controlled Drugs are prescribed on approved prescribing documents. A unique code must be on all prescription forms and charts identifying the prescriber.
- 2. The name of the prescriber is recorded in controlled drug registers when dispensed.
- 3. The details of the controlled drug prescription are entered in the shared patient record immediately, or as soon as possible after consultation and should not exceed 48 hours except under exceptional circumstances.
- 4. The organisation has a system in place to report, monitor and take action on complaints, incidents and near misses involving the prescribing of controlled drugs by non-medical prescribers. The Accountable Officer must also be informed.

2.9 Staff training for management of CDs

- 1. Within designated bodies, the Controlled Drugs Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of CDs receive appropriate training to enable them carry out their duties.
- 2. Staff should receive appropriate training on local SOPs for CDs when they first become involved in prescribing, supplying, administering or disposing of CDs and then regularly thereafter. The frequency of training should be determined locally.
- 3. Staff should be informed and, if necessary, receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

2.10 Glossary of Terms

Controlled drugsOfficer in a designated body who is responsible for the safe and effectiveAccountablemanagement and use of CDs. Appointment required by Controlled DrugsOfficer(Supervision and Management of Use) Regulations 2006.

- Administer To give a medicine either by introduction into the body, whether by direct contact with the body or not, (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing). There are specific definitions in medicines legislation as follows: "external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations; "parenteral administration" means administration by breach of the skin or mucous membrane.
- ControlledThe drugs listed in schedules 1-5 of the Misuse of Drugs Regulations 2001Drugs (CDs)(as amended). Drugs listed in different schedules are subject to differing
levels of control.
- CD record book Bound book in which records are made of CDs received and administered (CDRB) in wards, theatres and departments.
- CD register Bound book, as specified in the Misuse of Drugs Regulations 2001 (as amended), in which records are made of CDs received and issued by pharmacies.
- DesignatedOrganisationsdefinedintheControlledDrugs(Supervisionandbody/bodiesManagement of Use)Regulations 2006.
- Discrepancy Difference between the amount shown in the register or record book and the amount that is physically present
- Dispense, Dispensing of CDs Preparation (including compounding, dissolving, dispensing diluting, packing and labelling) and giving out of medicines for individual patients.
- Diversion Removal of CDs for unauthorised use; theft
- HealthcareOrganisations responsible for the delivery of healthcare, includes NHSorganisationshospitals and independent hospitals
- Local A network established by the Controlled Drug Accountable Officer of an

Intelligence NHS Board for sharing information about CDs.

Network

charge

- Midwife Allow registered midwives to sell, or supply specified medicines in the exemptions course of their professional practice. In addition, midwives are allowed to administer certain parenteral medicines in the course of their professional practice.
- MDR Misuse of Drugs Regulations made under the Misuse of Drugs Act (1971). "Must" Used in this document in connection with legal requirements.
- Order To make a formal order for CDs. Can only be done by a person who is entitled to be in possession of CDs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
- Patient Group Written directions developed by a senior doctor (or dentist) and a senior Directions pharmacist and authorised by a representative of the appropriate (PGD). organisation giving registered nurses, pharmacists and other specified healthcare professionals a general authority to supply and administer specified medicines to patients, who may not be individually identifiable, in specified clinical situations.
- PCA Patient-controlled analgesia
- PODs Patient's own drugs. In this context CDs brought into the hospital by the patient on admission.
- Prescribe Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Prescription Only Medicines (Human Use) Order 1997. The term has however become commonly used to describe authorising - by means of an NHS prescription - the supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient.
- RegisteredThe registered nurse or registered midwife who is in charge for the timenurse orbeing (senior registered nurse or midwife on duty) and is thereforemidwife inresponsible for the management of CDs.
- RegisteredPerson registered in the register of pharmacists maintained by the GeneralpharmacistPharmaceutical Council
- RegisteredPharmacy technician whose name is on the register held by the GeneralpharmacyPharmaceutical Council.

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 59 of 100

technician

RelevantDefined under the Controlled Drugs (Supervision of Management and Use)personsRegulations 2006.

Requisition To make a formal, written request for a supply of a CD for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made in stationery designed specifically for that purpose Sometimes known as "Controlled Drug Order Books".

ResponsibleBodies listed in regulation 22 of the Controlled Drugs (Supervision of
Management and Use) Regulations 2006.

SEPA Scottish Environmental Protection Agency

Service LevelWritten agreement between two parties that specifies the service to beAgreementprovided.

- (SLA)
- "Should" Used in this document in connection with recommendations concerned with good practice.

StandardA standard operating procedure specifies in writing what should be done,Operatingwhen, where and by whom in order to manage safely and accountably anyProcedure (SOP)set of processes, in this case around the total management of CDs. Full
guidance is given in CEL(2007)14

- Supervisor of A person appointed by the local supervising authority to exercise midwives supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) www.hmso.gov.uk.
- Supply Making a supply against a signed order or a prescription. In medicines legislation, "supply" is described as "retail sale or supply in circumstances corresponding to retail sale".
- Transcribe To copy the details of one document on to another.

CHAPTER 3 – ORDERING

Medicines are obtained from the Pharmacy Department.

In most wards and departments a stock list of medicines has been agreed between nursing and pharmacy staff. These medicines will be ordered either by a top-up system operated by pharmacy staff or requisitions signed by the person in charge of the ward or department. Supplies of other medicines will be ordered either by a pharmacist or pharmacy technician or the person in charge of ward/department, on the appropriate form and may require pharmacy to view the medicine chart or a copy.

3.1 Out of Hours

BGH site (including Mental Health Inpatient units and Community Hospitals):-

- 1. When the pharmacy is closed medicines may be obtained from the emergency drug cupboard (the key is held by the senior nurses on duty for the BGH).
- 2. Medicines may only be borrowed from a ward/department when the pharmacy is closed and they are not obtainable from the emergency cupboard.
- 3. A record of medicines transferred will be completed and kept on the ward.
- 4. If a medicine is unavailable when the pharmacy is closed then a doctor or nurse in charge may contact the on-call pharmacist for advice via the BGH switchboard.
- 5. The pharmacist will use their discretion regarding appropriate action to supply.

CHAPTER 4 – STORAGE AND SECURITY

The pharmacy service is responsible for ensuring that storage facilities for medicines comply with the appropriate standards.

- All medicines cupboards and fridges should be locked unless they are in use.
- It is the responsibility of the receiving staff in a ward/department to ensure medicines are stored safely and securely in a timely manner (especially CDs and fridge items).
- All medicines must be stored in accordance with The Safe and Secure Handling of Medicines (Duthie Report 2005), which recommends the following locked storage facilities (These arrangements will be audited periodically).

4.1 Hospitals/Health Centres/other departments

- 1. Storage locations:-
 - Controlled Drug Cupboards outer doors must not be marked to indicate CDs stored inside
 - Internal medicines cupboard
 - External medicines cupboard
 - Medicines fridge
 - Urine testing reagent cupboard
 - Medicines trolley (for medicines in current use only) must be fixed securely to the wall when not in use.
 - Individual patient drug lockers fixed to wall or furniture.
 - Electronic medication storage cabinets (follow local guidelines for use)
- 2. Separate secure storage should be provided as follows:
 - Area for intravenous and sterile topical fluids
 - Area for inflammable gases and liquids
- A limited range of medicines where appropriate, for life-threatening emergencies may be kept on a resuscitation trolley in accordance with an agreed list. Drug cupboards for internal and external medicines must comply with the current British Standard (BS2881 (1989) – NHS Estates Building Note No.29)

4.2 Medicines security and keys

- 1. Medicines security and storage are the responsibility of the nurse in charge. Medicines keys must be kept on their person at all times or may be given to another suitably qualified nominated person but the nurse in charge retains responsibility for them.
- 2. Medicines keys for trolleys, cupboards, fridges and other locked containers in a clinical area should all be kept on a single key ring designated for this purpose. The only exception to this is that Keys for Controlled Drug Cupboards must be kept on a separate key ring which is not marked as being for the CD cabinet.
- 3. Keys to patients own drugs (PODs) cupboards may be issued to the patient who signs for receipt of this key. The key that is issued to an individual patient must only open their

designated medicine cupboard and must be kept securely by the patient. On discharge or when the patient is no longer self-administering their medicines, the key must be returned to safekeeping and a record made.

- 4. The nurse/designated or responsible person in charge is responsible for:-
 - Rotation of stock
 - Balancing, checking, recording and maintaining security of stocks of Controlled Drugs
 - Holding keys for medicines storage
 - Return of excess stock prior to expiry date (in addition to ward staff checks, pharmacy staff will check expiries of 'topped up' stock drugs)
 - Reviewing stock lists with the pharmacy department
 - Regular checks of cupboards and records
- 5. The Nurse in Charge must ensure there are robust systems in place for the checking expiry dates of drugs (including stock in drug fridges). Stock should be checked at least once a month.
- 6. Medicines cupboards and stocks will be subject to a 3 monthly check by a member of pharmacy staff.
- 7. Any losses or discrepancies of medicines stocks must be reported immediately to the Nurse Manager and Pharmacy Department and an incident form completed.

4.3 Medication in the home

- 1. Community Staff are reminded that the responsibility for medication in a patient's home lies with the patient or carer and they should not assume responsibility for any aspect relating to storage and security of that medication other than giving advice.
- 2. Staff should share any concerns with the patient's doctor or pharmacist.
- 3. It is good practice to record stock balance of controlled drug medication being administered by the community nurse.

4.4 Transport of medication by community staff

- Community Staff should only transport such medications for the purposes of treatment as they would expect to use in exercising their professional duties. In the case of controlled drugs these should not be transported routinely and should only occur where there is no other reasonable mechanism available. All drugs should be kept out of sight during transportation. See Standard 7, NMC Standards for Medicines Management.
- 2. In situations where Controlled Drugs need to be removed & returned to the community pharmacy following a patient's death a risk assessment should be carried out by the health professional to identify the most appropriate person to carry out the return. Only in exceptional circumstances should the healthcare professional carry out the return themselves e.g. no family available or suspicion of diversion if controlled drugs are left in the home.

