Medicines Policy (Acute, Mental Health, Learning Disabilities and Community Services)

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V15	13/07/2021	MMOG CWCDG	13/07/2021 25/082021	25/08/2021	25/08/2024

Brief Summary of Document:	This document provides information on the prescribing, administration, ordering, transport, storage, control and disposal of medicinal products (including Controlled Drugs) within the Acute and Community settings of Hywel Dda University Health Board (HDUHB), so that these processes comply with current legislation, professional guidance and local policies, guidelines and procedures.
Scope:	This policy applies to: • All Health Board employees who prescribe, administer, order, transport, store, control and dispose of medicinal products including Controlled Drugs e.g. registered nurses and midwives, medical staff, pharmacists, student nurses/midwives,

	operating department assistants and practitioners, allied health professionals, healthcare support workers, staff and volunteers. • All patients under the care of the HDUHB. This policy applies to all services within the acute and community setting.
To be read in conjunction with:	008 Consent to Examination or Treatment Policy 374 Mental Capacity Act 2005 Policy 176 Non Medical Prescribing Policy 163 Deprivation of Liberty Safeguards: Guidance and procedure for staff Controlled Drugs Governance Policy 467 Medical Devices Management Policy 556 Antimicrobial Stewardship Policy 331Enteral Feeding Policy 341 Prescription and administration of emergency oxygen in adults AWMSG Guidance for adults who cannot swallow. AWMSG Polypharmacy Guidance
Patient information:	Links to patient information are contained in the relevant linked procedures and guidelines

Owning Committee/ Group	Medicines Management Operational Group Sub-Committee Chair: Associate Medical Director for Quality and Safety with Responsibility for Medicines

Executive Director:	Dr Phil Kloer	Job Title	Medical Director and Director of Clinical Strategy

Reviews and updates		
Version no:	Summary of Amendments:	Date Approved:
10	Three year full revision. New template and new version based on C&V Medicines Code 2017.	31/08/2019
11	Addition of JIC bag/box to section 7.12, amendment of 7.4.3, Deletion of 4.1.7 Updating links in 4.1.4 General reformatting and hyperlinking of Contents table	March 2019 Nov 2018 Sept 2019 Sept 2019
12	Addition of: Appendix Guidance for Medication use in instances of Section 136 Management of prescription charts during MDT multi-site reviews to Part 2.17.3 page 48 Update of Medicines Refrigerator Temperature Checking Procedure Appendix Addition of transcribing rights for Physician Assistants to Part2.2 Page 28 Definition of Physician Associate added to glossary Addition of appendix link for Guidance on medication use in instances of Section 136 at Part 2.31 page 52 and 5.8 page 91 Update of the Pharmacists Enabling & Therapeutic Switch Guideline to v3	Dec 2019
13	Updating of Part 5.3.2 Covert administration of Medicines Page 81 in line with District Judge Bellamy (AG v Agnor [2016] EWCOP37) and hyperlinking to the Covert medication for patients aged 16 and over: Record of best interests decision' form 268 Medicines Policy IP&C Control Variation	Jan 2020
14	Update of the Pharmacist Enabling and Therapeutic Substitution Guideline v4 Extension of the use of HCSW as second checker in Mental Health in exceptional circumstances. Update of the Student nurses/student midwives administration of medicines.	Feb 2021
15	Three year full revision. Major changes to 5.1.4 Administration requiring two registered healthcare professions, frequency of pharmacy stock CD checks, clarification of prescribing of unlicensed and 'off label' medicines by non-medical independent prescribers and variable doses in end-of-life care. . Renewal of links and addition of links to new documents	25/08/2021

Glossary of terms

Term	Definition
Adverse Drug Reaction (ADR)	An adverse drug reaction is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs under normal conditions of use, which is suspected to be related to the drug.

All Wales In-patient Medication Administration Record	For the purpose of this policy the prescription chart and All Wales In-patient Medication Administration Record are inter changeable and relate to the same document.
ART	Acute Response Team (which form part of Community Services)
Carer	A person, usually a relative, parent, spouse, partner, child or friend, who provides regular and substantial voluntary care, often in lieu of a paid care worker, to someone who is disabled, severely or chronically ill, frail or who has a mental health problem.
Controlled Drugs	A Controlled Drug is one that is listed in Schedules 1-5 of the Misuse of Drugs Regulations 2001(and subsequent amendments). NB The Health Board may take a decision to increase the regulation requirements locally for certain substances.
Dentist	A dentist holding registration with the General Dental Council
Dietician	A dietician holding registration for practice as a dietician with the Health Professions Council.
Doctor	A doctor holding both registration and licence to practice with the General Medical Council.
Drug related 'Patient Safety Incidents'	A patient safety incident is defined by the NPSA as: "an unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare."
Green Bags	Green plastic bags are used to contain patient's own medicines in order to transfer them between home (ambulance services) and hospital and between wards. This is to reduce the risk of the loss of patients' own medicines. Green bags can be obtained from the hospital pharmacy departments.
Healthcare Support Worker	A person working alongside, and undertaking care, as delegated by a registered nurse midwife or health professional.
Medicinal Products	For the purpose of this document, Medicinal Products are defined as any substances or articles administered to a human being for medicinal purpose. These include drugs, dressing and wound management products, and dietary supplements (enteral and parenteral), as defined in the current British National Formulary.
MHRA	Medicines and Health products Regulatory Agency
MTeD	Medicines Transcribing and e-Discharge system
Midwife	A professional on the midwives part of the Nursing and Midwifery

	Councils register
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency
NRLS	National Learning and Reporting System
Nurse	A nurse whose name is held on the Nursing and Midwifery Council register as a person who is capable of safe and effective practice as a nurse.
Operating Department Practitioner (ODP)	A person who is registered as an operating department practitioner under the Health Professions Order 2001.
PGD	Patient Group Direction Written instructions for the supply or administration of medicines to a group of patients who may not be individually identified before presentation for treatment.
Parenteral Administration	Administration of a medicine by means other than the alimentary canal e.g. IV, IM or s/c
Patients Own Medicine/Patients Own Drugs	Medicines brought into hospital by a patient having been dispensed for that patient outside of the hospital. It also includes over the counter (OTC) medication purchased by the patient and brought into the hospital.
Pharmacist	A pharmacist holding registration for practice with The General Pharmaceutical Council
Physician Associate	Medically trained, generalist healthcare professionals, who work alongside doctors and provide medical care as an integral part of the multidisciplinary team. Physician associates are dependent practitioners working with a dedicated medical supervisor, but who are able to work autonomously with appropriate support.
PSA	Patient Safety Alerts issued by Patient Safety Wales following analysis of reports of patient safety incidents submitted to the National Reporting and Learning System (NRLS).
PSD	Patient Specific Direction Written instructions from an independent prescriber (doctor, dentist or non-medical prescriber) to another healthcare professional, to supply and/or administer a medicine directly to a named patient, or to several named patients.
Prescription	Written instructions from a registered prescriber permitting a person so authorised to supply a prescription only medicine (POM) to the holder of the prescription.
Prescription chart	For the purpose of this policy the prescription chart and All Wales In-patient Medication Administration Record are inter changeable and relate to the same document.

Transcription	Copying of something written e.g. prescription, from one record to another.
Unlicensed Medicine	A medicine that does not have a UK product licence.

Keywords	Prescribing, Administration, Dispensing, Storage, Medicines, Drugs, Disposal, Medication, CD, CDs, Drug, Prescription, Medicines, Pharmacy

Acknowledgement:
This version of the HDUHB Medicines Policy is based on the Cardiff and Vale UHB The Medicines Code November 2017 version 1 whose help is gratefully acknowledged.

Any questions or enquiries relating to the Medicines Policy should be emailed to Sue Beach Lead Clinical Development Pharmacist (sue.beach@wales.nhs.uk) or Mandy James, Senior Nurse Medicines Management (mandy.james@wales.nhs.uk) under the subject heading Medicines Policy

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1. Introduction

Hywel Dda University Health Board (HDUHB) is committed to the safe and secure handling of medicines to protect its patients, staff and visitors, and its financial resources.

This Medicines Policy updates and replaces previous Medicines Policies and Procedures used in HDUHB and predecessor organisations. This policy provides information on the prescribing, administration, ordering, transport, storage, control and disposal of medicinal products (including Controlled Drugs) within the Acute, Mental Health & Learning Disabilities and Community Services of Hywel Dda University Health Board (HDUHB) so that these processes comply with current legislation, professional guidance and local policies, guidelines and procedures.

2. Policy Statement

The purpose of the Medicines Policy is to set out a clinical and corporate governance framework to promote safe and secure systems for the controlling and handling of medicinal products in the hospitals and clinics operated by HDUHB as part of an overall medicines management process and to comply with current legislation and guidance from the UK Government and the Welsh Government..

Guidance on safe and appropriate prescribing has been considered and disseminated through the Medicines Policy by the HDUHB Medicines Management Operational Group (MMOG). In general, medicines need to satisfy tests of clinical and cost effectiveness and use should be justifiable on grounds of safety, given the alternative therapies available and the circumstances of the patient.

In addition to this Medicines Policy, healthcare professionals must abide with the current version of their relevant professional bodies Policies, Standards and Codes of Practice.

If extreme circumstances arise such that this Policy cannot be applied then the prime consideration will be the safe and effective treatment of any patient concerned. However, if any deviation from the Policy occurs, those staff involved must document all alternative measures taken in the appropriate records and inform senior professional leads.

3. Scope

This Medicines Policy, with the underpinning principles of legal, quality and safe practice, applies to all doctors, nurses, pharmacists, other health care professionals, staff and volunteers across HDdUHB involved in the ordering, supply, storage, prescribing, administration and disposal of medicines. The medicines include Prescription Only Medicines (POMs), Pharmacy Medicines (P), General Sales List Medicines (GSL) and Controlled Drugs (CDs). The Policy also includes complementary medicines, pharmaceuticals (non-therapeutic items) and certain medical devices traditionally supplied through hospital pharmacy departments. It applies to all patients under the care of the Health Board within the acute and community care settings.

4. Aim

The aim of this policy is to promote safe and secure systems for prescribing, administering, ordering, transport, control and disposal of medicinal products, including Controlled Drugs, in hospitals and clinics operated by HDUHB by setting out a framework as part of an overall medicines' management process.

5. Objectives

The objectives of the policy is for all HB employees

- prescribing
- administering
- ordering
- transporting
- storing
- controlling and disposing of medicines (including Controlled Drugs)

to act in compliance with legislation, professional guidance and HB requirements and procedures.

6. Classification of medicines

Medicines are considered as two main sub-groups, Controlled Drugs and Medicines.

a) Controlled Drugs

Controlled Drugs are those drugs classified under the 'Misuse of Drugs Act 1971', and its associated regulations.

b) Medicines

Medicines will be taken to be all substances defined under the Medicines Act 1968 and Human Medicines Regulations 2012.as being medicinal products. These include those restricted to supply on prescription (POM), those that can only be sold from a Pharmacy (P), and those that can be sold at any establishment, General Sales List medicines (GSL). Unlicensed medicines do not have a United Kingdom Product Licence.

c) Complementary medicines

The principles adopted for the use of medicines will also be followed for complementary medicines.

d) Pharmaceuticals/Medicinal Products

The term "pharmaceuticals" or "medicinal products" will be used to describe those non-therapeutic items covered by the policy (e.g. disinfecting and sterilizing agents). It will also include certain devices carrying a CE mark traditionally supplied by pharmacy.

e) Black triangle medicines are newly introduced medicines, subject to intensive monitoring for potential side effects by the Medicines and Healthcare Products Regulatory Agency (MHRA) (identified by ▼ in the British National Formulary (BNF).

f) Medicines used outside the product licence 'off label' are medicines used in a manner (e.g. different dose, indication, age group, administration route, indication) which is different to those defined in the Summary of Product Characteristics (SPC).

g) Specials are unlicensed medicines that do not have a product licence and are usually commissioned from a licensed manufacturing unit at the request of a prescriber, or by a pharmacist acting on behalf of that prescriber.

h) Medicines which do not have a UK product licence (**unlicensed medicines**) and are usually obtained on a named patient basis.

7. Governance of Medicines Management Guidelines and Procedures

The detailed Medicines Management Guidelines and Procedures in Part 10 are approved and reviewed by the Medicines Management Operational Group (MMOG) to ensure that they are compliant with current legislation and regulations, professional guidance and patient safety advice. The MMOG will also audit implementation and adherence to the guidelines and procedures and advise on action that needs to be taken to achieve compliance.

If IP&C controls or a civic emergency require that some elements of the Medicines Policy and associated guidelines or procedures cannot be followed, then temporary alternative guidelines or procedures (incorporating national and professional advice) should be put in place, to meet the overall aims and principles of the policy (patient safety and accountability) as far as possible, documented and approved by the appropriate group under HB delegation. MMOG will be informed and will then review and audit the actions taken in due course. [MMSC May 2020]

8. Responsibilities

8.1 Chief Executive and Board

The Chief Executive has overall responsibility for medicines management in HDUHB. The provision of resources to ensure the safe prescribing, administration, ordering, storage, transport, control and disposal of medicines is the responsibility of the Chief Executive and Board. It is their responsibility to ensure that guidance is consistent with the legal requirements, NHS, WG and local Health Board guidance.

The leadership of the organisation should put mechanisms in place to monitor adherence to this policy.

Where there is non-compliance the Board is responsible for ensuring that there are appropriate actions in place to mitigate any risks identified.

8.2 Medical Director

The above responsibility is delegated to the Health Board's Medical Director,

supported by the HDUHB Medicines Management Operational Group and is jointly responsible for ensuring the implementation and review of this policy in consultation with other Healthcare professionals.

8.3 Clinical Director of Pharmacy and Medicines Management.

The Clinical Director of Pharmacy and Medicines Management is responsible for organising, monitoring and reporting on medicines' management, its systems and procedures and is jointly responsible for ensuring the implementation and review of this policy in consultation with other Healthcare professionals.

The Clinical Director of Pharmacy and Medicines Management is responsible for ensuring that there are sufficient systems in place for the following:

- Providing a safe, effective, efficient and secure system for medicine stocks held within the Health Board pharmacies.
- Providing a safe, effective, efficient and secure system for medicine distribution.
- Providing a system for monitoring ward medicine usage and advising on appropriate stock range and stock holding levels.
- Providing advice on medicines and controlled drug security.
- Providing advice on appropriate environmental storage conditions.
- Providing advice on safe and proper means of disposal of unused/unwanted medicines.
- Providing advice on safe and effective systems and arrangements for medicine administration. This includes commenting and advising on medicine administration errors and near misses reported via the DATIX Incident Reporting system.
- Providing advice on transport of medicines and other pharmaceuticals.
- Providing a system, when the pharmacy is closed, of access to emergency medicine stocks and the availability of a pharmacist for emergency duties.
- Where a pharmacy led stock control service is provided there is a shared responsibility between the ward/unit ward manager/clinical lead and the clinical pharmacist
- Providing advice on clinical pharmacy services and ensuring that there is consistency of approach such that prescriptions are monitored and

appropriate action taken to ensure effective use of resources.

- Ensuring that there are adequate mechanisms in place to monitor and report on the use on medicines throughout the Health Board and to devise strategies to promote cost effective prescribing.
- Ensuring that there are systems in place for the use of medicines throughout the Health Board.
- Ensuring medicines are held to meet the need of hospitalised patients and immediate response to civilian emergency.