4.5 Security of prescription pads

- 1. Prescription pads should either be kept on the person of the prescriber to whom that pad is coded or in a locked drawer/cabinet within health board premises.
- 2. In the event of loss, suspected theft or forgery, the prescriber must report this

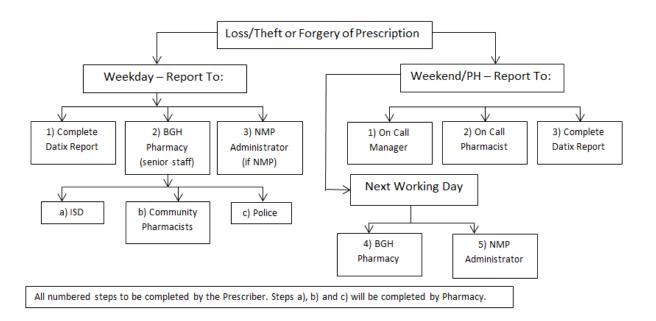
NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 63 of 100

immediately, or as soon as possible, to NHS Borders Pharmacy Service (the Director of Pharmacy) and where appropriate to the NHS Borders Non-Medical Prescribing Administrator. Local police in the area from which the pad was lost or stolen should be informed as soon as possible.

- 3. A Datix report should be completed by the practitioner concerned. This should include details of the numbers of prescriptions missing, when they were last seen/first missing and whether there were any witnesses to a theft.
- 4. Pharmacy systems will be responsible for notifying local community pharmacists and deciding upon action to minimise the abuse of the forms. This will include instructions to the prescriber to sign all scripts in a particular colour (usually red) for a period of two months.
- 5. If the theft occurs during a weekend/bank holiday the prescriber should notify the on-call manager and on-call pharmacist of the incident. If the prescriber is non-medical then the Non-Medical Prescribing Administrator will also need to be informed on the next working day.
- 6. It is the responsibility of both the prescriber and the employer to ensure that prescription pads are retrieved from prescribers who leave NHS Borders employment. Old pads should be returned to the BGH pharmacy or NMP administrator where they will be destroyed, by incineration, once the serial numbers have been recorded.

4.5.1 Prescription Fraud

Prescribers should be aware that if a fraudulent prescription is suspected by a pharmacist, they will contact the prescriber in order to clarify that the prescription is genuine. The pharmacist may also contact the prescriber if they or their signature is unknown to them.



4.6 Cold chain

1. The process of returns of ward/patients own medicines that require storage within the 'cold-chain' is detailed below. There is a high risk of expensive waste being incurred when medicines are left out of the cold-chain therefore it is imperative that staff follow this

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 64 of 100

process for returns.

- 2. A clearly marked pharmacy returns area is located in all ward cold storage areas. This consists of an orange tray marked "Pharmacy Returns".
- 3. Ward staff must place any cold chain items (including patient's own drugs) to be returned to pharmacy in the returns section of the ward fridge (orange tray).
- 4. During the ward top-up process the pharmacy ATO will check and collect any items in the fridge returns tray.
- 5. The pharmacy ATO will then remove the items and return them to pharmacy.
- 6. Items returned to pharmacy will be stored in the returns section of the main pharmacy cold store for immediate processing.
- 7. For further information on the cold chain process/arrangements please refer to the NHS Borders Cold Chain Policy.
- 8. Medication fridges should be hardwired to the electricity supply where possible or a secure plug system used to avoid inadvertent disruption to refrigeration from fridges being unplugged.

4.7 Falsified Medicine's Directive

- The Falsified Medicine's Directive (FMD), introduces EU-wide legislation to help prevent counterfeit prescription medicines entering the pharmaceutical supply chain that applies from the 9th of February 2019. All medicines packs will be tamper-proof and will feature a 2-D barcode containing a unique serial number as well as a product code, batch number and expiry date.
- 2. FMD dictates that any healthcare institution handling medicinal products that bear the safety features must verify and decommission each product.
- 3. **Verification** is a process that can take place at any time during movement of the medicine through the supply chain. It checks the Unique Identifier of the product against the repository to verify that the product is authentic.
- 4. **Decommissioning** happens once only (unless a product's status is reverted) and takes place at the end of the supply chain when the product is supplied to the patient or otherwise leaves control of the pharmacy (e.g. ward stock supply). Decommissioning removes the Unique Identifier (UI) from the repository.
- 5. In order to satisfy these requirements at the Borders General Hospital (BGH) orders that have been received through the EMIS pharmacy system will then be verified and decommissioned as a second step before they are placed into stock within Pharmacy.
- 6. This is the most logical and efficient place to do this in the medicines process as it allows medicines to then be dispensed, supplied for ward stock, issued to community hospitals and vaccines clinics without any further action being required. It creates a quarantine zone and requires the minimum amount of equipment.

CHAPTER 5 – PRESCRIBING

5.1 Authority to Prescribe

- 1. Medicines may only be administered on the authority of a prescription, patient group direction or other agreed procedure, approved by NHS Borders. This includes oxygen, which is a Prescription Only Medicine (POM).
- 2. All prescribing should follow the guidance in the NHS Borders Joint Formulary and be limited to medicines approved by the Area Drug & Therapeutics Committee.
- 3. A range of health professionals have authority to prescribe. This may be a statutory authority, e.g. extended prescribing rights, or supply and/or administration by means of a Patient Group Direction approved by the Area Drugs and Therapeutics Committee (ADTC) and NHS Borders, following the requirements within Patient Group Directions NHS HDL (2001) 7.
- 4. Provisionally registered medical staff may not write private prescriptions.
- 5. Prescribers must not prescribe medicines for staff or visitors unless they are being treated in the normal course of being a patient or under an agreed policy (e.g. needlestick injury).

5.1.1 Non-Medical Prescribing (NMP)

- Registered Professionals from specific groups are able to prescribe if they have qualified from an accredited NMP training program. The scope of their prescribing practice depends on the level of prescribing training they have achieved and any legislative restrictions that may exist. The three levels of prescribing practice are outlined below (please see NHSB NMP policy for further information):-
 - Independent Prescribing Involves the ability to prescribe as an independent practitioner from the full range of the British National Formulary but within the limits of the individuals own competence.
 - Supplementary Prescribing Prescribing as a supplementary practitioner in partnership with an Independent Medical Prescriber and with the agreement of the patient. Supplementary Prescribers must use an agreed patient specific Clinical Management Plan to inform their practice.
 - Community Formulary Prescribing This is a nursing specific route of prescribing where following educational preparation a nurse can prescribe from the set Nurse Prescribers Formulary and are limited to prescribing for the specific set conditions laid out within the formulary.

5.1.2 NMP prescribing in pregnancy

- Royal College of Nursing advice provides a summary of the NMC position in relation to prescribing of medicines to pregnant women by Independent and Supplementary Nurse/Midwife Prescribers. It has been developed in consultation with the Royal College of Nursing and the Royal College of Midwives. It applies to all Nurse/Midwife Prescribers who are registered with the Nursing and Midwifery Council (NMC).
- 2. <u>www.rcn.org.uk/clinical-topics/medicines-optimisation/specialistareas/prescribing-in-</u> pregnancy

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 66 of 100

- 3. Adult Nurses must be able to recognise and respond to the needs of all people who come into their care including babies, children and young people, pregnant and postnatal women, people with mental health problems, people with physical disabilities, people with learning disabilities, older people, and people with long term problems such as cognitive impairment. They must be able to recognise when the complexity of clinical decisions requires specialist knowledge and expertise, and consult or refer accordingly.
- 4. Independent and Supplementary Non-medical Prescribers may see pregnant women in GP surgeries and walk in centres who present with common minor illnesses such as headaches, upper respiratory tract infections, urinary tract infections and vaginal candida albicans. Many seemingly minor illnesses can have major implications for a pregnant woman.
- 5. Independent and Supplementary Non-medical Prescribers should refer all pregnant women to a Doctor or a Midwife. It the woman presents with a complaint that does not affect her pregnancy, for example minor injuries, the Independent Nurse Non-medical Prescriber may continue to prescribe accordingly.
- 6. A record must be made in the woman's hand held notes and the woman's GP and named
- 7. Midwife should be informed of any treatment prescribed.

5.1.3 Pharmacist Amendments

- 1. Within NHS Borders units prescriptions may be amended by pharmacists in respect of drug, dose, route or frequency of administration. Significant amendments will normally be discussed with or reported to the prescriber. Such amendments, signed by the pharmacist, are accepted as the definitive prescription.
- 2. Prescriptions may also be instituted by pharmacists at the request of a doctor.
- 3. Pharmacists will write in green, which other professionals should not use.

5.1.4 Prescribing for Children

1. Prescribing for children should follow the recommendations of the BNF for Children, and Simpsons Memorial Maternity Pavilion guidelines for neonates.

5.1.5 Prescribing Unlicensed Medicines/Outside Licensed Indications

- Prescribers may require to prescribe medicines that are unlicensed or for indications outside the licensed indications of a medicine. Prescribers will be taking responsibility for the effects of that medicine rather than the manufacturer. See NHS Borders Policy for the use of unlicensed (and off- label use) Medicines. For paediatrics refer to: THE USE OF UNLICENSED MEDICINES OR LICENSED MEDICINES FOR UNLICENSED APPLICATIONS IN PAEDIATRIC PRACTICE (a statement from the Standing Committee on Medicines, a joint committee of the Royal College of Paediatrics and Child Health and Neonatal and Paediatric Pharmacists Group).
- 2. Unlicensed medicines should not be used until approved by the ADTC.
- 3. The General Medical Council provides guidance for prescribers in their document 'Good Practice in Prescribing and Managing Medicines and Devices' (2013) when either prescribing a medicine outside the terms of its licence (off label) and when prescribing unlicensed medicines. This guidance can be accessed on the GMC website at: www.gmc-uk.org/guidance/ethical_guidance/14327.asp

5.2 In-Patients

5.2.1 Medicines Reconciliation

- 1. Accurate medicine reconciliation should be carried out on patient admission and discharge in NHS Borders:
 - Medicines reconciliation should be completed for every patient regardless of their mode of admission.
 - At least 2 reliable sources should be used to obtain an accurate medication history.
 - Patient demographics must be documented on the medicines page (unitary record).
 - Medication plan must be documented (unitary record).
 - Check allergy/ adverse drug reaction status.
 - Ensure medicines chart is accurately completed (See below).

5.2.2 Red wrist bands

- 1. The purpose of placing a red alert bracelet on a patient's wrist or ankle is to prompt healthcare staff to seek further information from the patient's notes about the known allergen.
- 2. The absence of a red alert bracelet should not be used as certainty that the patient has no known allergies. Clinical staff (medical, nursing, allied health and pharmacy staff) should confirm allergy information regularly.
- 3. As per current hospital procedure, the admitting clinicians (doctor and nurse/ midwife) must ascertain and document whether the patient has an allergy or has ever had an adverse reaction.
- 4. Once the allergy/adverse reaction has been appropriately documented, a red alert bracelet is to be placed on the patient's wrist and/or ankle. This should occur as early as possible. For example at triage for emergency admissions or on admission to ward/unit for elective admissions.
- 5. The red alert bracelet should be used in addition to white patient identification bracelet.
- 6. The details of the allergy or adverse reaction should not be documented on the bracelet.
- 7. Healthcare staff should refer to the patient's medical notes for specific details regarding the allergen.
- 8. In the instance that a red alert bracelet is removed for a procedure or treatment, the staff member responsible for removing the band must also take responsibility for having it replaced.
- 9. Mental Health inpatients will need to have their allergies documented and communicated in accordance with current hospital policy.
- 10. Red allergy bands can be ordered as a stock item and can be ordered from stores.

5.2.3 Use of the Medicine Chart

- 1. When writing prescriptions, the advice given in the British National Formulary (under "Guidance on Prescribing") should be observed.
- 2. The following important points must be adhered to when using the medicine chart:-
 - Ensure that **all personal details** of the patient, including the unit number and the weight, if available, are entered.

- The **date** of prescribing must coincide with the date of commencement of regular prescriptions, or the date on which once-only prescriptions are given.
- The name of the medicine **must** be clearly legible, preferably in capital letters.
- The **approved name** must be used for a medicine wherever possible. Where applicable, the proprietary name may also be used, e.g. combination products and in cases where different brands are **not** equivalent.
- The **dose** must be written clearly in the metric system. Wherever possible the use of decimal points must be avoided by the use of micrograms (or nanograms).
- The abbreviations 'g' and 'mg' may be used for grams and milligrams respectively.
- Micrograms, units or nanograms must not be abbreviated.
- The **time** of administration must be specifically indicated, using the 24 hour clock. g)
- The **route** of administration must be clearly indicated.
- 3. Only the following abbreviations may be used:-
 - IV Intravenous
 - IM Intramuscular
 - INH Inhalation
 - NEB by Nebulisation
 - PR Per Rectum
 - PV Per Vaginum
 - SC Subcutaneous
 - SL Sublingual
 - TOP Topical
- 4. Other routes of administration must be written in full.
- 5. "As required" prescriptions shall:-
 - Include the symptom to be relieved.
 - State the exact minimum time between doses
 - Where appropriate, the maximum daily dose should be indicated. This may be endorsed by the pharmacist.
- 6. The prescriber must sign the prescription and print their name on the medicine chart, if their signature is not clearly legible.
 - The minimum number of medicine charts should be in use for each patient at any one time.
 - The original date of commencement of each prescription must be used.
 - When re-writing a medicine chart it is good practice to have it checked by a second member of staff
- 7. Please note that there are different formats of the Borders Medicine Chart available depending upon the clinical area:-
 - **Supplementary Sheets** when used for prescribing, the prescriber must indicate the supplementary sheet in use on the main medicine chart. For example: warfarin chart, continuous infusion chart.
 - **Discontinuation or Cancellation of Medicines** Medicine charts should be reviewed frequently by medical staff with particular reference to cancellation of treatments which

are no longer required. Prescriptions should be rewritten rather than amended when a change is required.

- 8. To discontinue a "Regular" or "As required" prescription:-
 - a straight line must be drawn through the drug name;
 - the date discontinued written in the appropriate box;
 - the discontinuation must be initialed;
 - a diagonal line may be put through the remaining spaces for drug administration recording;
 - If a dose(s) to be given on day of discontinuation this must be made very clear on the chart.
- 9. Do not make the drug being discontinued unreadable.
- 10. Regular Medicine Check
- 11. The medicine chart may have prescriptions written on several pages of the form and these may not all be visible at the same time. To avoid the potential problem of prescriptions being overlooked all users must check all pages of the chart when administering or prescribing medicines.
- 12. Medicine charts are controlled stationery. Reasonable precautions must therefore be taken to ensure that blank documents are not available to non-authorised persons.
- 13. Any weight related doses need to be documented on the inpatient medicine chart.
- 14. Completed or old medicine charts should be filed in the patient notes.

5.2.4 Verbal Instruction

- 1. Verbal prescriptions by telephone are permitted for situations when the prescriber cannot be present immediately. This does not include Controlled Drugs which must be prescribed in person.
- 2. The message must be taken by a registered nurse/midwife and verified by a second registered nurse/midwife/assistant practitioner (or other competent member of staff if not available).
 - inform the prescriber of the name and dosage of other medicines currently prescribed for the patient,
 - write the full details of the verbal prescription on the appropriate section (once only, regular or PRN) of the medicine chart, entering "V/O" (for verbal order) and the doctor's name in the signature box.
 - the second member of staff reads the prescription back to the prescriber to ensure the message has been understood correctly.
 - the prescriber must subsequently sign and date the prescription on the medicine chart within 24 hours (up to 72 hours in community/mental health units).
 - the need for the prescription to be signed will be highlighted by marking/affixing a red dot in the box requiring signing.
- 3. In the case of an emergency situation, where a prescriber present in the ward/department gives a verbal instruction for administration of a medicine, the nurse/midwife must check the medicine and measured dose with the prescriber before administration.
- 4. The normal procedure for recording the prescription and administration of medicine must

be followed.

5.3 Patient group directions (PGDs)

- 1. It is usually necessary that all medicines administered or supplied to a patient by a practitioner be done so on the authority of an authorised prescriber.
- 2. Patient Group Directions allow specific professional groups of staff to administer and/or initiate a supply of medicines without the authority of an authorised prescriber.
- Patient Group Directions must be authorised by the Medical Director, Director of Pharmacy, clinical lead (i.e. Director of Nursing and Midwifery for PGDs used in Nursing/Midwifery), and Area Drugs and Therapeutics Committee on behalf of NHS Borders.
- 4. Patient Group Directions (PGD) must contain the following requirements:-
 - Details of the condition or situation to which the PGD applies.
 - Details of which patients are included and excluded from the PGD and what action to take if patients are excluded.
 - A description of the treatment available under the PGD including dose, frequency and the aims of the treatment.
 - Characteristics of the professional staff authorised to supply or administer treatment.
 - Details of records to be kept for audit purposes.
 - Details of practitioners responsible for drawing up the PGD.
 - Signatures of the Medical Director, Director of Pharmacy, and Lead Practitioner of Profession(s) eligible to work under the PGD.
 - Date for Review.
- 5. When developing PGD's the NHS Education for Scotland resource: 'To PGD or not to PGD' should be used to identify whether the planned implementation of the PGDs fits within the legislative framework.
- 6. It is the responsibility of the appointed practitioner in charge of each clinical area to ensure that if medicines are administered or supplied under a PGD that it is valid, the practitioner is authorised to work under the PGD and all appropriate documentation is completed.
- 7. Copies of approved PGDs must be available in the areas they are to be used.
- 8. A practitioner working under a PGD cannot delegate responsibility for administering and/or supplying a medicine under the PGD.
- 9. The Area Drugs and Therapeutics Committee are responsible for monitoring all Patient Group Directions in use and for ensuring the Patient Group Directions are reviewed in a timely manner (usually 2 years).
- 10. Individual practitioners are responsible for ensuring that they maintain their competency to work under a PGD and that they access any appropriate training required.

5.4 Patient specific directions (PSDs)

- 1. A PSD is a written and signed instruction from a qualified and registered prescriber for a medicine to be supplied or administered to a specific named patient. This should include full written details of dose, route and frequency. Details of any appliance to be used will also need to be detailed.
- 2. A PSD can be written in patients notes, on a patients medicines chart or, with the example NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page **71** of **100**

of routine vaccinations could be written for a list of patients as long as each patient to be treated is specifically named on the PSD and assessed by the prescriber as an individual.

- 3. PSDs differ in their application to PGDs as they can be used in planned care situations. PGDs are developed specifically as an option for unplanned care.
- 4. In the case of controlled drugs it is essential to comply with full prescription requirements.

5.5 Medicines act exemptions

- 1. Exemptions allow specific groups of healthcare professionals to sell, supply and administer specific medicines directly to patients.
- 2. Professionals may only supply and administer under an Exemption order where the order pertains to them.
- 3. Examples of professional groups that have access to exemptions include; Midwives, Occupation Health Nurses and certain Allied Health Professionals.

5.6 Patients' relatives

- 1. Borders General Hospital although relatives or visitors of patients should not routinely have medication prescribed for them by BGH staff, there are rare exceptions when prescribing is appropriate. For example, if a relative:-
 - has left essential medication at home and cannot obtain it in a reasonable time and it is deemed important for them to receive it, then sufficient doses may be prescribed and administered, until they can retrieve their own medication. Such relatives or visitors should be referred to Borders Urgent Care Centre (BUCCs previously BECS) for assessment and prescribing.
- 2. Prescribing should be on a HBP pad (blue) with 'dispense from BGH pharmacy' written on it
- 3. Prophylaxis for infectious diseases may be prescribed by public health doctors or the ConsultantMicrobiologist.