8.4 Director of Nursing, Quality and Patient Experience

The Executive Nurse Director is responsible for ensuring that systems are in place within wards and departmental clinics to facilitate the processes within the Medicines Policy and that the information and guidance within this Medicines Policy is available to staff and adhered to for

- The ordering of medicines and pharmaceuticals.
- The appropriate storage (physical and environmental conditions of medicines and pharmaceuticals).
- The administration of medicines including patients' own medicines other than those administered by a doctor
- The recording of administration of medicines.
- The security of medicines and prescription forms.
- The supply of medicines to patients in accordance with Patient Group Directions (PGDs)/ Patient Specific Directions (PSDs).
- The reporting of medicines related incidents and errors via the DATIX Incident Reporting System.
- The safe and proper disposal of unused/unwanted medicines and pharmaceuticals.
- The retention of documents relating to the ordering, storage and administration and supply of medicines.
- The induction of new staff with respect to informing them of the Health Board's Medicines Policy
- The education and training required to enable nurses to comply with this

Medicines Policy and for ensuring that a copy is readily available to staff. and is jointly responsible for ensuring the implementation and review of this policy in consultation with other Healthcare professionals.

8.5 Director of Therapies & Health Science

Is jointly responsible for ensuring the implementation and review of this policy in consultation with other Healthcare Professionals.

8.6 Senior Management Leads

The Heads of Nursing, Heads of Community Services, Site Lead Pharmacists, Hospital Directors and Professional Heads of Department are responsible for the dissemination of this Policy, the education and training required, monitoring the implementation of and auditing adherence to this policy.

8.7 Responsibility of the ward manager/clinical lead.

The ward manager/clinical lead will have joint responsibility with the site pharmacy for the ordering system where there is a pharmacy provided led stock control service.

The ward sister/charge nurse/clinical lead are responsible for the dissemination of this Policy, the education and training required, monitoring the implementation of and auditing adherence to this policy and for the secure storage of medicines in their area.

8.8 Responsibility of individual health care professionals involved in the medicines management process

Each individual health care professional is responsible for:

- Reading and understanding this Medicines Policy.
- Complying with this Medicines Policy and their own regulatory body's guidance, standards and policies.
- Referring to other Health Board policies, guidelines and procedures where appropriate.
- Ensuring they have the required qualifications, competence and/or authority to complete the tasks.
- Maintaining the security of medicines within their practice area.
- Reporting any incidents where this policy is not adhered to.

8.9 Responsibility of prescribers

Medical and non-medical prescribers will practice in accordance with local procedures and guidance and will comply with their respective professional Policy of Practice.

8.10 HDUHB Medicines Management Operational group and Clinical Written Control Document Review Group

The Medicines Management Operational Group (MMOG) and the Clinical Written Control Document Review Group (CWCDRG) are responsible for approving this policy and any subsequent amendments.

9. Resources

(References are placed in the texts with links where available)

- Summary of Product Characteristics (SPC) for each medicine is produced by the manufacturer and accessed via the electronic Medicines Compendium
- The Injectable Medicines Guide is a database accessible via the Access to IT Systems/Databases page of the Hywel Dda UHB Intranet
- British National Formulary (BNF) and BNF for Children
- Royal Marsden Manual of Clinical Nursing Procedures

- Specialist information on medicines can be obtained from the Hywel Dda Medicines Information Centre 01437 773641
- General Medical Council
- Royal Pharmaceutical Society of Great Britain
- Royal College of Nursing
- General Pharmaceutical Council
- Nursing & Midwifery Council
- Health & Care Professions Council
- Medicines and Healthcare products Regulation Agency
- National Institute for Health and Care Excellence
- All Wales Medicines Strategy Group
- Specialist Pharmacy Service
- Welsh Health Circulars

- The Human Medicines Regulations 2012 and subsequent amendments
- Misuse of Drugs Act 1971 and Regulations
- The Medicines Act 1968 https://www.legislation.gov.uk/ukpga/1968/67 (mostly repealed and replaced by The Human Medicines Regulations 2012)
- Medicines and Healthcare products Regulation Agency. Off-label or unlicensed use of medicines: prescribers' responsibilities.
- SPS Retention of Pharmacy Records https://www.sps.nhs.uk/articles/retention-of-pharmacy-records/
- NHS Choices. Medicines Information – Licensing www.nhs.uk/Conditions/Medicinesinfo/Pages/Safetyissues.aspx accessed 20/3/2017
- NHS Wales Shared Services Partnership Welsh Risk Pool Services Technical note 14: Prescribing of unlicensed drugs or using drugs for unlicensed indicators. Reviewed 8/11/2004
- General Medical Council. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices
- WG Chief Medical Officer letters http://gov.wales/topics/health/cmo/publications/cmo/?lang=en
- WG Chief Pharmaceutical Officer http://gov.wales/topics/health/cmo/professionals/pharmaceutical/?lang=en
- WG Chief Nursing Officer
- http://gov.wales/topics/health/cmo/professionals/officechiefnursing/?lang=en
- NHS Patient Safety (links to NPSA) http://www.nrls.npsa.nhs.uk/
- Patient Safety Wales https://du.nhs.wales/patient-safety-wales/
- Trusted to Care Andrews/Butler Report http://gov.wales/docs/dhss/publications/140512trustedtocareen.pdf

- All Wales Medicines Strategy Group, Llandough (2015) 'All Wales Guidance for Health Boards/Trusts and Social Care Providers in Respect of Medicines and Care Support Workers https://awmsg.nhs.wales/files/guidelines-and-pils/all-wales-guidance-for-health-boards-trusts-and-social-care-in-respect-of-medicines-and-care-support-workers-pdf/

10. Detailed Medicines Management Guideline and Procedures

Part 1: Medicines Audit, Suspected Fraud and Theft

1.1 Monitoring and audit

As part of the responsibility for delivery of the medicines' management process, the Clinical Director of Pharmacy and Medicines Management will ensure that the following explicit, written, quality standards are prepared and regularly audited as part of the HDUHB audit cycle:

- The process of prescribing of medicines in HDUHB hospitals
- The appropriateness of medicines prescribed for individual patients including license status and adherence to agreed therapeutic guidelines.
- The preparation of parenteral medicines. This will include all HDUHB hospital clinical areas as well as the main pharmacy department.
- The clinical pharmacy review of prescriptions and dispensing of medicines.
- The administration of medicines to patients.
- The supply of medicines to take home and the counselling of patients about those medicines.
- The reporting of medication errors.
- Medicines administered for clinical research and drug trials.
- The safe storage of medicines [PSN055]

1.2 Risk management and patient safety initiatives

The Clinical Director of Pharmacy and Medicines Management and/or the Medicines Safety Officer will lead on safe medicines practice within the Health Board. This will be via Medicines Event Review Group (MERG), a multi professional sub group of the HB's Medicines Management Operational Group (MMOG). MERG will maintain clear and identified links with the HDUHB Assurance, Safety and Improvement Team.

The Clinical Director of Pharmacy and Medicines Management, MERG and Pharmacy Management Team will actively participate in patient safety initiatives.

The risks inherent in medicines management and the effectiveness of risk control measures must be monitored and reviewed on a continual basis.

Senior Management, both within Pharmacy and HDUHB, must be informed of any significant risks and risk control measures.

Medication incidents should be regularly monitored and issues of significance reported to the HDUHB Quality, Safety & Experience Assurance Committee via MERG and MMOG.

1.3 Anti-theft and fraud culture

HDUHB has a zero-tolerance anti-fraud and theft culture and is committed to the principle that the NHS resource of medicines is always used for the patient in need of that prescribed medicine. HDUHB will seek to reduce medicine losses from theft and fraud to an absolute minimum by sanctions against those determined to steal or defraud the NHS. Possible sanctions may include criminal, civil or disciplinary proceedings, and HDUHB will seek to recover the cost of stolen or defrauded medicines. Incidents involving members of staff, patients or visitors that are suspected to have stolen HDUHB medicines or prescription forms or pads, must be reported through a Datix entry completed by the senior nurse or senior pharmacist on duty. The Security and Case Manager must be notified.

The lead nurse and/or senior clinical pharmacist may conduct initial enquiries and then, should matters proceed to an investigation, the local security manager will then take responsibility for any subsequent investigation of alleged theft. The security manager will liaise with Dyfed Powys Police and the human resources manager as appropriate.

1.4. Suspected fraud in respect of medicines

Some examples of NHS medicine and prescription frauds are as follows:

- Falsified medicine stock records e.g. false entries in a Controlled Drugs register
- Falsified orders for medicines
- Prescription fraud e.g. forged signatures and/or false representation by the patient for medicine not prescribed by an authorised NHS prescriber
- Self-prescribing
- Prescribing for family members or friends
- Prescribing for those who are not entitled to be prescribed NHS medicines e.g.

foreign nationals who are not entitled to NHS treatment

This list is not exhaustive and those determined to commit fraud may develop new and sophisticated methods to avoid detection.

If an alleged theft involves suspected fraud, the Site Lead Pharmacist and/or the Security Manager will refer the incident to the Local Counter Fraud Specialist of HDUHB.

Any referral to the Counter Fraud Department will be investigated and where necessary a Criminal investigation will be undertaken in line the Health Boards Counter Fraud, Bribery and Corruption Policy.

Part 2 Prescribing Medicines

2.1 Prescribing medicines

All prescribing must be on HDUHB approved prescription stationery before supply or administration to patient may occur. This includes self-administration or administration by patients, relatives or carers. The only exemptions, in strictly defined situations, are via:

- a Patient Group Direction
- a HDUHB locally agreed protocol. [MMG October 2014],
- a verbal order,
- as part of the professional role of specified healthcare professionals (for example, midwife exemptions) or
- the use of specified parenteral medicines for the purpose of saving life in an emergency a prescription is not necessary to authorise administration.

In all situations, appropriate records of the authorisation to administer or supply medicines must be made. Details of the records to made are defined in the PGD or local protocol; in the other situations in the patient's clinical record.

For the purpose of this policy the prescription chart and All Wales In-patient Medication Administration Record are interchangeable and relate to the same document. All documents used for prescribing, administering and monitoring medicines (for example, insulin charts, Diabetic Ketoacidosis charts, supplementary prescriptions for epidural levobupivacaine, Termination of Pregnancy prescription labels) must be approved by MMOG before use. [MMG 2015]

Each prescriber has a duty of care when issuing prescriptions to patients, to ensure that they are issued appropriately to patients under their care.

When prescribing for patients the principles of prudent health care should be followed. Advice on avoiding polypharmacy can be found at AWMSG Polypharmacy: Guidance for prescribing: https://awmsg.nhs.wales/medicines-appraisals-and-guidance/medicines-optimisation/prescribing-guidance/polypharmacy-guidance-for-prescribing/

Prescription forms and pads are controlled stationery and therefore must be stored in accordance to the HDUHB guidance.

Each prescriber is responsible for the safe storage of any blank prescription forms and pads issued to them. Should blank forms or pads be lost, they must inform their line manger must be immediately informed and an investigation instigated.

For outpatient prescriptions for Sexual Health and Genitourinary Medicine it is acceptable for the unique patient number, first name and Date of Birth to be used in place of the full name, address and hospital number.[MMG Jan 2015]

The prescribing of Controlled Drugs within Schedules 1, 2, 3, 4 and 5 of the Misuse of Drugs Act 1971 must be in accordance with current legislation as set out in the British National Formulary (BNF) in line with the Misuse of Drugs Regulations 2001 (and subsequent amendments) http://www.legislation.gov.uk/uksi/2001/3998/contents/made. The Health Board may take a decision to increase the regulation requirements locally for certain substances. For the current local requirements see: http://howis.wales.nhs.uk/sitesplus/documents/862/Local%20Requirements%20for%20the%20Storage%20Admin%20%26%20Prescription%20for%20Controlled%20Drugs%20in%20HDUHB1.pdf

2.2 Persons authorised to prescribe medicines

Only those employed by HDUHB or working under a service level agreement (or contractual arrangement) and legally authorised to prescribe (doctor, dentist, registered non-medical prescribers [NMPs]), may prescribe medicinal products. Non-medical prescribers must have gained sign off from their appropriate line manager. NMP's must also be registered on the HDUHB NMP database before prescribing within their area of competence. Provisionally registered doctors (FY1s) may only prescribe in connection with their employment with HDUHB and cannot prescribe for out-patients.

Dentists are required by their registration to restrict their prescribing to their areas of competence.

Medical/dental students, doctors undertaking clinical attachments, nurses and other non-medical staff are not allowed to prescribe or to copy prescriptions for signature by medical/dental staff other than in a defined clinical situation/ environment which has been

previously approved through the HDdUHB Medicines Management Operational Group (MMOG).

Medical Students are permitted to rewrite prescriptions and write prescriptions as part of their final year Student Assistantships. All Prescriptions charts and prescriptions must be checked and countersigned immediately signed by a supervising qualified medical prescriber (F1 and above). Clinical responsibility rests with the prescriber who signed it. [MMG Jan 2014]

Physician Associates and Physician Associate Students are permitted to transcribe/ rewrite prescriptions and write prescriptions. All Prescriptions charts and prescriptions must be checked and signed immediately by a supervising qualified medical prescriber (F1 and above). Clinical responsibility rests with the prescriber who signed it. This excludes cytotoxics or controlled drugs. [MMOG Nov 2019]

Pharmacists and Medicines Management accredited Pharmacy Technicians are permitted to transcribe/write out TTHs and Outpatient prescriptions using hospital discharge prescriptions or WP10HP and WP10HIP for signature by medical or independent prescribers. Accredited Checking Pharmacy Technicians are permitted to transcribe/write out Outpatient prescriptions for the purpose of providing a continuous supply of repatriated medicines to a patient. Prescriptions transcribed by Pharmacy Technicians will be clinically checked by a Pharmacist as per pharmacy SOPs prior to the prescriber signing the prescription. [MMG Mar 2015 and Feb 2018]

2.3 Prescription Exemptions

2.3.1 Specified Healthcare Professionals

Midwives must refer to their own additional guidance which can be found on the NMC website (Midwives exemptions frequently asked questions) which sets out exemptions and specific regulations relating to their own profession. Other Healthcare Professionals (e.g. podiatrists, paramedics) must refer to their own professional bodies for a list of current medicines that fall into this prescription exemption.

The full list of all exemptions can be found at:
https://www.gov.uk/government/publications/rules-for-the-sale-supply-and-administration-of-medicines/rules-for-the-sale-supply-and-administration-of-medicines-for-specific-healthcare-

professionals

2.3.2 Administration for the purpose of saving life in an emergency

Regulation 238 of the Human Medicines Regulations 2012 allows for certain prescription only medicines to be administered by anyone for the purpose of saving life in an emergency without a prescription. These include naloxone, glucagon and hydrocortisone. Adrenaline 1 in 1000 (1mg/mL) by intramuscular injection can be administered for the emergency treatment of anaphylaxis. Current clinical guidelines should be followed. The full list of exemptions can be found at: http://www.legislation.gov.uk/uksi/2012/1916/schedule/19/made

2.3.3 Patient Group Directions (PGDs)

Each department/service is responsible for gaining approval of the HDUHB Medicines Management Operational Group (via the PGD Sub-Group) for their Patient Group Directions. PGDs must be prepared in accordance with WHC/CMO(2000)1 using a HDUHB template for PGDs. Advice in the preparation of PGDs can be obtained from the PGD Sub-Group. When the review date arrives the relevant PGD coordinator will be responsible for reviewing and updating the PGD.

Approved HDUHB PGDs can be accessed on the HDUHB intranet at:
http://howis.wales.nhs.uk/sitesplus/862/page/58130

The process for development and approval of PGDs can be accessed at:

http://howis.wales.nhs.uk/sitesplus/documents/862/268-AppR-PGDProcess1.pdf

2.4 Prescribing guidance

2.4.1 Formulary and non-formulary medicines

All newly initiated medicines for both in and out-patients should be prescribed from the approved formulary list.

Patients admitted on most non-formulary medicines will be continued on these medicines but, in certain situations, pharmacy will agree substitution with an alternative formulary item in accordance with a local procedure approved by the HDUHB Medicines Management Operational Group.

If a non-formulary medicine is needed for treatment while an in-patient the patient's own medicine supply should be used as a first option. If/when a further supply is needed a medicines review should be undertaken and medicines swapped to formulary items where appropriate.
Further details on the Managed Entry of New Drugs (MEND) onto the HDUHB Formulary can be found at: http://howis.wales.nhs.uk/sitesplus/documents/862/268-AppQ-ManagedEntryofNewMedicinalProductsFormularyProcedure1.pdf

2.4.2 Unlicensed medicines
See Medicines Policy: Part 10.

2.4.3 Off License / Off Label medicines
See Medicines Policy: Part 10

2.4.4 Anti-cancer medicines
The prescribing of cancer medication is limited to authorised prescribers in HDUHB. For further information see: All Wales Competencies for Review, Authorisation and Prescribing of Systemic Anti-Cancer Therapy (SACT) For Adult Patients

2.4.5 Controlled Drugs
See Medicines Policy Part 7

2.4.6 Intravenous (IV) and parenteral medication
See Medicines Policy Part 6

2.4.7 Dietetic products
Whilst dietetic products are not medicines, dietitians can initiate formulary dietetic products by writing them on the patient's in-patient medicines administration prescription chart or a HDUHB approved nutrition chart. They should endorse any item not to be continued at discharge as 'For in-patient use only'. This avoids inadvertent long term continuation.
The Primary and Secondary Care - Oral Nutritional Supplements Formulary can be found at:

http://howis.wales.nhs.uk/sitesplus/documents/862/HDUHB%20Oral%20Nutritional%20Supplement%20Formulary%20updated%20September%202020.pdf

2.4. 8 Wound Care Management Products

The prescribing/supply of wound cleansing and management products should be guided by the HDUHB Tissue Viability and Wound Management Guidelines which can be accessed via the HDUHB Formulary (http://hywelddahb.inform.wales.nhs.uk/)

2.4.9 Stoma Products

The prescribing of stoma products should be guided by the HDUHB Stoma Formulary Guidelines.

http://howis.wales.nhs.uk/sitesplus/documents/862/HDHBStomaguidanceFormularyFinal%20v2%20Sept%202014.pdf

2.4.10 Oxygen

Oxygen should be prescribed in line with the British Thoracic Society guidelines. Please refer to the BTS Guideline for oxygen use in healthcare and emergency settings (2017 Update 2019) for full details: https://www.brit-thoracic.org.uk/quality-improvement/guidelines/emergency-oxygen/

Prescription of oxygen in the Community should comply with: BTS Guidelines for Home Oxygen Use in Adults (2015): https://www.brit-thoracic.org.uk/quality-improvement/guidelines/home-oxygen/

2.4.11 Prescribing Controlled Drugs for treating addiction or dependence

No doctor may administer or authorise the supply of cocaine, diamorphine or dipipanone to 'registered addicts' (dependent patients), except for the purpose of treating organic disease or injury, unless licensed to do so by the Secretary of State.

If a newly admitted patient states that they are an addict on medication for their addiction, then the medication and dosage must be confirmed with a third party. The prescriber is responsible for obtaining this confirmation.

The third party must be any of the following:

- patient's G.P.
- patient's community pharmacist or,
- a member of the Community Drug & Alcohol Team.

The ward nurse/midwife or hospital pharmacist must inform whoever supplies the patient's

medication in the community (community pharmacy or Community Drug & Alcohol Team) of the patient's admission. The hospital team should liaise with the supplying community pharmacy or Community Drug & Alcohol Team on discharge to communicate details of dosage and quantity supplied and when the next supply is due.

2. 4.12 Complementary Therapies

Healthcare Professionals must enquire whether patients are using complementary therapies when taking a medication history. If a patient or client desires to continue to use complementary therapies, the practitioner must be mindful that potential difficulties might arise, for example, the complementary medicines may:

- cause the presenting symptoms;
- mask symptoms, or
- Interact with prescribed medicines.

The local hospital pharmacy or HDUHB Medicines Information Centre (01437 773641) should be contacted for further information and advice.

In such situations, the practitioner, acting in the interests of the patient or client, must ensure that the relevant registered medical practitioner is aware of the patient's full medication history and their desire to continue to use complementary therapies. Within the hospital setting, such agents must be recorded as a substance that the patient is self-administrating on the in-patient prescription chart in the normal way as other conventional medicinal products. Healthcare Professionals must understand the use of the complementary medicines and any potential adverse reactions or drug interactions before administering it to the patient. Complementary therapies are usually non-formulary and not stocked by the hospital pharmacies. The practitioner must always remain mindful of the need to respect the patient's rights and beliefs.

2.5 Prescription writing

2.5.1 Handwritten prescriptions

Each prescription must be legal, legible, unambiguous and written or printed in **black** indelible ink that can be photocopied. Upper or lower case may be consistently used. It is good practice for prescribers to add their appropriate professional registration number.

A simple test for legibility is for another person, who is unfamiliar with the prescriber's handwriting, to read it without difficulty. Amendments to prescriptions must be made in indelible ink, signed and dated with the professional registration number.

2.5.2 Computer generated prescriptions

The planning, development and implementation of any electronic prescribing system must be approved by the HDUHB Medicines Management Operational Group.

Electronic prescribing will be limited to prescribers trained in use of the particular system. Prescribers must adhere to the HDUHB Information Technology (IT) policies. For further information on mTED see 2.18.

2.6 Prescribing competence

All authorised prescribers must ensure they have appropriate knowledge and experience to prescribe competently in their area of practice. Knowledge of the "Guidance on Prescribing" sections in the current British National Formulary is essential. Completion of the e –prescribing training package for the All Wales In-Patient Medication Administration Record is mandatory. (See prescribing e-learning package on Learning@nhswales esr).

2.7 Prescription documentation

Permanent changes to prescribed medicines must be noted within the patient record along with the indication for treatment or reason for stopping treatment (e.g. ineffective / side effects).

2.7.1 In-patient medication administration record (prescription chart)

The All Wales In-Patient Medication Administration Record is to be completed in accordance with the instructions for this task. (See prescribing e-learning package on Learning@nhswales esr). There are specific All Wales In-Patient Medication Administration Records for Paediatrics and Mental Health currently in use in HDUHB.

The following patient details must be entered:

- Name
- Address

- Hospital number and NHS number when practicable
- Date of birth
- Name of consultant
- Weight (as soon as practical)
- Medicine sensitivity and allergies

A pre-printed addressograph label should be used whenever possible and attached to the prescription chart or form before other details are added.

If more than one chart is in use “1 of 2” etc. must be written.

The clerking doctor must complete the drug/allergen section on admission, even if no allergies are known (write ‘No Known Allergies’); this must be signed and dated. An allergy record in medical clerking notes is not sufficient. The medicine(s) in question must be specified and the type of allergy noted or the ‘none known’ box signed and dated. Medication must not be administered until this section is completed.

A doctor, nurse, pharmacist or a pharmacy medicines management technician can complete the allergy section at a later stage if an allergy is subsequently discovered or the detail is initially incomplete.

The weight of the patient must be entered for all paediatric patients and for patients where medicine dose adjustments by weight will be made e.g. paracetamol for audlt patients weighing less than 50kg [MMOG May 2021]. The height of the patient will also be recorded where it is required to calculate medicine doses (e.g. aciclovir or chemotherapy).

If an additional specialist chart is in use e.g. warfarin, insulin or other options, as shown on the front of the All Wales In-Patient Medication Administration Record, it must be indicated on the main chart.
The following medication details must be entered:

- Route of administration

- The recommended International Non-Proprietary Name (rINN) (i.e. the approved / generic name) of the medicine should be written legibly using either upper or lower case.
- Proprietary names (i.e. brand names) may only be used for
    - multi-ingredient preparations with no approved name,
    - products whose proprietary name defines a specific formulation (e.g. slow release theophylline preparations, certain creams and ointments) or
    - safety reasons to avoid mis-selection of product (e.g. OxyNorm(R) and OxyContin(R)) or bioavailability (e.g. Neoral(P) and Sandimmun(R))
- The dose, expressed in metric terms. Milligrams, micrograms, nanograms must be written in full to avoid confusion. For combination products, the administration dose expressed as the number of tablets (e.g. co-amilofruse 5/40, dose 1 tab in the morning).

Medicine names must not be abbreviated e.g. [MTX, MMT, ISMN, GTN, $FeSO_4$, NaCl are not acceptable].

The date on which the treatment is to commence must be entered on the prescription chart. If rewritten, the *original* start date, not the rewrite date is used.

2.7.2 Variable routes

Medicines for administration by variable routes in certain circumstance can be prescribed once on the prescription chart indicating the routes e.g. PO/IV but only where the doses by each route are the same e.g. metoclopramide. When the doses by each route are different e.g. prochlorperazine each route required must be prescribed individually**.**

2.7.3 Variable doses

End-of-Life Care: The use of dose ranges and verbal orders confirming the administration of an increased dose for continuous subcutaneous infusions and syringe drivers should comply with the guidance set out in Section 13 of the HDUHB 161 Palliative Care: Opioids for Pain Guidelines: Prescribing doses as a range for example 10-20mg of morphine sulphate liquid 10mg/5ml PRN up to hourly is discouraged. The dose to be administered is a clinical decision that should be the prescribers' responsibility. If the same medication is indicated at different doses for two indications e.g. morphine sulphate liquid 10mg/5ml 2.5mg PRN hourly for breakthrough pain but 5mg PRN for incident pain such as prior to a procedure, the two doses

should be prescribed separately and the indication for each marked clearly on the drug chart. Dose ranges for syringe drivers are not recommended. If there is thought to be an essential clinical need for a range to be prescribed, this needs to be documented clearly in the patients' medical notes along with any instructions for the person setting up the driver to be aware of documented on the relevant section of the syringe driver chart.
For clinical situations where there is doubt about this topic please seek further specialist advice. This issue was highlighted by the Gosport Report which showed many examples of where this practice had led to adverse outcomes. [MMOG July 2021]

Critical Care: The use of dose ranges to permit the titration of medicine dose against clinical response should comply with predetermined parameters that are prescribed on the medication chart.

2. 7.4 Approved abbreviations for routes of administration

IM	intramuscular
INH	inhalation
IV	intravenous
NEB	nebulisation
PO/O	oral
PR	rectal
PV	vaginal
SC	subcutaneous
S/L or SL	sublingual
Top	topical

Intrathecal must always be written in full

Intracavernous must always be written in full

Other routes of administration should be written in full. No Latin abbreviations are permitted on inpatient charts

2.7.5 Further guidance

Further guidance on prescribing, how doses should be expressed, permitted terminology and

the use of multiple charts, can be found within the British National Formulary section on prescribing http://howis.wales.nhs.uk/sitesplus/878/page/58137. .

2.7.6 Dose frequency

For regular medication the prescriber should preferentially use the pre-set medicine round times to indicate administration time, The 24-hour clock must be used when specific timings are needed e.g. for antibiotics to space doses evenly through 24 hours, neonates or for frequent dosage regimens used in Parkinson's Disease.

2.7.7 When required medicines (pro re nata/ p.r.n.)

For "when/as required" medicines. Full details of the directions for administration of a when/as required medicine must be recorded. The time or frequency of administration and maximum dose in 24 hours must be stated (for example: Cyclizine 50mg p.r.n. is not acceptable; this should be written "cyclizine 50mg every 6 – 8 hours p.r.n., MAX 150mg in 24hours. Temazepam 10mg p.r.n. is not acceptable; "Temazepam 10mg p.r.n. at night for sleeping" is acceptable).

2.7.8 Discontinued medicines

A diagonal line must be drawn through the prescription so that cancellation is obvious, but the prescription is not obliterated. This should be signed and dated by the responsible prescriber. In some cases a large 'Z' or a can be used as an alternative to a diagonal line and this should be signed and dated.

2.7.9 Care pathways and the use of pre-printed prescriptions and/or pre-printed labels

Certain patient pathways include pre-printed prescription details and/or preprinted labels that are used where there is a need for clarity when prescribing complex regimens, or to provide a safe and complete package of care. Examples are insulin regimens where there is dosage titration dependent upon blood glucose results, in post-operative pain relief for parenteral or epidural opioid analgesia and IV gentamicin in newborn babies. All pre-printed prescriptions or labels must be approved by MMOG prior to use.

The prescriber is responsible for placing the prescription label on the patient's chart and must sign and date the prescription in order to authorise its use. The signed chart becomes a

Patient Specific Direction (PSD). Medication must not be administered until there is an authorised prescriber's signature present.

2.8 Medicines Reconciliation

To assist in the medicines reconciliation process it is requested that all patients are admitted from primary care with sufficient information about their medication and medical history. This information is referred to as the minimum data set.

It is understood that patients presenting directly to the Emergency Unit may not bring this information with them, but it should be obtained from their relative, carer or GP's surgery at the earliest opportunity.

The doctor's responsibilities on admission:

On admission to hospital it is the admitting doctor's responsibility to:

- Take a medication history from the patient, and/or carer to the best of their ability and using the information sources available to them at that time, including the ambulance handover sheet.
- Document this on the medicines assessment form and include this with the admission documentation in the patient's medical notes.

Use the medicines assessment form to document any intentional changes to regular medication made on admission and during the patient's hospital stay i.e. stopped (with reason), withheld (with intended review date) or amended (with reason).

- Annotate the medicines assessment form indicating the sources used to find the medication history, the name, signature and bleep number of the admitting doctor.
- Write an inpatient medicines administration record prescription chart for the patient's hospital stay.
- For antimicrobial prescriptions, the antimicrobial review date must be added to encourage good antimicrobial stewardship.
- Respond promptly (within 24 hours) to any amendments or discrepancies highlighted by the pharmacy team on the medicines assessment form; update the patient's prescription chart as necessary.

It is understood that the quality and accuracy of the initial medication history may be limited, particularly outside of normal working hours, owing to lack of access to key information sources

e.g. GP records. Every effort should be made to obtain this information e.g. using the patient's individual health record (IHR). Any inaccuracies and incomplete information must be rectified as soon as possible.