5.7 Out-patients Clinics (BGH and Outreach)

- 1. Changes in medication required for patients attending out-patient clinics will be referred to their general practitioner and should be in accordance with the Joint Formulary.
- 2. If prescribing is necessary from clinic, medicines should be prescribed on an HBP ('blue') prescription which can be taken to a community pharmacy for dispensing. HBP prescriptions will only be dispensed at BGH Pharmacy if this is requested on the prescription. Prescriptions should normally be for a maximum of 56 days.
- 3. Once only medicines which are required to:-
 - be given to facilitate investigations being carried out, or
 - for urgent treatment.
- 4. These must be prescribed and the administration recorded in the patient's case notes. Prescribing and administration must be carried out in accordance with this Code of Practice.
- 5. Where repeat administration of medicines is required for patients attending clinics, the
- 6. BGH Medicine Chart must be used, e.g. Dermatology dressing clinics. The guidance given in Sections 1 and 2 should be followed.
- 7. It is recommended to review serial prescriptions at an appropriate clinical interval no

greater than 12 months.

5.8 Emergency department (ED) & Borders Urgent Care Centre (BUCCs), BGH

5.8.1 Medicines Required in ED or BUCCs, BGH

- 1. ED "Once only" prescriptions may be prescribed and the administration recorded on the Emergency Department record, otherwise the Borders General Hospital Medicine Chart should be used.
- 2. BUCCs All medicines must be prescribed on the GP10 prescription forms, either electronically or on paper forms if in patients' homes and recorded on Adastra.
- 3. There are specific arrangements for the prescribing of controlled drugs within the Emergency Department setting. This includes restrictions around the prescribing of strong opiates by prescribers working within the department unless signed by the ED consultant in person. For full details please see the Emergency Department Analgesia and Benzodiazepine Policy.
- 4. The guidance given above in numbers 1 and 2 should be followed.

5.8.2 Medicines Required at Discharge

- 1. The prescriber will use or HBP/GP10 (for community pharmacy to dispense) to prescribe medicines at discharge as described in 5.7 above.
- 2. When prescribing in this context a 7 day supply should be the standard amount supplied at the point of discharge.
- 3. Out with community pharmacy opening hours, a doctor or registered nurse may issue these drugs from those available as pre-packs for this purpose. The nurse or doctor must complete the required details on the pre-pack label.
- 4. Where other drugs are required for ED attendees at discharge out with pharmacy hours the prescriber may use prescription form HBP.

5.8 Prescribing of medicines in hospital- discharge medications

5.8.1 Medicines reconciliation

- 1. Accurate medicine reconciliation should be carried out on patient admission and discharge in NHS Borders.
- 2. Ensure medications that have been withheld whilst in hospital are reviewed and represcribed if required upon discharge.
- 3. Record allergy status.
- 4. State medications discontinued, requiring review and new medication.

5.8.2 Discharge Supply

- 1. At discharge from hospital in-patients receive a minimum of a 7 day supply of medicines and other required products, unless a shorter period completes a treatment course, or if it is a part of the patients care plan.
- 2. If patient has regular medication at home, and agrees they do not need additional supplies from BGH, then this is not necessary. Endorse on discharge letter "at home".
- 3. These medicines are prescribed on the NHS Borders Discharge Letter (usually electronic (eDL) on the Trakcare system) or appropriate community documentation and dispensed in

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 73 of 100

the BGH pharmacy. For patients going home on warfarin the Warfarin Prescribing and Monitoring Form must to be completed and sent with the immediate discharge letter. For patients going home 'on pass' (i.e. to return in a few days) medicines must be prescribed in the same way as discharge medicines.

- 4. When prescribing, prescribers must:-
 - rationalise all drugs being prescribed
 - indicate the period of continuation for therapeutic courses
 - record which drugs have been discontinued during the inpatient episode and why
 - ensure that any items for ongoing use that are not included on the inpatient medicines record are provided at point of discharge e.g. wound products, catheters, stoma products etc.
- 5. For Controlled Drug prescriptions the following additional legal requirements apply:-
 - the prescription must be printed or written in ink;
 - it must be signed and dated by the prescriber.
- 6. It must state the following:-
 - the name and address of the patient;
 - the form of the preparation (eg tablets, injection, solution);
 - the strength of preparation;
 - the dose and frequency of administration;
 - the total quantity to be dispensed in both words and figures, e.g. Twenty (20) tablets or TWO hundred (200) ml.
- If using the eDL then the appropriate process is followed. If using paper discharge form all3 copies of this form should be sent to pharmacy for dispensing along with the patient's medicine chart and warfarin chart, if on warfarin.
- 8. Interventions made by pharmacists to clarify prescriptions must be recorded on the prescription, either electronically or in writing.
- 9. See: <u>Community Hospital Discharge Policy</u> on NHS Borders Clinical Area of Intranet.

5.8.3 Short Notice Discharge – Community Hospitals

- 1. If insufficient notice is given of a patient being discharged from a community hospital, a general practitioner or non-medical prescriber may prescribe medication on prescription form GP10 or GP10 (NMP).
- 2. The prescription is then dispensed by a community pharmacist.

5.8.4 Doctors Own Prescribing

1. Doctors own prescribing is not permitted within the Borders General Hospital.

CHAPTER 6 – DISPENSING

All medicines prescribed should be dispensed in a form suitable to go to a patient or to a health care professional for administration to a patient. This includes the provision of stock medicines to wards and departments, dispensing of medicines for out-patients, in-patients and for discharge. Only pharmacy staff may dispense medicines for patients, except where an alternative policy has been agreed with NHS Borders.

6.1 Borders General Hospital

- 1. Some medicines may be dispensed in "pre-packs", these have been over-labelled with a white NHS Borders Pharmacy label by Pharmacy and dispensed to the clinical areas. Staff members must complete the labels ready for patients to take home from the emergency department and some wards. A registered nurse or assistant practitioner may issue these medicines after receiving a signed prescription and completing any details required on the pre-pack. Prescribers should avoid prescribing and dispensing as this removes the 'second check'.
 - A discharge prescription is completed as above.
 - Supplies of medicines may be issued by a registered nurse/midwife and checked by a second registered nurse/midwife/assistant practitioner (or other competent witness if in a situation where a second qualified nurse is not available) both of whom must initial the prescription.
 - Containers and labels supplied by pharmacy must be used.
 - The container must be labelled with the following details:
 - o name of patient,
 - o date of issue,
 - o name and strength of medicine,
 - o quantity issued,
 - o directions for use,
 - "Keep out of reach of children",
 - appropriate supplementary labelling instructions as detailed in the British National Formulary (BNF), e.g. with or after food,
 - o the ward and hospital address,
 - o the medicines patient information leaflet included where possible.
 - A record of this must be made on the discharge prescription form.
 - Ward medicines stocks MUST NOT be used. Staff should not independently over-label ward stock medications.

If medications are unavailable as a 'pre-pack' a prescription may be written by a Registered Prescriber for dispensing at a Community Pharmacy. If out with Community Pharmacy hours the On-call Pharmacist may be contacted for advice.

Discharge prescriptions with Controlled Drugs must not be dispensed from stock, the On- Call Pharmacist must be contacted.

CHAPTER 7 – ADMINISTRATION AND RECORDING OF MEDICINAL PRODUCTS

Medication administration to the patient shall be accomplished in one of the following ways:-

- Administration by a registered nurse/midwife/AHP or other appropriate registered health professional (practitioner).
- Student nurses/midwives will participate in the administration and recording of medicinal products, at the appropriate level for their training, as outlined in the relevant practice placement assessment documents. This will be under the direct supervision of a registered nurse/midwife.
- 'Assistant Practitioners will participate in the administration and recording of oral, topical, medicinal products, at the appropriate level for their training, as outlined in the local standard operating procedure (SOP) documents. This will be following delegation and preparation by the registered nurse/midwife.'
- Hospital at Home Band 3 Care Assistants may support patients in their own homes with the administration of the patients own medication. They must follow approved training and competency according to local SOPs which have been approved by the Area Drugs and Therapeutics Committee.
- Self-administration by an in-patient in designated areas, in accordance with policies approved by medical, nursing and pharmacy staff.

7.1 Single practitioner administration

- 1. Where a system of one practitioner administration is used the practitioner must follow full checking procedures.
- 2. Medicines may be administered by a single practitioner except administration that involves:-
 - Controlled drugs
 - Calculation of dose (or calculation of the quantity of drug to be administered). A calculation includes a weight related dose, multiple vials or syringes are required to make up a dose, withdrawing a set dose/volume from a vial and not using the whole contents.
 - Administration to children under 16 d) Weight-related dose
 - IV administration

...in which case a second registered practitioner or assistant practitioner should check all aspects of administration.

- 3. When a second registered practitioner or assistant practitioner is not available for checking then a suitably trained unregistered professional e.g. health care support worker may provide the second check.
- 4. Lone practitioners administering medicines in the community e.g. on domiciliary visits, may administer subcutaneous, intramuscular and non-complex intravenous medicines and controlled drugs within their own level of competency.