The pharmacy team's responsibilities on admission:

On admission to hospital it is the pharmacy team's responsibility to:

- Check the medication history documented on the medicines assessment form by the doctor using at least one reliable source (preferably two). This can include sources previously accessed by the doctor.
- Reconcile the patient's medications by comparing the medication prescribed on the prescription chart to the medication history, ensuring that any omissions or changes are intentional by referring to the medicines assessment form.
- If changes and omissions have been made without reference to them on the medicines assessment form then an explanation and rationale will be requested from the doctor in charge of the patient's care and documented on the medicines assessment form for future reference.
- Any medication found to be required but not documented in the medication history obtained by the doctor will be documented on the medicines assessment form so that it is accurate and complete. These discrepancies will be communicated to the doctors in an appropriate and timely manner for their attention and appropriate action.
- Document which doctor the information has been relayed to and their bleep number.
- The pharmacist will sign and annotate the form with their name and contact/bleep number against the entries they have made.
- When the medicines assessment form is accurate and complete, and prescribers have made any changes as appropriate to the prescription chart then a full medicines reconciliation has been completed.

This should normally be carried out within 24 hours of admission except at weekends when there may be a delay of up to 72 hours. This would normally fit with likely access to GP records.

On confirming the drug history, the drug history section on the front of the drug chart must be signed and dated documenting the sources used.

When all medications have been successfully reconciled, the medicines reconciliation section on the front of the drug chart must be signed and dated by the pharmacist.

Any further changes to medication during a patient's hospital stay must be documented in the medical notes with a clear explanation of the reasons for change.

If a pharmacy technician finds any discrepancies when completing a Patient's Own Medicines (POMS) check then these should be highlighted to the pharmacist for action.
Discrepancies and action to be taken should be communicated to the nurse looking after the patient, where appropriate.

The nurses' responsibilities:

- Ensure all medicines supplied for a patient are held securely, are accessible, and are transferred with the patient. Medicines brought into hospital are the patient's personal property and should be dealt with accordingly.
- request patient/family/carers to obtain all medicines from home to bring into hospital
- Medicines reconciliation issues may be picked up whilst administering the patient's medication. Any discrepancies should be discussed with the doctor and/or pharmacist.
- Any outstanding issues concerning medicines on the patient assessment documentation form should be discussed with the prescriber.
- As part of the discharge process nursing staff should go through each item of their discharge medication with the patient and/ or carer to make sure they are aware of any changes made during admission.
- Any concerns or questions raised by the patient/carer must be confirmed by reference to the medicines assessment form or referred to the doctor.

On Discharge:

When the patient is discharged it is important to communicate information about medication changes to the patient's GP. This should be done on **both** the discharge prescription ("To Take Home" or TTH form, e-discharge letter or MTeD communication) and the discharge summary by the doctor. This is because there is sometimes a delay in the discharge summary being written or reaching the GP's practice and the TTH form generally reaches the practice sooner.

2.9 Prescribing for patients with swallowing difficulties or patients with naso-gastric or gastrostomy tubing

Some patients are unable to take medication in solid oral dosage forms. A stepwise approach is suggested to choose a suitable alternative:

- If possible, use a licensed medicine in a suitable formulation to meet the

patient's needs(e.g. a dispersible tablet or licensed liquid medicine)

- If there is no suitable licensed formulation, consider using a licensed medicine in an unlicensed manner, for example by crushing tablets or opening capsules
- In order to use a licensed medicine, consider switching to a different therapeutic agent in the same class, or to a different route of administration. In most cases a suitable licensed preparation will be available to meet the patient's needs.
- In the few situations where the patient's needs cannot be met by licensed medicines, the use of special-order "unlicensed" products ('specials') may be considered.

Prescribers should be aware that many medicines are not available in a form that can be administered via naso-gastric or gastrostomy tubing. The crushing of a tablet or opening of a capsule changes its licensed status. If a tablet requires crushing or a capsule requires opening to facilitate their administration, the pharmacist should indicate this on the patient's inpatient drug administration medicine chart. In the absence of such directions a pharmacist should be consulted for advice. Alterations that change the licensed status of a medicine must be brought to the prescriber's attention and recorded in writing.

Be aware that crushing some tablets or opening some capsules (particularly modified-release) may alter the clinical effects of the medicine. A discussion with pharmacists should take place for suitable alternatives (See Section 2.9 for additional information.)

Refer to the All Wales Medicines Strategy Group guidance on the following link:

Primary Care Guidance: Prescribing medicines for adults who are unable to swallow oral solid dosage forms.

https://awmsg.nhs.wales/medicines-appraisals-and-guidance/medicines-optimisation/prescribing-guidance/prescribing-medicines-for-adults-who-are-unable-to-swallow-oral-solid-dosage-forms/

The HDUHB Enteral Feeding Policy for Adults with Operational Guidelines provides procedures and information on the administration of medicines via feeding tubes and can be accessed at: http://howis.wales.nhs.uk/sitesplus/documents/862/331-EnteralFeedingPolicyforAdultsincOperationalGuidelines-ext31.3.20.pdf

2.10 Prescribing in theatres and recovery

All medicines should be prescribed on the patient's All Wales Administration Record, anesthetic record or patients Acute Clinical Record (medical notes) prior to administration. (Reference: The College of Operating Department Practitioners. Standard of Good Practice Guidance in relation to Controlled Drugs 2007).

Before the patient is transferred to a ward from recovery a check must be made that all medicines administered to patients in theatre and recovery have been prescribed and administration recorded on the patient's All Wales Administration Record, anesthetic record or patients Acute Clinical Record (medical notes) before being transferred to a ward and any cannula flushed.(Ref: PSN014)

2.11 Day Patients (medical, surgical. mental health and rehabilitation)

When a patient is admitted as a day patient a formal record of the medicines that the patient is taking is made and a formal assessment of whether the patient is suitable for self-administration must be undertaken. HDUHB Guidelines for the Self-Administration of Inpatients' Own Medicines can be accessed at:
http://howis.wales.nhs.uk/sitesplus/documents/862/Self%20administration%20Appendix%20J%202017%20Update1.pdf

2.12 Out-Patient prescribing

Out-patient prescribing and supply should be minimal, limited to hospital only products or when an urgent clinical need exists. The internal hospital out-patient prescription form HMR 112(W) can only be dispensed from the hospital pharmacy. Routine and non urgent amendments to medication should be made by the use of a GP prescribing referral form. An 'Outpatient Department GP Medication review' form is available to facilitate this process

The WP10HP (or non-medical prescriber {NMP} equivalent WP10HIP prescription form may only be used in circumstances agreed in advance with the Site Lead Pharmacist e.g. clinic held remotely to a hospital pharmacy. This form can be dispensed from community pharmacies. Prescribing quantities should be for short duration of therapy, and regular supply of medicines will be obtained from the patient's GP. The maximum quantity prescribed will usually be not more than one original pack. The WP10HP or WP10HIP must not be used to circumvent any hospital prescribing procedure e.g. non formulary medicine and prescribers need to be aware that data from WP10HPs or WP10HIPs is audited for compliance. The

prescriber must clearly print their name and contact number when using a WP10HP or WP10HIP, to enable contact should a query arise from the dispensing community pharmacy.

When medicines are to be prescribed for administration in out-patients they should be written within the patient notes or written on a prescription chart to allow the details of administration to be recorded and signed.

2.12.1 Sexual Health and Genitourinary Medicine Outpatient Prescriptions

For outpatient prescriptions for Sexual Health and Genitourinary Medicine it is acceptable for the unique patient number, first name and Date of Birth to be used in place of the full name, address and hospital number.[MMG Jan 2015]

2.13 Community Services

Any medication that is administered by HB employees in the community should be prescribed using one of the following processes:

- WP10 prescription by a GP (or non medical independent prescriber) and dispensed by a community pharmacy.
- WP10HP prescription by a hospital doctor (or hospital based non medical independent prescriber WP10HIP) and dispensed by a community pharmacy.
- prescribed using a hospital discharge prescription (dispensed from the hospital pharmacy or using approved stock held by the Acute Response Team) and administered on an All Wales In-Patient Medication Administration Chart (both need to be signed by the prescriber). Signed electronically generated prescription and administration records (for example, for erythropoietin from the Renal Unit in Morriston [MMOG April 2018]) are also acceptable

2.14 Prescription amendment in order to correct individual prescriptions

Under an agreed enabling protocol pharmacists may amend in-patient medication records and out-patient prescriptions and transcribe GP treatments onto prescription charts for elective and emergency admissions in order to correct and/or clarify prescriber's intentions.

Any pharmacy alteration must be legible, dated, and identify the amending pharmacist by their initials and bleep number for contact. It will specify when appropriate which clinician

agreed the amendment.

Where amendments would decrease readability, the prescription will be rewritten and signed by the pharmacist. The nurse is permitted to administer the medicine without a medical countersignature. Where actual or potential clinical reasons exist for omitted items, the item will not be added to chart. If the reason for omission is not documented a note will be left on the in-patient medication record or contact made with the prescriber, depending on the urgency. The pharmacist will not amend anything beyond their experience or competence. Communication with the prescriber is essential to maintain safety and ensure correct treatment.

For out-patient prescriptions this should be annotated on the out-patient prescription [MMG Jan 2015].

The amendments to prescriptions are detailed in the HDUHB Pharmacist Enabling and Therapeutic Switch SOP (Acute Sector) which is available at:

http://howis.wales.nhs.uk/sitesplus/documents/862/Pharmacist%20Enabling%20and%20Therapeutic%20Switch%20%28PETS%29%20guideline%20v4%20Nov%202020.pdf

2.15 Validity of an in-patient prescription

The prescription is valid until stopped by prescriber, administration section is full or patient is discharged. A new medicines record must be written if patient is readmitted.

The use of a continuation sheet is not allowed when the administration section is full. A new All Wales In-patient Medication Administration Record must be written and the charts numbered accordingly (e.g. 1 of 2, 2 of 2).

Only charts originating within HDUHB are valid.

2.16 Validity of out-patient prescriptions

An out-patient prescription is valid for 6 months.

Prescriptions for Schedule 2, 3 and 4 Controlled Drug are valid for 28 days.

2.17 Prescribing for discharge (To Take Home)

TTH prescriptions or MTeD Discharge advice letter should ideally be written 24 hours prior to discharge to avoid delays in dispensing. They may be written by an authorised prescriber

from the responsible consultant team, by other medical prescribers covering shifts or by a non medical independent prescriber.

2.17.1 Patients being discharged from hospital or transferred to other establishments

All prescriptions for out-patients and patients discharged from hospital or transferred to other establishments **must** be written on an appropriate discharge form for the unit, a WP10HP, or the discharge prescription form. It must state following patient details:

- full name
- address
- NHS number (or hospital number)
- ward
- date of birth
- details of any known drug idiosyncrasies/allergies
- weight where clinically appropriate

In addition, the following medication details must be included:

- the frequency of doses and/or time of administration.
- an indication as to whether treatment is to be continued by the General Practitioner, including any information on dose titrations to be carried out.
- signature and date.

In the case of community hospitals, it is acceptable to fax this through to the hospital pharmacy, or following discussion and agreement with the general practitioner, by issuing a WP10HP for the patient to obtain the prescription from a community pharmacy.

After the discharge (TTH) prescription has been dispensed one copy is retained in pharmacy, one in the patient's notes, one copy is sent to the GP (either via the patient or directly according to local practice) and the final copy is sent to Clinical Coding.

In Outpatients a Hospital Recommendation Form may be used to advise GPs on medication that is required following the consultation

2.17.1.1 Issuing medication to patients on discharge

On discharge, the registered nurse is responsible for ensuring that the medicines:

- have been clinically checked by the pharmacist,
- are over-labelled for the patient
- the patient has the correct medicines, prescription or discharge summary
- the patient has had sufficient medicinal products prescribed, dispensed and supplied to cover a period of time to enable them to access further supplies from their usual practitioner
- the patient is aware of any changes to their medication, that is: new medicine, dose, brand, route
- the patient has been educated and given patient information leaflets relating to all medication whether current or new
- the patient takes all their medicinal products home with them or has given permission to dispose of the medicines no longer prescribed
- where the patient wishes to retain their discontinued medicines the risk of confusion and possible under or overdose needs to be pointed out to them. [MMG Sept 2017]

In the event that a patient needs to be discharged outside of pharmacy department opening hours a nurse and the discharging doctor will take responsibility for "assembling" and "dispensing" the TTH. **Both** the nurse and doctor will be required to sign the dispensed section of the TTH, and the appropriate copy must be kept in a designated area for the pharmacy department to collect. Any discrepancies between the TTH and the medicines available in the cabinet must be discussed with the on-call pharmacist. The Standing Operating Procedure for Provision of Safe Patient Discharge during Out of Hours Dispensing in pharmacy out of hours can be accessed at: ,http://howis.wales.nhs.uk/sitesplus/documents/862/268-AppD-ProvisionofSafePatientDischargeDuringPharmacyOutofHoursGuideline.pdfz [MMG Jan 2015]

Where a patient is discharged home without medicines because they have an appropriate supply at home, the pharmacy department (or nurse/doctor outside of pharmacy opening hours) do not need to supply a patient information leaflet (as they are included in the patient's medicines at home). [MMG Sept 2017]

2.17.2 Transfer to establishments outside HDUHB

When patients are transferred to an establishment outside HDUB, a full medical summary including the medication record and the time the last doses were administered should be provided. The original prescription must not be send; a signed and dated photocopy is acceptable.

2.17.3 Transfer within HDUHB wards and hospitals

When patients are transferred between the Health Board's own wards/hospitals, continuation of the All Wales Inpatient Medication Administration Record is acceptable, with review by the medical practitioner to whom responsibility for the patient's care has been transferred.

Where a patient's treatment is being reviewed in conjunction with the original ward/team (for example, the patient is sent home on leave but reviewed at a site closer to home) only one prescription chart is to be used at any one time for a patient. The inpatient prescription chart used prior to the patients leave must be shared using photocopying, scanning and email or uploading onto a shared electronic patient medical record eg. CarePartner). At each patient review (particularly where teleconferencing or video-conferencing is used) all members must ensure that they are all using the same prescription chart as a basis for their discussions and decisions. [MMSC Sept 2019]

Ward details must be amended to ensure medications are distributed to the correct area. Individually dispensed medication together with the patient's own drugs must also be transferred. The green bags should be used to ensure the safe transfer of all medicines for that patient. Green bags are ordered via the Oracle ordering system.

2.18 MTeD

The Medicines Transcription and electronic Discharge (MTeD) system is a module of the Welsh Clinical Portal which has been implemented across most inpatient wards across Hywel Dda UHB. MTeD allows for the electronic transcription of a list of patient's medication which contributes to a final discharge advice letter (DAL). The DAL is sent electronically to a patient's GP in any area of Wales automatically when a patient is discharged and is stored on the Welsh Clinical Portal.

A patient's medication can be transcribed from the chart onto the MTED system by a pharmacy technician, pharmacist or prescriber at any stage during the inpatient stay, depending on the agreed procedure for each ward. On many wards the transcribed medication list is kept up to date by pharmacy during the inpatient stay and must be reviewed by the doctor at discharge when the DAL is prepared. Therefore, MTeD provides a comprehensive list to the GP of all medication continued, started, stopped or withheld while in hospital. It is used during the inpatient stay for ordering of medication both on site and remotely, and any additional information regarding supply in the community can be recorded. On other wards all medication is transcribed at the time of discharge by the prescriber. The final DAL is printed and signed by the prescriber ready for assembly by pharmacy in during opening hours, or ward staff out of hours according to the SOP (see 2.16.1.1).