- 5. In community practice where there is an NHS Borders approved protocol for a specific medicine or medicines, then the requirement for a second practitioner check can be mitigated by the use of appropriate checks within the protocol, which must be clearly documented. (e.g. Treatment Dose Low Molecular Weight Heparin: Protocol for Transfer of Care to Home (Short Term)).
- 6. Where calculations are made it is important that each person carries out the calculation separately. This avoids two people making the same mistake.
- 7. A record of administration must be made and the administering nurse/midwife identified.
- 8. Where a second nurse/midwife checks the administration of a medicine the identity of the checking nurse/midwife must also be recorded. The ultimate responsibility remains with the administering nurse/midwife. In addition, where a Controlled Drug is administered, a record must be made in the controlled drug register by the nurse administering and the checker.
- 9. Medication refused or wasted must be similarly recorded as detailed on the medicine chart and if a Controlled Drug, a record must be made in the controlled drug register.
- 10. One registered nurse/midwife may administer intravenous additives for infusion, which have been prepared in a ready to use form as follows:-
 - by the pharmacy department
 - by medical staff
 - by nursing/midwifery staff in specific areas under an approved policy.

7.1.1 Weight-related dose

- 1. Standard 8 of the NMC Standards for Medicines Administration (2010) states:-
 - "you must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications"
 - "you must have considered the dosage, weight where appropriate, method of administration, route and timing".
- 2. Weight may not always be available and in emergency or exceptional circumstances it may be necessary to use judgment to estimate weight utilising the Malnutrition Universal Screening Tool guidance (MUST).

7.1.2 IV administration

- 1. Standard 20 of the NMC Standards for Medicines Administration (2010) states:-
 - "Wherever possible two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medication".
- 2. This includes calculation of flow rates for administration of intravenous drugs. A record is made on the IV charts of the persons involved in the setting up of the medication which is administered continuously.
- 3. A suitably trained assistant practitioner or unregistered support worker may provide a second check when a second registered practitioner is not available. When a witness is required to administer medicines all steps of the procedure must be witnessed independently and both must sign all relevant documentation.
- 4. Where it is not possible for a second person to check administration e.g. administration

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 77 of 100

takes place in the patient's home, a risk assessment must be undertaken, and the action taken to minimise the risk must be documented. For example, a nurse administering a drug they are unfamiliar with in the community should double check the details with a suitably qualified registered practitioner before administering. For palliative care this will be the Margaret Kerr Unit or a Marie Curie nurse.

- 5. All items used to prepare and administer IV therapy must be used within their expiry date.
- 6. Medications that are made up in the clinical area must be used immediately and documented according to the SOP.
- 7. IV medicines may not be compatible with certain IV fluid or other medicines so the Registered Nurse/Midwife must check the recommended diluent and compatibility of each medicine with infusion fluid before administration using product manufacturer's information. (Refer to the current British National Formulary (BNF available online) relevant appendix and other locally approved information sources e.g. Medusa).
- 8. The Registered Nurse/Midwife who prepares the medication is responsible for the immediate labeling and must commence the administration following positive patient identification and second allergy check.
- 9. For blood and blood components there is an additional requirement to comply with traceability regulations as detailed in the NHS Borders Transfusion Policy.

7.2 Administration

Before administering a medicine, the nurse/midwife must ensure that the prescriber's instructions concerning drug, dosage, time and route of administration are clearly written and UNDERSTOOD.

If there is any uncertainty or doubt about the prescription the nurse/midwife must not administer the medicine and must IMMEDIATELY consult a prescriber.

The nurse/midwife should satisfy themselves that the patient has consented to receive treatment.

In addition, each registered nurse/midwife is accountable for her/his practice and is individually responsible for ensuring that she/he has up to date knowledge of the drugs being administered and their side effects as detailed in the NMC Guidelines for Administration of Medicines.

- 1. Ensure that all personal details including the CHI number and weight, if available, are entered on the medicine chart.
- 2. Read each prescription carefully. The prescription must be clearly written and unambiguous.
- 3. Check that the prescribed dose has not already been administered.
- 4. Select the medicine required and check the label with the prescription, noting any special instructions regarding administration or any drug sensitivities/allergies and checking the expiry date of the medicine where available.
- 5. If administering staff are reasonably concerned that they are unable to identify a medicine by its' appearance/packaging then this should be discussed with a clinical pharmacist (in

NHS Borders Code of Practice for the Control of Medicines; Updated Nov 2022 Review Nov 2024 Page 78 of 100

hours) or on call pharmacist (out of hours) who, with the administering staff, will identify if there is a further supply of the medicine available and/or assess the potential risk of omitting the medicine(s) and advise accordingly.

- 6. Check the dose prescribed and the route of administration and perform any necessary calculations with a second nurse/midwife.
- 7. Take the medicine and the prescription to the patient.
- 8. Check that the name and CHI number on the patient's medicine chart corresponds with the name and unit number on the patient's identity bracelet or use an alternative method of confirming the patients identity if bracelets are not in use (e.g. patient photograph).
- 9. Nurses/midwives should always stay with the patient until the medicine has been taken. If a patient requires additional assistance in the ingestion or application of a medicinal product, this task may be delegated, however the registered practitioner remains accountable to ensure the patient, carer or care assistant is competent to carry out the task.
- 10. Medicines must not be left on a patient's bedside locker unless special instructions have been given (e.g. glyceryl trinitrate, inhalers).
- 11. At the bedside the nurse/midwife must then make a clear, accurate and immediate record of medicines administered, intentionally withheld or refused on the medicine chart. The current date must be entered in the column across the top of the page of the medicine chart. The initials of those involved in the administration of a medicine must be recorded in the appropriate space.

7.2.1 Controlled Drugs

Administration and/or wastage should be recorded in the *Controlled Drug Register*.

1. If a medicine is not given, the appropriate code number for the reason must be recorded. Substances prepared for administration and subsequently not given to the patient concerned must be rendered irretrievable by emptying into a sharps bin in the presence of the person checking the drugs, where appropriate. They **must not** be returned to the container from which they were removed. If controlled drug injections are wasted this must be recorded in each section from which drugs were issued (i.e. if Diamorphine 10mg and 30mg injections were used to make up the injection then it should be recorded on both pages).

Where tablets need to be halved to administer the correct dose, the remaining half must be disposed of, as detailed above.

- 2. If a **missed** dose is given later to a patient, the date and time of administration must be recorded in the 'Administration Comments' column of the medicine chart.
- 3. Patients who have been ordered "nil by mouth" prior to surgery or other procedures should have their regular medication administered with a small amount of fluid, unless there is a specific instruction to the contrary.
- 4. If a decision has been taken that a patient may self-medicate this must follow a written protocol drawn up after discussion locally by nurses, doctors and pharmacists. The prescriber must record the prescription by writing it in the usual manner, with "Self-admin" noted on the medicine chart. For each day that the patient self-administers, this must be

written across the administration record. Where insulin is self-administered the patient must record the dose given and time of administration on the diabetic chart to ensure there is a clear record of each administration.

5. If an error or near miss is made or observed in drug administration or prescribing, then it must be reported via the DATIX electronic reporting system as a medication error.

7.3 Covert Administration of Medication

This section should be read in conjunction with the Mental Welfare Commission for Scotland Guidance (2013) on covert administration of medicines accessed at:

<u>www.mwcscot.org.uk/publications/good-practice-guides</u>and the *NHS Borders Consent to Treatment Policy*.

- 1. Covert administration of medication should only ever be considered as a last resort and only in situations where the Mental Welfare Commission Guidance can be applied in its entirety.
- 2. Types of covert administration:-
 - Administration of medication where the medicinal product in hidden such as in a drink or food without their knowledge/awareness.
 - If administration within a food/drink/yoghurt for swallowing difficulty has not been fully disclosed and discussed with the patient/their carers/relatives.
- 3. Not classed as covert administration:-
 - Medicine that is given in a food/drink/yoghurt purely to aid swallowing on the advice of a specialist (Speech and Language Specialist/ Pharmacist/ Medical Staff) and where the patient understands what they are being given and the reasons for it being given in this way.
- 4. Any incidence of covert administration of medication where the Mental Welfare Commission guidance is not followed could result in disciplinary action for any staff involved.

7.4 Administration of Parenteral Medicines

7.4.1 Intravenous (IV) cytotoxic chemotherapy

 Should only be administered by a chemotherapy trained nurse, appropriate consultant or appropriately trained other grade of hospital doctor and only reconstituted for use/dispensed by the BGH Pharmacy Chemotherapy and Aseptic Dispensing Unit (see *Guidelines for the Safe Use of Cytotoxic Chemotherapy in the Clinical Environment*).

7.4.2 Parenteral nutrition

- 2. Solutions must only have additions made to the bag by the BGH Pharmacy.
- 3. Prescribing and administration of IV drugs by anaesthetists in Theatres should follow locally agreed professional standard operating procedures.

CHAPTER 8 – INTRAVENOUS ADMINISTRATION

8.1 Prescriber's Responsibility

- 1. It is the prescriber's responsibility to ensure that all routes of administration are considered before prescribing intravenously:-
 - That the medicine to be given by the intravenous route is appropriate for this method of administration and for the vehicle in which it is to be given.
 - Prescribers must ensure that they are fully competent to prescribe IV medicines as the prescriber holds responsibility for that prescription.
 - The prescriber must ensure when they write prescriptions for this form of therapy that their instructions are complete and clear. They should also be aware of the extent to which this policy allows them to delegate responsibilities concerned with the addition or administration of medicines via intravenous infusion fluids.

8.2 Responsibility for Administration

- 1. Registered health professionals who have completed IV therapy training may administer intravenous drugs.
- 2. It is the practitioner's responsibility to achieve the competencies following attendance at the NHS Borders IV Therapy/Cannulation study day before being considered to be competent in administering or preparing medications for administration by the IV route. The registrant must access the Competency, Recording Assessment System (CARS) and ensure that this is updated and completed within 6 months of attendance at the study day.
- 3. A self-review every 3 months to ensure maintenance of competence in practice is recommended.
- 4. Formal reassessment of competence:-
 - Demonstration of continued competence is required at annual PDP meeting, and
 - Formal reassessment of practical competence must be undertaken every 2 years.
 - One of each relevant intravenous preparation and administration methods must be supervised and assessed by a peer I.V. supervisor/ assessor.
 - Intravenous therapy supervisors/assessors must meet the standards for theoretical and practical update.
- 5. Practitioners should be familiar with and must follow Protocols and SOPs relating to IV/SC administration including (but not limited to):-
 - Medical Infusion Protocol
 - Central Line Protocol
 - Hickman Line Protocol
 - PICC Line Protocol
 - Midline protocol
 - Standard Operating Procedures for Intravenous Therapy/Cannulation
 - Procedure for administration of subcutaneous fluids
- 6. For all of the above procedures nurses must use an aseptic non-touch technique with observation of standard precautions and product sterility.