2.19 Leave medication

Leave medication should be ordered as set out above in 2.16 'Prescribing for Discharge'. Where a local procedure exists, and it has been approved by the Directorate and, if appropriate, the HDUHB Medicines Management Operational Group, medication dispensed and labeled by pharmacy for leave can be supplied to cover the period of time until the patient is readmitted to hospital in accordance with the procedure. Nurses must not dispense medication from ward stock to facilitate supply of leave medication as this is a contravention of Regulations under the Medicines Act 1968 and Human Medicines Regulations 2012.

2.20 Discharge of patients from community hospitals

Community Hospitals will arrange prescriptions for discharge medication as for acute hospitals in 2.16 above. This will ensure a safe process for prescription writing, dispensing and supply of discharge medicines for patients to take home. Supply of discharge medication may be obtained from the local hospital pharmacy or by use of the patients own drugs (PODs) or from a local community pharmacy if a HDUHB approved procedure is in place.

2.21 Scanned and Emailed (or Faxed) prescriptions for discharge (TTHs)

Scanned and emailed (or faxed) discharge prescriptions are not permitted within acute hospitals. In community hospitals, where a Patients' Own Medicines (POMs) system of medicines management is not in operation, discharge prescription supply is usually obtained by sending the original discharge prescription to the local hospital pharmacy for dispensing.

In certain circumstances, the use of scanned and emailed (or faxed) prescriptions to the local hospital pharmacy may be used to facilitate efficient discharge. Each scanned and emailed (or faxed) discharge prescription must be accompanied by a copy of the in-patient medication record. Controlled Drugs (Schedule 2) cannot be issued from scanned and emailed (or faxed) prescriptions, but may be dispensed and supplied only when the original prescription is received and checked against the electronic or facsimile copy.

2.22 Prescribing for relatives and visitors of in-patients

Relatives and visitors of in-patients may occasionally stay overnight locally or within the hospital. They are responsible for supplying their own medication. When they have not brought their own medication to the hospital and their health may suffer as a consequence they should obtain an emergency supply from a community pharmacy or, if not local to the area, a local GP practice may be willing to prescribe as a temporary resident. The GP Out of Hours Service can issue a prescription to a temporary resident, and in certain circumstances attendance for treatment at the Accident and Emergency Department is appropriate.

If relatives cannot leave the hospital, and the consultant team treating the patient agrees to take prescribing responsibility, the hospital pharmacy may agree to dispense a prescription written by the hospital team treating the inpatient.

2.23 Verbal prescriptions to nursing staff - prescribing by telephone

Verbal prescribing is <u>not acceptable</u> other than in <u>emergency situations</u> when the doctor is not present and the prescription will be written when the clinical situation allows at the earliest possible opportunity but no later than 24 hours. Non-medical independent prescribers must also follow their professional guidance.

The use of dose ranges and verbal orders confirming the administration of an increased dose for continuous subcutaneous infusions and syringe drivers (used mainly in end-of -life care) should comply with the guidance set out in Section 6.9 of the HDUHB Opioid Medicines in Adults: Prescribing, Dispensing and Administration Guidelines. [MMG Jan 2016]

Telephoned prescriptions are permitted only in exceptional circumstances when in the nurses' professional judgment, patient safety or care would otherwise be compromised. Exceptional

circumstances will mainly be for areas where there are no doctors on site, e.g. Community Hospitals, Minor Injuries Units, and when treatment is needed to urgently relieve symptoms.

Verbal prescriptions can amend, delete or add a prescription item. They cannot be used for controlled drugs. Any refusal by a nurse to accept a verbal prescription must be documented by the nurse.

The following principles for confirmation of prescription should apply:

- The prescriber must be informed of other medicines currently prescribed for that patient
- The prescriber must be informed of known allergies for that patient
- A verbal order must be received by a nurse and confirmed ideally by a second nurse (except in circumstances detailed in paragraph below).

The prescriber must state:

- The identity of the patient
- The prescriber's identity
- The name of the medicine to be administered (spelt to avoid confusion)
- The dose to be administered
- The route and time to be administered

This information must be given to the first nurse, entered on the in-patient medication record or casualty card and then repeated back to the prescriber by the second nurse.

The nurse taking the verbal message should be familiar with the medicinal product.

When it is not possible for two nurses to be present to receive the verbal order, a second member of staff who may be qualified or non-qualified should be present. Both members of staff involved must sign and date the entry.

In exceptional circumstances, when a community health professional is working alone and is unable to receive an electronically transferred instruction, the health professional may accept a verbal order from a prescriber to administer an urgent single dose of a medicine until such time as a fax or electronically transferred instruction can be made.

2.24 Verbal prescriptions to pharmacists – corrections by telephone

Verbal orders can be given by a prescriber to a pharmacist to amend delete or add a prescription item. This need often results from a pharmacist initiated query.

Having confirmed the identity and name of the patient with the prescriber, the pharmacist

must confirm the following details:

- The patient hospital number
- Date of birth
- Address
- The medicine name, form and dose
- The name of the prescriber.

The pharmacist must also have access to sufficient information to assure themselves of the appropriateness of the medicine and dose. The pharmacist must read the alteration or addition back to the prescriber who must then affirm the original instructions.

The pharmacist will then amend the in-patient medication record or out-patient prescription recording the name of the prescriber, who has been contacted, then sign and date the amendment.

If the alteration is to formulation, frequency or timings of dose, then that part of the prescription may be crossed out and altered to ensure that the alteration is clear.

If the alteration involves any other changes e.g. new medicine, change in dose, then the whole prescription for that item must be written out as a new entry on the in-patient medication record or outpatient prescription form.

2.25 Controlled Drug prescribing

See Part 7

2.26 Prescribing for Controlled Drug Dependency

See Part 2.4.11

2.27 Prescribing medicines which carry a black triangle symbol in the BNF

The black triangle symbol ▼ identifies those preparations in the BNF that are monitored intensively by the Medicines and Healthcare Products Regulatory Agency (MHRA). Prescribers are urged to exercise caution when prescribing these preparations and should report adverse drug reactions to the MHRA (https://yellowcard.mhra.gov.uk/)

2.28 Prescribing medicines for which the Patient Safety Wales (and former NPSA) has issued safety concerns

Patient Safety Wales and formerly the National Patient Safety Agency (NPSA) may/have

identified certain medicines as having particular risks associated when they are prescribed. This risk is highlighted by the production of a Patient Safety Notice/Alert (NPSA through the issue of a Rapid Response Report (RRR)). Prescribers are urged to familiarise themselves with these. They can be found at:

Patient Safety Wales http://www.patientsafety.wales.nhs.uk/home

NHS Patient Safety (links to NPSA) http://www.nrls.npsa.nhs.uk/

2.29 Prescribing for patients detained under 'The Mental Health Act'

Circumstances arise where a patient is detained under The Mental Health Act and will need medication prescribed either by consent or against the patient's wishes. The prescribing team must ensure that any prescribing will be in accordance with the current legislation set out under the Mental Health Act (http://howis.wales.nhs.uk/sitesplus/862/page/43173#MENTAL HEALTH ACT DOCUMENTATION)

2.30 Prescribing for staff who are unwell at work

Prescribers **must not** prescribe / administer any medicine for themselves, close family, friends or other staff (except when they are registered patients).

Self-prescribing is held to be generally undesirable to many authorities, including the General Medical Council, and will not be accepted. This avoids the dangers associated with the loss of objectivity, misdiagnosis and circumvention of the normal general practitioner-patient relationship. All routine medicines for doctors, their families and other hospital staff should be obtained through the General Practitioner Services. Prescriptions are subject to routine and random audit and exceptions to this protocol will be brought to the attention of the HDUHB Internal Audit department. This ensures compliance with the Welsh counter fraud initiative and the principles of clinical governance.

Further information can be found at: http://howis.wales.nhs.uk/sitesplus/documents/862/Self%20Prescribing%20Letter%20v%203%20Final.pdf

If staff require treatment they should attend their registered GP, GP Out-of-Hours, seek advice from their Occupational Health department or Accident & Emergency (in exceptional circumstances). Staff must not use ward or departmental stock, patients' own medicines,

medicines dispensed for individual patients or medicines due for disposal for their own self-treatment.

2.31 Medication use under Section 136 Mental Health Act in Sec136 suites

The prescribing and administration of medicines to patients admitted under Section 136 of the Mental Health Act held in Sec 136 suites is detailed in Appendix: Guidance for Medication use in instances of Section 136 which can be found at:

http://howis.wales.nhs.uk/sitesplus/documents/862/Section%20136%20document%20Final%20Nov%202019.pdf

Part 3 Ordering of Medicines

3.1 Ordering ward stocks of medicines

The process of ordering and receiving medication from pharmacy as stock medication for a ward or unit must ensure that certain controls are in place to cover the safety and security of the medicines (to include a clear documented audit trail), ensure that only controlled stationery is used, prevent overstocking of the area, ensure safety of the staff and patients, and clearly show who has the direct responsibility for each stage of the process.

3.1.1 Stock control

Each ward or unit must have an agreed stock list of medicines which are either used regularly on that ward or unit, or are required in case of an emergency. The stock level should be agreed between the pharmacy department and the clinical lead and this should be reviewed on a regular basis (usually at least twice a year). A named pharmacist will be provided for each ward as a point of contact for any issues relating to pharmacy and medicines management. This does not mean that no other member of the pharmacy team or the dispensary can be contacted but will provide the ward with a regular point of contact to discuss and address any ongoing issues/concerns. The named pharmacist will liaise with the ward on a regular, mutually agreed, timescale with the senior ward sister. This may be daily, weekly or monthly.

The sister/charge nurse/clinical lead has responsibility for all medicines on that ward or unit. This overall responsibility cannot be transferred to anyone else since it covers the strategic elements of medication handling on the ward or unit which ensures that day to day practice is in line with current legislation, local and national policies/guidance. The pharmacy will arrange which system of regular top-ups/stock control is be best suited for that ward or unit, and the frequency with which these will take place. Ad-hoc orders should be processed as described in the Medicines Policy. Community Hospitals will order stock medicines as arranged with their local hospital pharmacy.

3.1.2 Ordering ward stock

The ordering system in use on that ward or unit will determine who raises the order. Where

wards or units have a pharmacy top-up/stock control, the pharmacy staff that carry out the top-up/stock control will initiate the order. Wards or units that do not have pharmacy top-up/stock control will order using an agreed medicines requisition that will be completed by a member of the ward or unit staff who has been authorised to initiate orders. Authorisation of staff will be the responsibility of the ward/clinical lead and all authorised staff will have their name and signature logged with pharmacy. Ad-hoc orders maybe initiated by the ward or unit staff, but they can only be made in the manner agreed with pharmacy and by a member of staff who has been authorised to initiate orders.

3.1.3 Stock ordering for specific areas

3.1.3.1 Acute Response Team (ART) Stock

The Acute Response Team should access all stock items through their stock drug cupboard (where used) in the first instance and then access the drugs from the pharmacy department using a TTH or outpatient prescription form. An in-patient medicines administration chart must also be completed.

3.1.3.2 Medicinal Products for use in Community Clinics or Family Planning Clinics

a. A designated person (who shall be a registered Healthcare Professional) will be responsible for controlling access to medicinal products and for their security in clinics.
b. The said designated person may decide to delegate some of the duties, but the responsibility always remains with that designated person.
c. Each clinic site must have a written procedure to ensure the safety, security and the ordering of medicinal products. The Pharmacy department supplying the Clinic can advise on the contents and template of the procedure.

3.1.3.3 Medicinal Products for use by Other Hospital Departments

a. A designated person (who must be a registered Healthcare Professional) must ensure that medicinal products are ordered on the appropriate order form.
b. The range of medicinal products provided as stock will be agreed with the Pharmacy Department.
c. The designated person has responsibility for supplying accurate and up-to-date signatory lists to the Pharmacy department twice yearly.

3.1.4 Documentation

All documentation used in the ordering of medicines will be classed as “controlled stationery” and as such should be stored safely except when in use. Access to medicines requisitions should only be to authorised staff and any electronic medicines ordering documents or system is limited to staff with authorisation attached to their individual user name and log on. All order documentation records whether paper or electronic will need to be kept for 2 years as a record of the transaction for audit purposes.

The ward sister/charge nurse has responsibility for supplying accurate and up-to-date signatory lists to the Pharmacy department twice yearly.

3.1.5 Order assembly and transfer of medicines

Order assembly and the transfer back to the ward or unit will be the responsibility of the pharmacy department. The pharmacy will highlight medicines needing special storage or temperature conditions, to ensure the security and stability of the medicines until they are delivered to the ward or unit.

3.2 Receipt of medicines on the ward or department

When medicines have been delivered to the ward or department the delivery must be signed for. The ward/clinical lead in charge should delegate a member of the ward staff to check the medicines received against the delivery note issued with the medication. If all the items are correct then the nurse shall sign and date the delivery note and then put away the medicines in their designated locked cupboards on that ward or unit. Any discrepancy identified must be notified to pharmacy as soon as possible.

Part 4 Control and Storage of Medicines

4.1 Storage of medicines

Medicines dispensed by pharmacy will be labeled in a manner to indicate to patients and nurses, the correct manner of storage and use of medicines. Medicines needing storage in a controlled drug cupboard will be labeled 'Store in a Controlled Drugs cupboard' Medicines needing cold storage will be labeled 'Store in a refrigerator'. Certain medicines can carry risk of harm to those who need to handle the medicines e.g. cytotoxic medication or hormonal medication and will carry warning labels indicating this risk. Information on the shelf life of oral liquid medicines can be found at: http://howis.wales.nhs.uk/sitesplus/documents/862/268-AppP-ShelfLifeofOralLiquidMedicines1.pdf

4.1.2 Stock medicines in clinical areas

The stock held in a ward or department should be the minimum for safe and effective patient treatment and efficient service provision. The ward or clinical area will agree the items to be held as ward stock with pharmacy whose staff are authorised to inspect all medicines on any HDUHB premises at any time. Storage of medicines no longer in use can increase risk of error and they should be returned as set out in this Policy. If it is found that the storage conditions are inappropriate; the nurse with continuing responsibility must be informed. If this does not resolve the situation, Senior Nurse Medicines Management will notify in writing the Senior Nurse responsible for the ward or clinical area.

4.1.3 Patient's own drugs (PODs)

When a patient is in hospital, the term 'Patient's Own Drugs' (PODs) refers to medicines that have been brought into hospital by the patient, having been dispensed for that patient outside of the hospital. It also includes over the counter (OTC) medication purchased by a patient and brought into the hospital. PODs medicines are not HDUHB property but to ensure safe use and control for an individual patient their medicines must be stored and handled as set out in 4.1.3.1

On admission, the Registered Healthcare Professional must encourage the patient or a

responsible relative to provide all medicines used by the patient for reconciliation and identification by the medical/dental officer or pharmacist. If a medical/dental officer or pharmacist is not available the medicinal products must be placed in an individual patient medication bag and stored in a locked cupboard until identification can take place.

NOTE: These medicinal products remain the property of the patient.

4.1.3.1 Storage of Patient Own Drugs

Where appropriate, PODs are stored in lockable bedside medicine cupboards used exclusively for that patient. Cupboards or lockers designated for PODs storage must only be used for storage of PODs, and must not be used for patient's own property, money, food or valuables. If a ward is not utilising PODs then the PODs must be stored in a cupboard or trolley until such time that they can be returned to the patient or relative. PODs should be assessed for suitability for use by a pharmacist or pharmacy technician or registered nurse/midwife in accordance to the local pharmacy procedure.

An in-patient may be self- administering certain medicines that are used for the acute relief of symptoms (including GTN spray or tablets, nicotine replacement treatments, lubricant eye-drops and creams (emollients) for application when required and reliever inhalers (including those licensed for SMART or MART administration) that is not practical nor it is expedient to be kept in a locked cupboard. These need not be stored in a locked cupboard when prescribed and used by those patients capable of self administration and are left in the possession of the patient to use, as required, and stored safely out of sight and the reach of other people when this is appropriate[MMG July 2016].

PODs that need cold storage must be kept in a refrigerator and the place of storage noted on the patient's medication record.

It is the responsibility of the nursing staff to ensure that patients own drugs and any individually dispensed items are transferred with the patient.

Any drugs remaining after a patient has been discharged must be removed immediately and returned to the pharmacy department for safe disposal/reuse as appropriate.

4.1.4 Suspicious substances or suspected illicit materials

Where a patient has brought in with them medicines that cannot be identified and there is

suspicion that they are a suspicious substance or suspected illicit materials, the patient must be asked to surrender these medicines in order to ensure continued safety of any medical intervention.

The declaration form must be completed (available at: http://howis.wales.nhs.uk/sitesplus/documents/862/6.1%20-%20Patient%20Letter%20Unidentifiable%20tablets%20Substance%20v2%20%20Oct%202018%20-%20Copy.pdf) and the substance removed and returned to pharmacy for safe disposal (Medicines Policy Part 7 and 8). The incident must be reported via Datix. In addition to this the guidance below should be followed:

- An entry must be made on the appropriate form by a registered nurse, noting the date and description of the substance. This must be countersigned by another nurse.
  The form can be found at:
  http://howis.wales.nhs.uk/sitesplus/documents/862/Transfer%20of%20an%20unidentified%20suspicious%20substance%20or%20suspected%20illicit%20material%20to%20Pharmacy%20Form%20v%201%20Oct%202018.pdf

- The substance must be locked in the Controlled Drug cupboard and pharmacy informed. If it is outside normal pharmacy working hours, wait until the next time the pharmacy is open. The patient's consent must be obtained and if consent is not given this must be documented and further advice sought

- A pharmacist will attend the ward and will remove the substance from there. They will sign the form indicating date of removal, and a registered nurse will countersign the pharmacist's signature.

- The substance once in pharmacy will be weighed and then locked in the pharmacy Controlled Drugs cupboard (with the expired Controlled Drugs). An entry will be made in the Controlled Drugs destruction book, noting the date the substance was taken into pharmacy, the description of the substance, the weight of the substance and the signature of the pharmacist who took it off the ward.

- The police must be informed of the substance, who will then attend to collect it for destruction. The police officer removing the substance will provide identification and sign the Controlled Drug destruction book. The police officer will not have access to the declaration form.

- **NB** Patient confidentiality must be maintained.

- Where there is concern that action needs to be taken to protect the public interest and/or to prevent a crime, advice must be sought from the appropriate Senior Nurse Manager or Site Lead Pharmacist. Information Governance and the Caldicott Guardian will be useful sources of information and advice regarding disclosure or information sharing with other public bodies.

4.1.5 Medicines cupboards and trolleys

A ward or clinical area must have sufficient and proper storage cupboards, medicines trolleys, racking and shelving to safely store medication in a dedicated room or area. Each area where medicines are stored must be kept clean, be well ordered and comply with legislation for storage of medicines. PSN055 sets out the current requirements. Internal and external medicines should be stored in separate cupboards or, where this is not possible, on separate shelving within a cupboard. Testing reagents shall be stored in a separate locked cupboard. Disinfectants shall be stored in a locked cupboard, separate to internal medicines. Where a traditional ward medicines trolley is used to facilitate medicines administration it is good practice to ensure that medicines held on the trolley are restricted to individually dispensed items and the minimum stock from ward stock required to meet the needs of the medicine round. When the trolley is in use it must not be left unattended unless locked. When the trolley is not in use it must be locked and secured to the wall or floor by a chain, padlock or security system. Medicines must not be left on top of the trolley or on any exposed shelf of the trolley. CDs must not be stored in the medicines trolley. Where an automated ward or department medicine storage system is in use, the system and its access controls must be approved by pharmacy. Infusion fluids, peritoneal solutions and large volume sterile irrigations are best stored in a locked cupboard, but where they are stored on shelving it must be in a secured

area, providing clean conditions and where there is not public access. Medicines that do not have to be stored in a refrigerator must be stored between 8°C and 25°C. The room temperature must be monitored with a thermometer and recorded on a temperature chart. The chart can be accessed here (Opens in a new tab).

4.1.6 Medicines refrigerators

Medicines labeled 'Store in a refrigerator' shall be stored between 2-8˚C in a dedicated locked medicines refrigerator. Guidance is set out in Patient Safety Notice PSN015. Medicines refrigerators should preferably be hard wired to the electrical supply to prevent accidental switching off. If not, a cautionary notice must be placed on plugs or sockets to prevent accidental interruption of power supply. The use of refrigerators with temperature recording charts is preferred. Medicines refrigerators must have the temperature monitored and recorded daily, and this should be regularly audited by a named individual. Immediate action must be taken if the temperature is not within the acceptable limits. The Standard Operating Procedure for the Medicines Refrigerators' Temperature Checking can be accessed here: http://howis.wales.nhs.uk/sitesplus/862/page/73497 (Opens in a new tab)

Non medicines e.g. milk or food must not be stored in a dedicated medicines refrigerator.

In the community, medicines may be stored in a patient's own refrigerator.

4.1.7 Epidural levobupivacaine bags

Epidural levobupivacaine bags must be stored separately from intravenous infusion bags to minimise risk of erroneous selection of levobupivacaine and inadvertent administration by an incorrect route. Compound epidural bags containing levobupivacaine and fentanyl must be stored in a CD cupboard.

4.1.8 Emergency boxes, anaphylaxis kits and hypo (hypoglycaemia) boxes

These medicines are provided to wards to provide immediate life saving treatment therefore they should not be stored in locked cupboards, but be kept in a safe location in the clinical area so as to be readily available when needed. This must be balanced against the need for medicine security, therefore wherever possible they should be stored out of direct view of the public. Some areas will have alarmed trolleys for storage of emergency boxes. Each

emergency box will have a tamper evident seal and expiry date, and once the seal is broken or the box expires it should be replaced via the pharmacy as soon as possible.

4.1.9 Medicines and Health and Safety

Flammable materials must be stored away from sources of ignition and preferably locked.

4.1.9.1 Inhalation Anaesthetic Agents

In all areas, such as operating theatres, stocks must be stored in a separate metal lockable cupboard.

4.1.9.2 Medical Gas Cylinders

These must ideally be stored in purpose built medical gas stores. In operating theatres running stocks will be stored in the areas designated for this purpose. On the wards, the cylinders must be chained to the wall as detailed in NPSA alert Oxygen Safety in Hospitals (NPSA/2009/RRR006) Issue Date 29th September 2009.
http://www.nrls.npsa.nhs.uk/resources/?entryid45=62811

4.1.10 Storage of Controlled Drugs

See Part 7

4.1.11 Storage of medicines by community nurses

Where community staff need to carry medicines to a patient's home or elsewhere, they must ensure that the medicine is securely stored until use or return to the originating storage cupboard at base. If the medicine requires cold storage the medicine must be carried in appropriate packaging to maintain the 'cold chain'. Medicines should be carried concealed in the boot of a vehicle and should not be left unattended,

4.2 Security of medicines

4.2.1 Custody of keys controlling access to medicines

4.2.1.1 Pharmacy

The safe custody of medicines within the pharmacy, pharmacy keys and pharmacy entry

swipe cards are the responsibility of the Site Lead Pharmacists.

4.2.1.2 Wards

In wards or clinical areas the responsibility for safe custody is that of the Ward Sister/Charge Nurse. The person with continuing responsibility can delegate responsibility for the possession and custody of the keys to the medicine cupboards, medicine refrigerator and medicines trolleys. All ward medicines keys must be passed to the next Registered Healthcare professional at handover. Unauthorised persons must not be permitted access to medicines within hospital premises.

A master key for PODs cupboards is held by each ward team. Lost keys must be reported in accordance with the local security procedure. A patient may hold the key to their individual bedside PODs cupboard where they have been assessed to be able to self-administer their medication according to a HDUHB approved local procedure.

4.2.2 Custody of Controlled Drugs

See Part 7

4.2.3 Discrepancy or misappropriation of medicines

Each member of staff will maintain their own record of any incident and their subsequent action. The Ward Sister/Departmental Head will make initial enquiries to establish if any suspected theft or suspected fraud may have occurred. See section 1.3 and 1.4

4.2.4 Apparent loss of medicines in clinical area

The person in charge of the clinical area should assess the significance of the loss of the medicine (whether it is a CD or not) and then determine if the procedure set out for missing CDs will be followed (see Section 7.11). If theft or fraud is suspected see sections 1.3 & 1.4. All losses involving CDs must be referred as soon as possible to the senior nurse who will contact the Site Lead or Emergency Duty Duty Pharmacist as necessary and the procedure set out in the Controlled Drug section of the Medicines Policy must be followed.

4.2.5 Apparent loss within the pharmacy

Any apparent loss of medicines within the pharmacy must be reported immediately to the Senior Pharmacist on duty. The senior pharmacist and the person reporting the loss should examine the records against the physical stock to confirm the apparent loss. If no satisfactory explanation is forthcoming the senior pharmacist will inform the Lead Site Pharmacist or their deputy who will again check the stock records against physical stock. Should the apparent loss remain unexplained, the or deputy will inform the Security Manager of the loss and in consultation with them may report the incident to the Police and ask for an independent investigation. The relevant disciplinary and finance procedures will be applied, if appropriate.

4.2.6 Dispensing errors discovered on a ward

When an apparent dispensing error is discovered on a ward or in a department the Senior sister/Department Head in charge of the ward or department will contact the pharmacy as soon as it is practical, in order to confirm the status of the medication and ensure that where necessary a new supply is made available to the patient . The ward staff should complete a Clinical Incident Report on Datix detailing the error or provide information to the local hospital pharmacy for completion. Dispensing errors are considered ‘must report incidents’ within the HDUHB policy for clinical incident reporting.

The pharmacist receiving such a report will complete a pharmacy incident report to be submitted to the Site Lead Pharmacist. The pharmacy will maintain a record of such incidents for audit and clinical governance purpose. If a patient has wrongly received any medicine, the consultant in charge of that patient will be informed of the incident so that any clinical action needed can be taken, and that the patient and/or relatives can be informed.

4.2.7 Samples of medicines left by pharmaceutical representatives

It is imperative that HDUHB must know what products are being used within its boundaries. Samples of medicines must not be left in clinical areas, or issued to individual healthcare staff by pharmaceutical representatives for use within HDUHB. Representatives wishing to discuss supply of samples for use for evaluation of a medicinal product must be referred to the hospital pharmacy. All pilot studies or evaluations using non-formulary medicines or medicinal

products must be approved by the Medicines Management Operational Group prior to initiation. Samples of oral nutritional supplements and emollients which are already on formulary can be used by dieticians and clinicians to aid patients in choosing appropriate formulary products.

4.3 Transport of medicines

When medicines are being transported from the pharmacy to ward or unit it shall be in such a manner that ensures they reach their destination safely, undamaged and have been kept under the correct storage conditions. Each hospital pharmacy will put in place a system for recording dispatch and delivery of medicines from the originating pharmacy.

4.3 1 Storage conditions in transport

Whenever medication is to be transported from one area to another, then the recommended storage conditions e.g. Safe storage for Controlled Drugs, temperature or humidity must be considered and the method of transfer must take these storage conditions into account. When sending out items with highly sensitive temperature conditions e.g. vaccines, it is good practice to notify the receiving unit of the day/date of transportation to maintain the cold chain as described in the NPSA Rapid Response directive (RRR008 Cold Storage).

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4.3.2 Packaging for transportation

When transporting any medicine, due regard must be taken of the fragility of the item being dispatched. Those items known to be fragile e.g. items already packed in a glass container, or items which are known to have a COSHH hazard must be packed carefully (these may require extra padding around the container) in order to remain intact throughout the transport process. It is essential that when the item reaches its destination it is still intact and can be used for a patient.

Pharmacy must be notified immediately of any damage to medicines on receipt.

4.3.3 Transport documentation

Medication should only be transferred from pharmacy to a ward or unit on the same site by hospital staff. In most cases this will be pharmacy/hospital porters. Other staff e.g. pharmacy,

nursing or health care workers can also transport medication, but only if they can be identified by their employer identification badge. For any transfer that is going off site to another health premises, then the person carrying out the delivery must sign a pharmacy transport note on pickup within pharmacy and also ensure that the receiving staff signs for receipt of the medication to ensure a complete audit trail. The carriers in this case will be signing for the outer transport bag or box and not for the individual contents. The record of receipt will be returned to the supplying pharmacy as soon as possible. If voluntary transport arrangements are in use then a badge or similar identification system must be in place.

4.3.4 Transport between NHS Organisations from Pharmacy Departments (Including Community & GP practices)

The pharmacy department has responsibility to ensure that the individual transporting the medicine is clear on the following:

- who the medicine is to be delivered to – this ideally should be a named person.
- security of the medicine in transit

Transport for the delivery of medicines must not be externally distinguishable from other vehicles.

No unauthorised passengers shall be carried in vans, which deliver medicines, and the vehicles must be locked when unoccupied.

Transport staff shall be trained to ensure understanding of the procedures and the need for security. This must include instruction on the action to be taken in the event of a physical threat.

All medicines must be transported in tamper proof containers. This may be a heat-sealed, tagged or locked container dependent on the number and volume of items. Where medicines need to be kept between 2°C and 8°C.they must be packed in a validated cool box (carrier) wrapped in bubble wrap or similar insulation material and with previously, chilled cool packs included.

A pre-printed consignment note/record of the containers to be transported at any one time will be signed for by the driver on collection of the delivery, carried by the driver and be signed by the individual accepting the delivery. It must be returned to the pharmacy department for reconciliation.

Controlled Drugs must be in a separate locked/tamper proof sealed container and signed for individually on delivery. The delivery note must be returned to pharmacy for reconciliation.

4.4.4 Delivery of Medicines to Patient's Home (External Contractors - Taxis)

A named patient/patient representative must sign for receipt of the medicine unless previous arranged with the person responsible for delivery e.g. ward/pharmacy. The receipt does not need to identify all medicines within the container, only details to enable identification of the patient e.g. name and address. The named person must be advised of their responsibilities in relation to confidentiality.

The signed delivery sheet must be returned to the issuing department e.g. ward or pharmacy department within 24 hrs of delivery. Any problems with delivery must be flagged up immediately (e.g. unable to deliver/delays).