- 7. Before undertaking the preparation of a drug additive to an intravenous infusion or the administration of an intravenous drug, the practitioner must ensure that the prescriber's instructions are clear and complete.
- A practitioner must exercise professional judgement in determining the suitability of IV administration and must be prepared to seek further advice if necessary before administration (For nurses/midwives NMC *The Code (2015), NMC Guidelines for administration of Medicines (2010)*. For Allied Health Professionals HPC *Standards of Conduct, Performance and Ethics (2008)* (Also see the professional standards of proficiency developed for each profession registered with the HPC)).
- 9. 'Practitioners involved in checking, preparing and administering medication by the intravenous route should witness the whole process from preparation to administration.
- 10. Assistant Practitioners may independently second check:-
 - drug calculations,
 - administration of medicines &controlled drugs
 - second signatory in Controlled Drug Record Books
 - Controlled drugs stock checks
 - Verbal orders
 - 'pre-pack' medicines issued by a registered nurse/ midwife for patients taking home **This specifically EXCLUDES:-**
 - Medicines that require blood investigations/ interpretation
 - Doses that are weight related
 - Infusions requiring specific on-going monitoring of the patient
 - Patients with more than one concurrent infusion
 - Medications identified for bolus infusion as high risk (identified in IV study day)
- 11. Assistant Practitioners skills may be developed in specific areas, where this is appropriate the Area Drugs and Therapeutics Committee must be formally approached to agree exceptions to this policy. This will include single vial dilution, where the full vial is administered but excludes part doses
- 12. Assistant Practitioners may administer prophylactic low molecular weight s/c heparins such as Dalteparin where it is prescribed in the pre-printed section of the medicines chart only.
- 13. Registered health professionals that may administer IV medicines after completing IV Therapy training are: nurses/midwives, AHPs and doctors.
- 14. Registered staff may delegate IV practice to appropriately trained unregistered staff when supported by an organisationally approved framework. This must take into consideration the competence of the unregistered staff and have been reflected within a clinical service risk assessment.
- 15. Any of the above practitioners plus pharmacists may check IV medicine administration. Anaesthetists in operating theatres may calculate doses and administer IV drugs alone within the framework provided by the Controlled Drug Theatres Standard Operating Procedures.

8.3 Pharmacy Service Responsibility

It is the pharmacy service's responsibility to provide an intravenous additive service for those products identified as requiring preparation in a pharmacy aseptic unit.

- 1. The pharmacist must provide advice on all aspects of intravenous therapy and should direct health care workers to appropriate literature sources for information. The pharmacist must help maintain any information required for their ward policies.
- 2. The pharmacist also has an important role to play in monitoring prescriptions and in highlighting problems concerning safety, stability and compatibility.

8.4 Dosage Calculations by the Intravenous Route

- Two persons must always be involved in all aspects of administration of medicines when given by the intravenous route. This is particularly important when complex dosage calculations are involved. (Complex calculations are defined by the NMC for the purposes of administration as any calculation which involves two stages or more), (Also see; NPSA – Safer administration of medications for injection).
 - these must be independently calculated and the dosage verified before administration
 - additional care must be taken with neo-natal, paediatric and low weight adults (below50kg) dosage calculations
 - particular care must be taken when calculations involve a decimal point
 - all calculations should be written on paper, not solely done by mental arithmetic or electronic calculator
 - a record of the calculation should be filed in the patient's case notes
 - all practitioners Involved in IV calculation must meet the NHS Borders Standard for Numeracy Competence

8.5 Authority to Prepare IV Additives

- 1. Medicines may be added to intravenous infusion fluids by:-
 - pharmacy department as part of an intravenous additive service
 - Practitioners who have completed specific NHS Borders approved training on the *Principles of Intravenous Therapy Management*.
- 2. In an inpatient setting the nurse in charge must be satisfied that the nurse having been trained is proficient to administer medicine by the IV route. Registers must be kept of all participants of the above training.
- 3. All practitioners are required to complete an IV therapy update every 2 years and review competencies as part of their annual personal development Plan/Appraisal.
- 4. The training programme must be approved by the Director of Nursing and the Director/Deputy Director of Pharmacy.
- 5. Being IV Therapy trained authorises a practitioner to add appropriate medication to:-
 - a standard infusion fluid container (bag/bottle) of appropriate volume for continuous or intermittent infusion.
 - an appropriate sized syringe with or without diluent for continuous, intermittent or bolus injection into an existing mechanical port (avoiding the cannula port where possible).

6. Some methods of administration and appliances used are specific to certain clinical areas. There is both an individual and managerial responsibility to ensure that competence is maintained for the appropriate methods/appliances.

8.6 Other Parenteral Routes

1. Departments that administer drugs via other parenteral routes must have local policies and procedures in place.

8.7 Infusion Pumps and Drivers

- 1. This section should be read in conjunction with the NHS Borders Infusion Device Protocol which can be located on the Medicines intranet site.
- 2. Only registered nurses who have received training in the use of Infusion pumps and who have demonstrated their proficiency in the use of this equipment may administer medicines intravenously by this means, provided clear and unambiguous written directions are given on the patient's Continuous Drug Infusion Chart or Intravenous Prescription and Fluid Balance Chart.
- 3. Practitioners must have achieved the clinical competency assessment relevant to the infusion device being used.
- 4. A second registered nurse/midwife/assistant practitioner/appropriate person who has been trained in the use of infusion pumps must check that the correct preparation in the prescribed dose is introduced into the syringe and that the syringe is fitted to the correct patient's pump and set at the correct rate. Both must sign the *Continuous Drug Infusion Chart* or *Intravenous Prescription and Fluid Balance Chart* to verify that these checks have been carried out:-
 - the manager will ensure that a register is kept of nurses/midwives who have received training in the use of IV pumps
 - a similar procedure should be adopted for subcutaneous pumps

8.8 Prescribing Process and Documentation of Medicines to be added to Intravenous Infusion Fluids

- 1. Medicines, which are to be added to intravenous infusion fluids, must be entered legibly and indelibly, on the medicine prescription sheet along with the words "As Charted". The entry must be signed and dated by a doctor or non-medical prescriber with the appropriate level of competence.
- 2. The medicines and the fluid into which they are to be added must also be entered, legibly and indelibly, on the Continuous Drug Infusion Chart or Intravenous Prescription and Fluid Balance Chart and signed and dated by the prescriber.
- 3. The prescription must clearly state:-
 - The name, strength and volume of the intravenous fluid to be administered.
 - The name and dose of any medicines to be added to the intravenous infusion fluid.
 - The rate at which the resultant mixture of medicines and fluid is to be administered. d) The time at which administration of the medicines in the infusion is to commence.
 - The duration of the infusion.

8.9 Labelling and Checking of Medicines added to Intravenous Infusion Fluids

- 1. All containers (bags/bottles/syringes) must be clearly labeled using an intravenous drug additive label. All sections of the label must be complete.
- 2. All injections should be labeled immediately after preparation, except for syringes intended for IV flush administration by the person who prepared them.
- 3. Under no circumstances should an operator be in possession of more than one unlabeled syringe at any one time, nor must an unlabeled syringe be fitted to a syringe driver or similar device.
- 4. Labels used on injectable medicines prepared in clinical areas should contain the following information:-
 - Name and CHI Number of Patient
 - Name of the medicine;
 - Strength;
 - Route of administration;
 - Diluent and final volume;
 - Signature of qualified practitioner
 - Batch number
- 5. All additions to intravenous infusion fluids must be checked before administration commences by registered nurses who are included in section 8.2 or by a doctor or pharmacist.
- 6. Continuous infusions containing drugs must be changed every 24 hours or less if the stability of drug demands this, unless specific recommendations allowing use for longer periods have been agreed by Pharmacy or the IV Therapy Group.

8.10 IV Safety Checks

- 1. It is expected that the following checks are undertaken every 4 hours for patients undergoing continuous IV infusions:-
 - All label details (see section 9.9)
 - Expiry
 - Patient ID
 - Device
 - Rate
 - Volume

8.11 Records

- 1. A record of all additions must be recorded in the appropriate sections of the *Continuous Drug Infusion Chart*.
- 2. A record of intravenous infusion fluids given must be made on the *Fluid Balance Chart* after the fluid has entered the patient.
- 3. All bolus drugs given must be recorded in the medicine chart as normal.
- 4. Batch numbers must be recorded, for bolus injections this should be recorded on either the *Medicines Chart* or the *Drug Infusion Chart*, and in all other cases this should be recorded in the *IV Fluid Chart*.

8.12 Subcutaneous Infusions

- 1. The NHS Borders Mckinley T34 Syringe Driver Protocol must be followed.
- 2. The *Subcutaneous Syringe Driver Chart* must be completed.

CHAPTER 9 – LOCAL PROCEDURES AND GUIDANCE

NHS Borders Policies and Protocols

Currently available on the A-Z of Clinical Policies in Clinical Area

Will be available on Right Decision Service App - early 2023

The Right Decision Service (RDS) app is a new development to provide easy access to NHS Borders' clinical guidelines, protocols and policies to support safe clinical practice, education and patient safety in the BGH.