Community healthcare professionals may transport medication to patients (including Controlled Drugs), where patients, their carers or representatives are unable to collect them, provided the healthcare professional is conveying the medication to a patient for whom the medicinal product has been prescribed, (for example, from a pharmacy to the patient's home)'.

However, it is considered good practice that health professionals should not routinely transport CDs in the course of their practice. This should only be undertaken in circumstances where there is no other reasonable mechanism available. All drugs should be kept out of sight during transportation

4.4.5 Additional Actions for Oncology Medicines

Oncology medicines pose an additional risk to individuals and the public. In order to reduce

the risk identified the following conditions and training must also be in place for a taxi service to transfer oncology medicines on a regular basis.

Oncology medicines must always be packed in a second outer container that is clearly marked ‘cytotoxic’. Packing must be used to protect the enclosed medicines as appropriate.

The driver must receive training provided by the pharmacy department before they are approved to carry oncology medicines. This includes the following:

- information on the type of medicine they are carrying i.e. cytotoxic
- information on the potential risks associated with the oncology medicine
- how to transport the medicines and any additional issues e.g. temperature controls, need to fasten safely in the car/van- place in the boot of the vehicle
- dealing with cytotoxic spillages.
- importance of ensuring a clear audit trail- signature on consignment notes and ensuring they are returned to the relevant pharmacy promptly.

Documentation of the transfer is on the Aseptic Services Transport of Cytotoxic/Biologic Medicines via Transport Provider Form (http://howis.wales.nhs.uk/sitesplus/862/page/73497)

4.4.6 Personnel

Staff involved in the transport of medicines will be kept to a minimum and be in a legitimate position to do so i.e. Health Board employee or Welsh Ambulance Service wherever possible and contracted Taxi drivers.

All staff involved in the transport of medicines will be trained to ensure understanding of the procedures and need for security, including instruction on action to be taken in the event of physical threat.

4.4.7 Community Services

It is permissible for community nurses to transport medicines (including CDs) for individual

patients providing that they are:

- in uniform (unless Mental Health or Community Paediatrics)
- have identification
- can confirm the address of the patient.

All medicines must be transported in tamper proof containers. This may be a heat-sealed, tagged or locked container dependent on the number and volume of items. Where medicines need to be kept between 2°C and 8°C.they must be packed in a validated cool box (carrier), wrapped in bubble wrap or similar insulation material and with previously, chilled cool packs included. The medicines should be kept out of sight and the vehicle locked when unoccupied.

Community nursing staff may be required to transport oxygen or Entonox® in their vehicles. It is the responsibility of each healthcare professional to ensure they have appropriate insurance to cover this activity and they must also display a badge (Compressed gases) to say they are carrying Oxygen (O_2) or Entonox® in their vehicle. The cylinders must be stored securely in the boot of the vehicle.

Part 5 Administration of Medicines

The purpose of this section is to establish the principles for safe practice in the management and administration of medicines by registered nurses, midwives and other healthcare professionals. It is aligned to the All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal (MARRS 2015) and the https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

- Definition of administration: Administer is '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); overseeing the self administration of medication by a patient or assisting the patient with administration of a medicine.

In order to support the newly registered nurses in the administration of medicines on the wards ward sisters/charge nurse may facilitate drug assessments during their initial preceptorship period.

Definition of second checker: A staff member usually authorised to administer medication. In certain defined situations the second checker may be a health care support worker who has undergone specific training for this task (in exceptional circumstances in Community Hospitals and Acute Mental Health wards ONLY) (See 5.1.5 for further information)

Standards of Practice for the administration of Medicinal Products

In the administration of medicinal products via any route, it is expected that every registered Healthcare Professional will demonstrate professional accountability for practice (guided by the WHO 5Rs Principles (RIGHT patient, medication, time, route, dose, NO allergy) by taking the following actions:

1. be certain of the identity of the patient to whom the medicine is to be administered.
2. check that the patient is **not allergic** to the medicine before administering it.
3. know the therapeutic uses of the medicine, its normal dosage, side effects, precautions and contra-indications (if medicines are unknown to the professional be certain to identify the above through recognised available resources).
4. be aware of the patient's care plan and medical status.

5. check that the prescription and the label on the medicine dispensed is clear and legible.
6. check the expiry date
7. check the package for any damage or tampering when first received
8. consider the dosage, weight (where appropriate), method of administration, route and timing.
9. use the opportunity to emphasise to patients and their carers, the importance and implications of the prescribed treatment and enhance their understanding of the effects and side-effects and provide additional relevant information when requested or required (e.g. Patient Information Leaflets (PIL))
10. make a clear, accurate and **immediate** record of all medicines administered- **administration must be observed before this record is made.**
11. where the medicine or fluid is given as an intermittent or continuous infusion the administration chart should be signed **immediately** after the infusion has been commenced**.**
12. monitor, evaluate and record the effects of the medicines administered and report to the appropriate prescribing medical practitioner or pharmacist immediately if any adverse reactions to the prescribed medication are identified.
13. when two or more All Wales Inpatient Medication Administration Records (e.g. two or more standard charts or a standard chart and a warfarin chart), are in use, ensure:
    - that they are secured together
    - that the patient's name and identification number is on each chart
    - that the number of All Wales Inpatient Medication Administration Records in use is clearly indicated on the front of all Inpatient Medication Administration Records (e.g. 1 of 2 charts).
14. that in the event of an intentionally withheld or refused drug administration by the patient or carer or guardian (in the case of a child), an **immediate**, clear and accurate record must be made. This must be discussed with the responsible medical practitioner (or on-call doctor). Also refer to 5.1.6.3.
15. Medicines must never be left unattended, and must be securely stored when not in use.

The administration of medicinal products must be guided by the relevant nursing procedures in the current edition of the Royal Marsden Manual of Clinical Nursing Procedures, (the Royal Marsden can be accessed via the HDUHB website on the Health Board Intranet or on www.blackwellroyalmarsdenmanual.com) and the HDUHB's policies/training manuals in relation to use of infusion devices, syringe drivers, dedicated pumps, PCA and epidural devices and the NPSA Safe Medication Practice Programme on Injectables (2007/8) http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812

5.1 Persons who are authorised to administer medicines

All health professionals set out below and deemed competent to administer medicines can administer medicines on the authorisation of a medical practitioner, dental officer, and non medical prescriber. Patient group directions only authorise those named within the PGD to administer the particular medicine. For in-patients they must be prescribed on an approved computer prescribing system or the appropriate hand-written prescription chart or stationery approved under a model of service. It is recommended that medicines to be administered orally and by injection should be prepared and given at separate times.

5.1.1 Nurses and Midwives authorised to administer medicines

All nurses and midwives with current registration with the NMC. Agency nurses must have received appropriate training and assessment by the agency providing the nurse and the agency must be able to demonstrate this to the UHB. This evidence may be confirmed following the agency checklist.

5.1.2 Non-nursing staff authorised to administer medicines

- Registered Medical Practitioners and Dentists
- Registered Operating Department Practitioners with the appropriate training and assessment of competence
- After appropriate training and competence assessment specific medicines may be given by all registered healthcare professionals and healthcare support workers who have demonstrated competency as set out in the All Wales Guidance for Health Boards/Trusts

and Social Care Providers in Respect of Medicines and Care Support Workers. Healthcare support workers may, as set out in the All Wales Minimum Standards for Immunisation training for HCSWs, administer vaccinations **only**, as part of a PSD, within a GP practice. In addition Health care support workers may administer medication following delegation by a registered healthcare professional provided they have completed Level 3 training and have been assessed as competent. Examples of these areas that support this practice include outpatients departments, community learning disability services and HCSW's who have been trained and assessed in cannulation to administer a flush of 0.9% sodium chloride using a pre-filled syringe only of up to 5mls to clear the catheter of residual blood and check positioning. If a needle free connector is to be attached immediately post cannula insertion the pre filled syringe can also be used to prime the extension set prior to attachment [MMG Dec 2017].

- On completion of an initial and recurring annual assessment, and the relevant Level 3 qualification or above on the Credit and Qualifications Framework for Wales (CQFW)3, or demonstrable equivalent training, the assistant practitioner (Band 4) can accept delegated responsibility for medicines management from a registered nurse to support an individual with their medicines [MMOG & SNMT Nov 2020].

Student nurses / student midwives administration of medicines

Students can administer medicines using a range of routes however, students must never administer or supply medicinal products without direct supervision of a registered healthcare professional

A registered healthcare professional is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the student nurse/midwife is competent to carry out the task.

For more detailed information refer to the Administration of medicines by Student Nurses/student midwives (Feb 2020)
http://howis.wales.nhs.uk/sitesplus/documents/862/Administration%20of%20Medicines%20by%20Student%20nurses%20%20midwives.pdf

Community settings Student nurses may be the 2nd person involved in the process of checking CD's.

5.1.3 Minimising interruptions during medication rounds within ward environments

- Whilst carrying out the medicines round, staff are expected NOT to be interrupted for other routine duties including other ward rounds, telephone calls etc.
- To ensure safe and effective administration of medication to patients within the ward environment all staff, undertaking the medicines round, may wear a red tabard indicating that the medicines round is in progress and that they should not be interrupted unless as a matter of priority.
- Tabards alone cannot be expected to reduce interruptions; they are one tool to support nurses having protected time to undertaken medicines administration.
- If a telephone call is taken or an interruption occurs which requires the attention of the nurse wearing the tabard, then the member of staff, if unable to deal with the query directly, will be expected to take a message for a reply at a more convenient opportunity.
- Contact details of the caller / enquiry, should be taken and an explanation offered that the nurse will contact them when the medicines round has been completed.
- In the event of an emergency / immediate need for a response, the nurse undertaking the medicines round, before responding to the query, will ensure that the medication trolley is locked and stored away securely in the treatment room, ensure that the patients drug locker is locked and any medication that has been administered has been signed for.
- If appropriate, a Datix should be completed giving reasons for the interruption.

5.1.4 Administration requiring two registered healthcare professionals

It is recognised that all healthcare professionals can make human errors. For the following types of medicinal products an independent full process two person check is recommended practice to reduce the risk of adverse drug events. In HDUHB this is required in the following

processes

- All medicines administered to a child less than 16 years of age.
- Controlled Drugs see 7.9
- Cytotoxic medicines
- All intravenous, epidural injections and infusions.
- Where a calculation is involved
- For the **SUBCUTANEOUS (S/C)** administration of all **High Risk medicines**. These are defined as insulin, methotrexate, heparin, low molecular weight heparin (treatment doses only*), medicines with a complex preparation method (e.g. IV liposomal amphotericin), immunoglobulins, anti-arrhythmic drugs and thrombolytic drugs.
- All intravenous or subcutaneous infusions that are initiated or where the dose and/or rate is changed require 2 Registered Nurses to check and 2 Registered Nurses to administer the medicine or fluids. The checking of the administration of any fluid being administered via an infusion device, gravity or drip sets of any description includes a check/confirmation of the accuracy of the settings on the infusion device. Both Registered Nurses must sign the prescription chart (divide the box to include both signatures ) and the Infusion Monitoring chart.
- Both Registered Nurses and/or Registered Healthcare Professional must sign the prescription chart in these circumstances so that accountability is clear.
- In addition, when any IV or S/C **infusion is** set up, an infusion bag is replaced or the rate of the infusion is changed, **two** Registered Nurses are **always** required for both the checking and the administration of the infusion. The administration check must include verifying the infusion rate set on the device against the prescription chart. The infusion rate set must be recorded on the Infusion Monitoring Chart. To demonstrate accountability, two signatures are required on **both** the prescription chart and the Infusion Monitoring Chart.

(* Pre-filled syringes of LMWH (for example, tinzaparin 3,500 units or 4,500 units) for prophylaxis S/C are considered ‘Bolus doses of low risk medications (not administered using an infusion device)’, see below for checking requirements.

- **Bolus doses of high risk medications (not administered using an infusion device)** will require 2 Registered Nurses or, if applicable, a Registered Nurse and a 2nd Registered Healthcare Professional (Doctor, Pharmacist, ODP) to check the preparation **and 2 Registered Nurses/Healthcare Professionals** to administer the medicine. The second Registered Healthcare professional **must** carry out the checks as outlined in **Section 5.1.6.2** (i.e. is certain of the identity of the patient, check the patient's allergy and so forth). The second Registered Healthcare Professional will be required to remain for the entire administration of the bolus dose of the medicine. Both Registered Healthcare Professionals must sign the prescription chart.

By definition the independent check must not be controlled or influenced by any other person. The independent check must include that the medicine matches the prescription, that the correct strength, dose and form has been selected, including any calculations that must be clearly documented, that the product has not expired and the patient is not allergic to the particular medicine. The process must include a check of the patient's identity at the bedside and the administration or start of the administration. Accountability for the preparation and administration remains with both professionals.

5.1.4 Exclusions for double checks:

(i) Controlled Drugs in Theatre where:

- Within Theatres only, the preparation of any Controlled Drug must be checked by the anaesthetist, or other medical practitioner, and another appropriately trained person, e.g. a registered nurse or an ODP
- If a 2nd dose of that previously prepared and checked drug is required, the anaesthetist, or other medical practitioner, may administer it without needing to be observed by a second person. This is in order to maintain the optimum anaesthesia or analgesia for the patient as required.
- The anaesthetist or other medical practitioner is responsible for documenting the name of the drug and dose given on the anaesthetic chart, on the All Wales In-patient Medication Administration Record, or elsewhere in the body of the notes.
- The anaesthetist, or other medical practitioner, is personally responsible for safely disposing of any unused drug in an open ampoule or syringe and for returning any

unopened ampoules to the nurse or ODP responsible for the Controlled Drugs at that time.

- Critical Care: The use of dose ranges to permit the titration of medicine dose against clinical response should comply with predetermined parameters that are already prescribed on the medication chart.

(ii) Community Services

Community nurses may administer IV drugs as prescribed by the appropriate medical (GP or hospital doctor) or non-independent prescriber without a second check.

However independent checking is required for any medicine, which the primary registered healthcare professional, who is administering, is not familiar; particular care must be taken with medicines that are to be administered parenterally.

(iii) Patient Group Directions

Where a Patient Group Direction defines the circumstances, training and competencies required administration, following a single registered professional check, is permitted. This clause covers the administration of LMX (lidocaine 4% cream by a single registered nurse under a Patient Group Direction [PGD subgroup July 2021].

Any exemptions to these requirements can only be authorised by Medicines Management Operational Group (MMOG) MMOG following a full risk-assessment and approval of any mitigation required to minimise patient safety risks. Approved special authorisations can be viewed here: http://howis.wales.nhs.uk/sitesplus/documents/862/268-AppV-TyBrynSpecialAuthorisationforExemptionFromDoubleCheckingInsulinAdmin1.pdf

5.1.5 In the absence of a registered second checker

In certain clinical areas, and exceptional circumstances*, if a second registrant is not available to confirm a second check, MMOG can approve a process for a member of staff e.g. healthcare support worker, to undergo suitable preparation and assessment to act as a second check.

N.B. Student nurses/midwives or student operating department practitioners, cannot act as a second check for preparation and administration of medicines.

***** Exceptional circumstances are defined as when all alternative processes (e.g. request for additional bank/agency staff, or overtime for existing staff) have been undertaken and are unable to provide the required registered staff to provide a second check.