Pharmacy Department, Borders General Hospital, Melrose - Standard Operating Procedure

Receiving controlled drugs delivered to BGH wards and departments from pharmacy

November 2020	Document No	SOP- CD020	Written by:	Shelley Scott	Signed ✓
November 2022	Supersedes:	NEW	Approved by:	Fiona Fealy Pharmacist – Controlled Drugs	Signed ✓

Purpose: To outline a safe process for the receipt of controlled drugs within BGH wards/departments which limits the possibility of diversion and is fully accountable

Relevant to: Healthcare support workers (HCSW), registered nurses, charge nurses

Procedure:

- 1. The Pharmacy porter will arrive on the ward with a security sealed envopak containing controlled drugs which will need to be signed for. As a matter of good practice, the receiving person should not be the same person who ordered the CDs. Check the pharmacy delivery of security sealed envopaks transit form (*Form 1*) against the security seal serial number of the envopak. If satisfied that the security seal number recorded on the transit form and the security seal of the envopak correspond and the security seal is intact then sign in the 'Received by' column and record the time the envopak was received on the ward. If the serial numbers do not correspond or the security seal is not intact then do not sign the transit form. Contact pharmacy immediately.
- 2. When ward staff are collecting controlled drugs from pharmacy, the pharmacy delivery of security sealed transit form must be completed following the above process. The staff member collecting the controlled drugs should return immediately to the ward.
- 3. The envopak containing the controlled drugs should be held in a secure place until a second witness is available. The second witness should be found as soon as is practically possible after the controlled drugs are received on the ward. (A healthcare support worker (HCSW) may act as the second witness to a registered nurse).
- 4. The registered nurse should then break the seal in the presence of the witness and remove the contents of the envopak. Check the contents against the appropriate requisition in the order book. It is essential to check that the following match:

- Drug name
- Strength of drug
- Form of drug
- Modified-release or immediate-release (if appropriate)
- Number or volume received
- 5. If both staff members are satisfied that the above are correct then the duplicate sheet in the CD requisition book should be signed by the registered nurse in the 'Received by' section.

Wards with Omnicell cabinets should check contents against the order receipt generated by the cabinet (*Form 2*).

If, when the tamper evident seal of the envopak is broken, the contents do not match the expected amount stated in the order book, the person in charge should contact the pharmacy department immediately.

- **6.** The controlled drug(s) must be entered onto the appropriate page(s) in the ward controlled drug register by a registered nurse.
 - Enter the serial number from the page of the order book that the drug has been ordered on in the register.
 - Enter the date the item has been received from pharmacy
 - Enter the amount received and 'from pharmacy' *ie.* '10 ampoules received from pharmacy'
 - Ensure that the running balance is updated and check that the balance tallies with the quantity that is physically present.
 - Enter the page number of the controlled drug register that the item is being recorded on onto the packaging of the item.

Wards with Omnicell cabinets should follow the process for receiving a controlled drug into the cabinet.

- 7. The entry into the ward controlled drug register must then be checked by a second witness (HCSW may act as a witness) against the items received. The witness must ensure that they are checking the following.
 - The correct serial number of the page of the order book the drug has been ordered on is entered in the register.
 - The drug received is recorded on the appropriate page of the register ie: correct name, strength, form, modified-release/immediate-release where appropriate
 - The amount being received into the register is correct
 - The running total is correct and that the physical stock matches the balance recorded in the register.
- 8. Once all items have been entered into the ward register then the registered nurse <u>and</u> the witness must sign the register to confirm receipt of the controlled drug. Any discrepancies must be reported immediately to the nurse in charge who will then

contact the pharmacy controlled drugs governance team if the discrepancy cannot be resolved.

- 9. Place the controlled drugs in the appropriate controlled drug cupboard, ensuring opened or shorter-dated stock is placed in front of any new controlled drugs received of the same type (name/strength/form).
- **10.** Lock the controlled drug order book in the controlled drug cupboard and ensure keys are returned to the appropriate staff member.

Form 1

PHARMACY	09	014
Y OF SECURITY SEA TRANSIT FOR	ALED ENVOPAKS	
	ne of Bun	
Security Seal No.	Received	Time Received
	Sector March 20	
	No. of States	
	1. States	
and the second		
	Contraction of the second	
	-	
and a start of the		
		1
	Y OF SECURITY SEA TRANSIT FOR.	Y OF SECURITY SEALED ENVOPAKS TRANSIT FORM

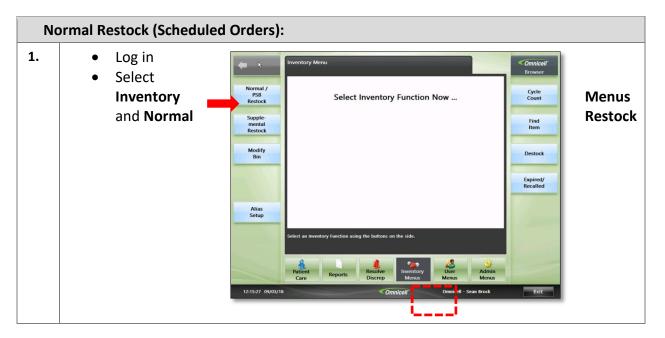
Form 2

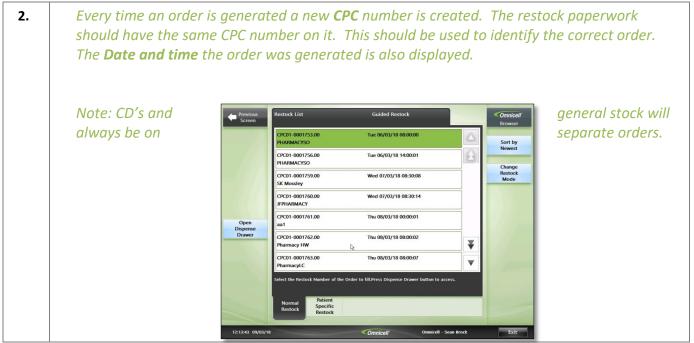
Comnice		FOR CO			RUG	PRINT DAT	
	IENCY DE			LL ORDER (CF	PC) No:		01-0002560
ASC173B	MORPHINE SU	LFATE 10mg/1m	nL 1mL INJ	-		20	AMP
ORDERED BY : SUPPLIED BY : ACCEPTED FOR RECEIVED BY :	Signature of Cherge Nurse Signature of Technician DELIVERY BY : Signatur	o / Pharmacist e of Messenger	1.1	f sip NO : sip NO :		DATE : DATE : DATE : DATE :	

APPENDIX 2 – GUIDE FOR RECEIVING CDs INTO CABINET

The purpose of this guide is to outline a process for receiving controlled drugs into the Omnicell cabinet.

The staff nurse receiving the controlled drug must log into the system using their fingerprint or user ID and password and navigate to the **Inventory menus** screen and select **Normal Restock**.





Controlled Drugs – Nurse User

Only if Omnicell is auto generating CD orders

Select the top CD Restock(the locations of all items on the CPC order will flash)

- The nurse user should open the drawer where the flashing light is an attempt to lift the lid indicated by the flashing green light **NB**: A witness will be required, the witness must use their fingerprint or ID and password to the complete the witness transaction.
- The nurse should then open the lid and then must count the current quantity on hand of the item and enter this using the number pad and pressing **OK**.
- The nurse user must confirm the quantity to be restocked.
- (The nurse user may be requested to enter the Expiry date of the shortest dated item in the illuminated location, including the stock being restocked)
- If safety stock is in use the nurse user should scan the barcode of the item being restocked
- The nurse user should then place the item being restocked into the opened bin location and then close the bin lid and the drawer to complete the transaction.

If using Safety Stock you will be asked to scan the item barcode. If no stock is available the item can be changed to zero, quantities should be changed to match **supplied amount**

You can exit at any point and the restock will remain there. The length of time is dependent on facility setup

NB: <u>All users must ensure they log out from the system when they have finished re</u> <u>stocking</u>.

APPENDIX 3 – MISSING CD KEYS

Pharmacy Department, Borders General Hospital, Melrose - Standard Operating Procedure

Date of Issue:	May 2022	Document No:	CD023	Written by:	Shelley Scott Controlled Drugs Governance Officer	Signed ✓
Revision Date:	May 2024	Supersedes:	NEW	Approved by:	Kirsten Thomson Lead Clinical Pharmacist	Signed ✓

Controlled drug cabinet key security

Purpose: To outline a process to ensure the security of controlled drugs keys

Relevant to: Nursing staff/Charge nurse

Procedure

- 1. All wards (including wards with Omnicell cabinets) will require 2 keys for the ward CD cabinet. One for use and the other to be stored securely in a safe place (ie: in lockable key store cabinet in charge nurses office) access to this and the CD keys should be restricted to as few staff members as possible.
- 2. CD keys should be kept separate from other ward drug cupboard keys.
- 3. If wards do not have a spare key this can be arranged through estates.
- 4. If during a shift the CD cabinet key cannot be located then the nurse in charge must be notified immediately. All nursing staff/medical staff who are on duty should be alerted and all asked to check in case they are in possession of the key. Any staff that are no longer on duty but had been at the time the key is suspected to have gone missing must also be contacted in case they have it with them.
- 5. It may be necessary to contact nursing staff/medical staff from the previous shift.
- 6. All staff should be asked if they are aware of when they last had access to the key or if they are aware of anyone else having had access to it.
- 7. A thorough search should be conducted throughout the ward.
- 8. The second key (emergency) key should only be used if the original key cannot be located and a thorough search has already been conducted.
- 9. If all staff that had been on duty have been questioned, a thorough search has been conducted on the ward and the key can still not be located a Datix must be completed and the police and hospital management must be informed so that they can assist with the investigation. This should be done within 48 hours of discovering that the keys are missing.
- 10. A staff list that had been on duty and questioned with regards to the missing keys must be provided to the police at the initial visit.

APPENDIX 4 – CD CHECKOMNICELL

The purpose of this guide is to outline a process for carrying controlled drugs

3.8 Cycle Count – Guided

Сус	cle Count – Guided:	
1.	 Login using Fingerprintor User ID an Select Inventory Menus Select Cycle Count 	d Password
		Select Inventory Function Now Cycle Count Find Rem Destock Depired/ Recalled
	• Select Guided Cycle Count.	
2.	 Select All and make sure Control is selected. Make the user aware that Control items are Controlled Drugs. Select Count Now 	Control Level 3 Control Level 4 Control Level 5 Control Level 5 Contro

3.	 Follow the guiding lights to the location. You should be guided to Training - Morphine 10mg/1ml 1ml Inj (A witness will be required)
	 Open the bin Depending on your facility setup cycle count will or will not show the current quantity Count the quantity on hand Enter an incorrect quantity

NHS Borders Code of Practice for the Control of Medicines; Updated July 2022 Review July 2024 Page 94 of 100

4.	A warning of Is this the correct count? Will display Note: This is a prompt to count again the quantity that you are entering is different than the Omnicell stored • Select No
5.	• Enter the correct quantity and close the bin. Note: You would usually be guided through all control level 2 (CD) items stored in the cabinet You can exit the guided count at any point and when the same user logs back in the count can be resumed from the cycle count menu by pressing Resume Count .
6.	Close the drawer
7.	• Exit

APPENDIX 5 – FORM FOR THE REMOVAL OF SUSPICOUS SUBSTANCES

NHS Borders - Form for the Removal of Unauthorised Drugs or Other Suspicious Substances

	cription of substance removed from the completed by the member of states of the second states		
Form:	(eg powder, tablets, cap	sules) Colour:	Quantity:
Removed from:	Patient's initials and hospital num	per:	
Ward/Dept:	Date:		Time:
Name of Finder:		Title:	Signed:
Ward/Dept Manag	er:	Title	Signed:
Witnessed by Seni	or Nurse Manager Signed:	Date:	Time:

Part B Action by Senior Nurse Manager and Doctor in charge of the patient			
We, (Senior Nurse Manager) and (Doctor in charge of the patient)			
 Action (1) We have therefore authorised the return of the substances to the Pharmacy Department.* Action (2) We have therefore contacted the Police.* 			
(1) are in agreement* (2) are not in agreement* that the unauthorised substance found on the person or property of the above patient are of a quantity consistent with her or her own personal use.			
Signed: Time:			
Signed: (Doctor) Date:			
*Delete both items (1) or both items (2) as appropriate.			

Part CCollection and removal to BGH Pharmacy for destructionSealed container received by Pharmacist

Signed:	Date:	Time:
Encourte Cool Noushow		

Envopak Seal Number:	

Part DCollection by policeSealed container collected by:-		
Officer's Name:	Signed:	
Witnessed by Nurse or Pharmacist	Name:	Signed:
Date: Time:		

NB: 1 copy to be filed in patient's medical record; 1 copy to be retained by Pharmacy Department; 1 copy to be given to the Police (if appropriate) susp-subs-frm

APPENDIX 6 – DEALING WITH CD DISCREPANCIES

The purpose of this guide is to outline a process on how to resolve a Controlled Drug (CD) discrepancy via Omnicell.

The balances in the Omnicell CD register should always tally with the amount of CDs in the cabinet. If they do not, the discrepancy must be reported, investigated and resolved.

Info	Ensure you understand the facility's policies for when (e.g., daily, at end of shifts), how, and who resolves discrepancies.
	If there are unresolved controlled Drug discrepancies on the cabinet the Resolve Discrep button is highlighted prior to logging on.
	Also, the screen saver will display There are Unresolved Discrepancies at This Cabinet.
	When a discrepancy is created, a report will automatically print the quantity expected, quantity found, and the names of the last two people who accessed that bin.
	Before resolving a discrepancy it is recommended that a cycle count of the medication be done to verify the correct countby using the FIND ITEM button within open cycle count.

NB: If a user notices a CD discrepancy it should be reported, investigated and resolved at the time, only in certain circumstances should it be left unresolved.

See Below – Once the user has logged into the system using their fingerprint or ID and password and have selected a drug to administer for a patient, if the remaining quantity entered does not match the systems records then the following message will appear.

The message **Is this the correct count prior to dispensing** will display This is indicating that the quantity entered is different to the Omnicell stored quantity.

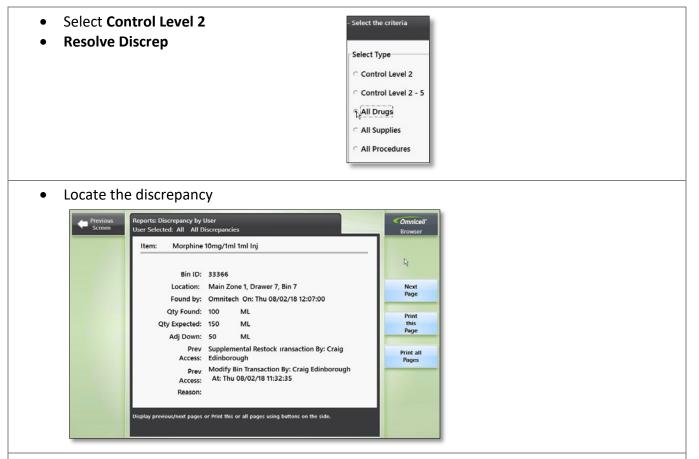
- Select Yes and continue with the transaction
- A Discrepancy will be created and a receipt will be printed
- Select Exit

The **Resolve Discprep** button is highlighted Analertwill also be sent to **Pharmacy**

- Log in
- SelectMain Menu



• Select Resolve Discrep



• Enter Error in countback

• SelectResolve Discrep

(Have the user login as a witness if required).

Sometimes 2 discrepancies will be created relating to a single error.

- 1. *Miscount* creates the Discrepancy
- 2. **CycleCount**back to **correct quantity** creates another Discrepancy

Both discrepancies will have to be resolved.

• Press Exit

Show that the highlighted **Resolve Discrep** has gone (as long as all discrepancies have been resolved).

All CD discrepancies should be investigated and reported within 3 days, the following should be carefully checked.

- All requisitions received have been received correctly through the Omnicell system.
- All CDs administered have been entered into the Omnicell system.
- Items have not been accidentally put into the wrong place.

If no errors or omissions are detected then the discrepancy should be reported to the ward pharmacist and ward charge nurse. If the discrepancy cannot be resolved it must be reported to the Controlled Drug Accountable Officer without delay and a local incident form completed in line with the healthcare organisation's policy or procedure for reporting incidents.

APPENDIX 7 - STUDENT NURSE MEDICINE ADMINISTRATION – A GUIDE



NHS

Edinburgh Napie

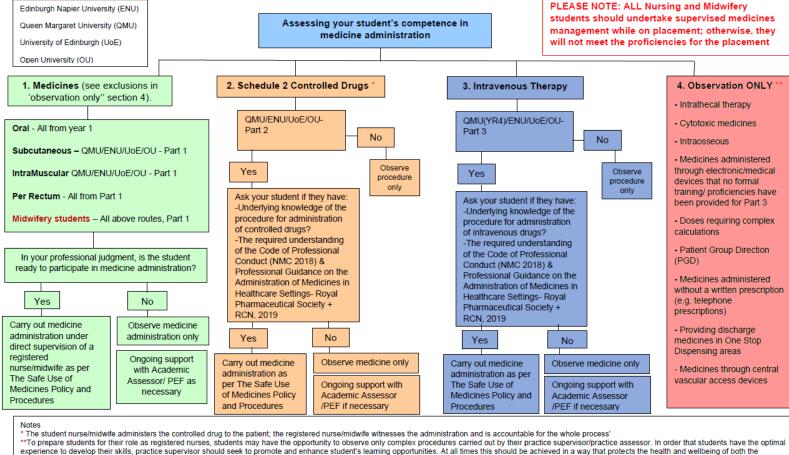




Queen Margaret University



Involvement of pre-registration nursing (except child) & midwifery students in medicine administration - A guide



patients and the public. For further information, see Practice Learning Support Hub

Author: Operations Manager for Simulation & Clinical Skills Edinburgh Napier University

Review Date: Sept 2025

Approved By: Deputy Nurse Director

NHS Borders Code of Practice for the Control of Medicines; Updated July 2022 Review July 2024 Page 99 of 100

BIBLIOGRAPHY

- The Safe and Secure Handling of Medicines A Team Approach. A revision of the Duthie report (1988) From Royal Pharmaceutical Society March 2005
- Medicines, Ethics and Practice; A Guide for Pharmacists, RPSGB, Current Edition.
- Patient Group Directions NHS HDL (2001)
- A Report on the Supply and Administration of Medicines under Group Protocols (from Review of Prescribing, Supply and Administration of Medicines, 1998, Department of Health)
- NMC The Code: Professional standards of practice and behaviour for nurses and midwives
- NMC Standards for Medicines Management
- Guidelines for Records and Record Keeping NMC Current Edition.
- NMC Standards for Nurse Prescribing
- Medicines Act 1968 (and subsequent amendments)
- Poisons Act 1972
- Misuse of Drugs Act 1971
- Standards for NHS Pharmacy Hospital and Community Services Health Services Accreditation 1998.
- CEL 30 (2012), Revised Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy (SACT).
- Safe Administration of Intrathecal Cytotoxic Chemotherapy HDL (2002)22
- THE USE OF UNLICENSED MEDICINES OR LICENSED MEDICINES FOR UNLICENSED APPLICATIONS IN PAEDIATRIC PRACTICE: a statement from Standing Committee on Medicines, a joint committee of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group
- Royal College of Paediatrics and Child Health 'Drugs for Children' 1999
- Good Practice Statement for the Preparation of Injections in Near-patient Areas including Clinical and Home Environments: CRAG Dec 2002
- Mental Health (Care and Treatment Act) (Scotland) 2003 Act
- Adults with Incapacity Act (2000)
- NPSA Promoting the Safer Use of Injectable Medicines; Patient Safety Alert 20 (March 2007)
- NHS Education for Scotland 2006; Guidance for Practitioners in the Preparation and Administration of Injections in Near Patient Areas; Quality Education Framework.