5.1.6 Selection and administration of medicines

5.1.6.1 Selection of medicines

When a healthcare professional is selecting a medicine for administration it is vital that the process results in the correct medicine to be given in the prescribed dose by the prescribed route and at the required time.

To support this process all medicines supplied from the pharmacy will be labeled by the original manufacturer or by the pharmacy in a manner that will allow identification of the medicine contents against the patient's prescription.

If the pharmacy repackages an original manufacturer pack, the pharmacy label will then identify the contents of the dispensed container. If the container is a box containing a strip of tablets it is good practice to confirm identity marked on the label with the tablet/capsule name and strength printed on the strip. This is necessary to ensure that a wrong strip has not been returned to another container box at a previous administration time. If the name and strength of a medicine is not clearly printed on a medicine strip, or a label seek advice from another healthcare professional. If there is any ambiguity it is advisable to check with the local pharmacy to confirm identity of the medicine.

Monitored Dose Systems (MDS) or medication compliance aids (MCA) ('Dosette Boxes')

Medicines can be administered from an MCA belonging to the patient if the healthcare professional can positively identify the medicine before administration.

5.1.6.2 Safe Administration of medicines

It is the responsibility of the Ward Sister / Charge Nurse to ensure that standards of medicines practice are adhered to and ensure that the person administering medicines has received the relevant training and education to enable them to safely administer medicines.

To ensure medicines are safely administered the administrator must-

- Know the therapeutic use of the medicine to be administered, its normal dose, side effects, precautions, contra-indications and monitoring requirements. In the event that the administrator is not aware of this information, they must be able to locate the information before administration. (Sources include BNF and Medusa).
- Be aware of the patients care plan, the patient's condition, in particular with regards to their medication needs.
- Be alert to potential errors in prescribing or dispensing.
- Contact the prescriber without delay if :-
  - Contraindications to the medicine are identified
  - The patient develops a reaction to the medicine
  - Assessment of the patient indicates that the medicine may no longer be suitable for the patient
  - If the prescription is not clear (e.g. illegible or incomplete).

5.1.6.3 Non- administration of medicines.

In some circumstances it may be appropriate for the administrator not to administer the prescribed medicine, either because they are unable to administer (e.g. patient refuses) or because the administrator feels there is an appropriate reason to withhold (e.g. with holding anti-hypertensive medication if the patient's blood pressure is too low). In the event of the non administration of medicines the administrator must annotate the medicines administration chart with the appropriate policy i.e.

X – Prescribers request.
2 - Patient not on ward.
3 – Patient unable to receive/no access.
4 - Patient refused.
5 – Medicines unavailable.
6 - See notes.
7 – self administration (Mental health)

It is the administrator's responsibility to inform the patient's medical team, or the ''on call' medical team, that the medicine has not been administered, the reasons why, and to discuss the need for alternative action. The patient's condition must be taken into account to determine the urgency with which this information needs to be passed onto the medical team. Discussion with the pharmacist may facilitate this.

A list of medicines whose administration is considered time critical can be found at: 268-AppU-HDUHBCriticalMedicinesListPoster1.pdf (wales.nhs.uk)

If for any reason it is not possible to administer the medicine and the healthcare professional has any concerns they should seek further advice, from the prescriber, pharmacy or the BNF, especially where the prescription is for administration every four hours or more frequently.

5.1.6.4 Administration of medicines to adult with swallowing difficulties

Not all tablets and capsules can be crushed or opened as the clinical effect of the medicine may be altered or adverse reactions occur. The Pharmacy Department must be contacted for advice on individual products. The crushing of tablets or opening of capsules and subsequent administration must be carried by the registered healthcare professional only after receiving advice from the Pharmacy Department. It should be noted that crushing or opening capsules might affect the licensing status of the product. Whatever action is decided upon must be recorded on the patient's chart.

Refer to the All Wales Medicines Strategy Group guidance on the following link:

Primary Care Guidance: Prescribing medicines for adults who are unable to swallow oral solid dosage forms. Prescribing medicines for adults who are unable to swallow oral solid dosage forms - All Wales Medicines Strategy Group (nhs.wales)

The HDUHB Enteral Feeding Policy for Adults with Operational Guidelines provides procedures and information on the administration of medicines via feeding tubes and can be accessed at: 331-EnteralFeedingPolicyforAdultsincOperationalGuidelines-ext31.3.20.pdf (wales.nhs.uk)

5.1.6.4.1 Enteral Syringes

Sterile purple enteral syringes must be used for the administration of all medication to be given via the enteral route (including patients who have nasogastric, gastrostomy or jejunostomy tubes) where a 5ml spoon or graduated measuring cup cannot be used (NPSA: Promoting safer measurement and administration of liquid medicines via oral and other enteral routes). The HDUHB Enteral Feeding Policy for Adults with Operational Guidelines gives further advice and

can be accessed at: 331-EnteralFeedingPolicyforAdultsincOperationalGuidelines-ext31.3.20.pdf (wales.nhs.uk)

5.1.7 Administering cytotoxic medication

Cytotoxic chemotherapy can only be administered to patients by those specific health professionals authorised to administer cytotoxic chemotherapy by HDUHB**.**

5.2 Administration via the intravenous route

Practitioners (including doctors, dentists, nurses and other health professions) are permitted to administer intravenous medicines provided they have received UHB delivered or endorsed appropriate education, training and assessment of competence. All intravenous medicines and fluids should be prepared and administered in accordance with HDUHB approved local procedures (See Part 6). Practitioners can only administer intravenous cytotoxic chemotherapy as set out in Part 6.

5.3 Consent and Covert administration

5.3.1 Consent

Every adult must be presumed to be able to consent to receive or to refuse medication unless there are reasons to doubt the person's mental capacity for this decision.

Wherever such circumstances arise the capacity of the patient must be formally assessed to determine his / her clinical condition at that precise time and the outcomes recorded in the health record. It must be borne in mind that capacity is variable and can change from day to day. A person will lack the necessary mental capacity to consent to or refuse medication if the assessment shows that they have an impairment or disturbance of the mind or brain which prevents the person from being able to do any of the following:

- to understand the nature and consequences of accepting or refusing the medication
- to retain the information about the medication provided by the treating staff long enough to make a decision
- to weigh up the information about the medication as part of the process of arriving at a decision.

- to communicate their decision in some way

Where adult patients are capable of giving or withholding consent, no medication should be given without their agreement since failure to do so may amount to criminal battery, civil trespass, or a breach of their human rights. **The exception to this principle applies to treatment authorised under Part IV of the Mental Health Act (1983)** (also see part.15 of Health Board Policy No: 008, 'Policy for Consent to Examination or Treatment' 008-HDUHBConsenttoExaminationorTreatmentPolicyv4.pdf (wales.nhs.uk)

Children under the age of 16 years are able to consent to or refuse medication providing they are have sufficient maturity and understanding to do so (known as Gillick competence) but the refusal of a competent child may be overridden by those with parental responsibility.

Young people aged 16 or 17 years are presumed to be able to consent for themselves in the same way as an adult. The refusal of a young person can also be over-ridden by a person with parental responsibility. However, the GMC Guidance ('0-18 years: guidance for all doctors', 2018) acknowledges this area of law as complex and suggests that, where a competent young person refuses medication the treating doctor thinks is in their best interests, legal advice is sought. In exceptional circumstances this may involve seeking an order from the court

The wishes of patients (adults) /parents/guardians who have the necessary competence to make a decision but refuse to consent to receive medication must be respected, even if this could have an adverse effect upon their condition.

5.3.2 Covert administration of Medicines

5.3.2.1 What is covert medication and when can it be used?

Covert medication is medicine which is administered in a disguised format, usually hidden in food or drink. Covert measures can only be used:

- where the patient lacks capacity to make decisions about their medication (adult patients [aged 18+] with capacity can refuse treatment and this refusal must be respected);
- in relation to essential medication;

- as a last resort, where failure to take essential medication would lead to a risk of serious harm to health or death.

Covert administration of medications must not develop into a routine practice but should only be undertaken following a thorough documented individual risk and care needs assessment of the patient.

It is essential that Hywel Dda UHB staff act in such a way as to protect the patient's human rights. District Judge Bellamy (AG v Agnor [2016] EWCOP37) argued that patients need proper safeguards to protect them against arbitrary decisions to use covert medication: 'Covert medication is a serious interference with a person's autonomy and right to self-determination under Article 8 (right to a private and family life) [European Convention on Human Rights 1950]'. Bellamy went on to endorse the following guidelines:

Medication should only be administered covertly in exceptional circumstances;

- There must be a best interest decision which includes the relevant health professionals and the person's family members;
- This must be recorded in the medical/care home record
- There must be an agreed management plan including details of how it is to be reviewed;
- If there is no agreement then there should be an immediate application to Court.

5.3.2.2 Steps required before resorting to covert measures

Every effort should be made to avoid the use of covert medication. The following are some of the steps that should be taken prior to reaching a decision that covert measures are necessary:

- Try to find out why the patient is refusing their medication and whether this is something that can be resolved;
- Talk to the patient to ascertain if they have any wishes, feelings, beliefs or values in relation to taking medication;
- Ensure that all appropriate non-covert means of encouraging the patient to take their medication have been exhausted e.g. provide the patient with information, explanation and encouragement, preferably by the team member who has the best rapport with the

patient and, where appropriate, with support from the patient's family, advocate or carers.

- Consult with relevant colleagues e.g. a pharmacist in relation to alternative formulations / a speech and language therapist in case difficulty swallowing is causing the patient to refuse their medication;
- Where a patient has been admitted from another care setting and is already receiving essential medication covertly, it is essential that this decision is reviewed as soon as possible during their hospital stay.

5.3.2.3 Best Interests decision

Once a decision is made to explore the use of covert medication, the prescriber must make a decision in the best interests of the patient (with the support of the multidisciplinary team). Prior to making their decision the Prescriber must consult with the patient and those close to the patient (e.g. family, friends, carer etc.), where it is practicable and appropriate, in order to ascertain the patient's wishes, feelings and likely views. If there is no-one appropriate to consult and the decision to give or withhold essential medication could have a serious impact on the patient then an Independent Mental Capacity Advocate (IMCA) should be instructed.

A pharmacist must support the decision making process, since crushing medication or adding it to food and drink can alter its chemical properties and thereby affect its performance.

The pharmacists input and the prescriber's decision making must be recorded on the form 'Covert medication for patients aged 16 and over: Record of Best Interests Decision'.
which has been developed for use in Secondary Care (Acute, Community Hospitals, Mental Health & Learning Disabilities)

If agreement cannot be reached about the decision the prescriber should consider holding a 'best interests' meeting or attempting some form of mediation. They should also seek advice from the Mental Capacity Team or the Legal Services Department. If the disagreement cannot be resolved it may be necessary to ask the Court of Protection to decide what is in the patient's best interests.

If there is a health and welfare Lasting Power of Attorney or a Court Appointed Deputy with the

authority to make a decision regarding use of covert medication, then the prescriber and pharmacist must support this person in reaching a decision. This must be documented on the above covert medication form.

Part H of the covert medication form must be completed with the name of the essential medications and the means by which they are to be covertly administered. This page of the form must then be photocopied and securely attached to the medicine chart so that nursing staff are aware of which medicines can be given covertly and how this should be done. The complete form must be filed in the patient's medical record.

5.3.2.4 Urgent decisions

In an emergency situation (or out of hours, when treatment cannot wait) covert essential medication can be given immediately, in the best interests of the patient. The continued need for covert administration must then be considered as soon as possible and the 'Covert medication for patients aged 16 and over: Record of Best Interests Decision' form completed.

5.3.2.5 Deprivation of liberty

District Judge Bellamy noted that use of covert medication amounts to continuous supervision and control and so is relevant to the existence of a deprivation of liberty. This means that a Deprivation of Liberty Safeguards (DoLS) referral must be made if covert medication has been agreed. If covert medication is introduced or changed when the patient is already subject to a DoLS authorisation, the DoLS Team must be informed. If a DoLS is authorised, any conditions relating to use of covert medication need to be checked in case they specify a review period.

5.3.2.6 Review

Agreed covert medications must be reviewed within the time period specified in Part H of the form, particularly where there is evidence of temporary or fluctuating capacity. [For mental health patients who are subject to the Mental Health (Wales) Measure Care and Treatment Programme Approach (CTP) re-assessment would take place as a minimum at each review date or between reviews if necessary].

The covert medication review should include consideration of the following:

- Does the patient still lack capacity? (If the patient regains decision making capacity then the use of covert medication must cease with immediate effect)
- Is the medication still essential?
- Is it still in the patient's best interests to have covert medication?
- Are there any additional essential medications that need to be added to the agreed list?
- Are there any unforeseen consequences of using covert medication?

5.3.2.7 Issues to consider

- If the patient has a valid and applicable Advance Decision to Refuse Treatment which refuses the essential medication in question, or which refuses the use of covert medication, then this must be followed.
- If the patient is refusing essential medication for a mental disorder and covert measures are required, the prescriber must consider whether they need to be assessed for detention under the Mental Health Act.
- Where patients are lawfully detained under the Mental Health Act (s.28 MCA & Part 4 MHA [but not Part 4a]), some forms of treatment given against the person's wishes are authorised by law. In these cases the appropriate MHA process must be adhered to and documented accurately. The 'Covert medication for patients aged 16 and over: Record of best interests decision' form does not need to be used.

5.3.2.8 Discharge

A copy of the completed 'Covert medication for patients aged 16 and over: Record of best interests decision' form must follow the patient between hospital and home/care home.

5.3.2.9 Care Homes

A Covert Administration of Oral Medication Plan Form has been developed for use in Care Homes in Primary Care.

5.4 Self administration

Hywel Dda UHB is committed to the continued improvement of patient care. Self-administration is regarded as the model for best practice in medicines management for hospitals. It provides substantial benefits for patients and hospitals. The term 'self-administration' for the purpose of this policy includes administration by a parent/guardian/carer/relative or other non-healthcare professional. All medicinal products administered **must be prescribed before administration.** The opportunity for self- and/or supervised administration of medicines allows:

- Improved opportunity to clarify regular medication and inform the therapeutic management plan.
- Difficulties with self-administration of medicines to be identified during the hospital stay.
- Improved opportunity to educate patients on their drug treatment
- Increased patient understanding and reduced potential for re-admission due to medication error.

Self-administration facilitates and supports the appropriate use of patients own medicines and self administration whilst in hospital. The aims of the self-administration system are:

- To introduce the concept of self-administration to the patient, medical, nursing, pharmacy and ward staff.
- Allow patients who are able and willing to continue to take their own medication while in hospital.
- To provide a method of assessing patients for self-administration.
- To demonstrate how the guidelines should be used, implemented and reviewed.
- To demonstrate improved communication between doctors, nurses, ward pharmacists and patients.
- To ensure that patients understand their medication regime and manage their own medication prior to discharge from hospital into primary care. This leads to a safer transfer of medication regime between secondary and primary care

Utilising patients own medicines whilst in hospital can help to reduce prescribing errors as well as avoiding duplication of supply. Costs are kept to a minimum and waste reduced. People at home usually administer their own medicines. With the appropriate assessment it is logical for

patients to have access to and administer their own medicines. Nurses play a major part in education of these patients to ensure the safe and effective use of the medicines, to allow self medication in hospital to develop further. For the purposes of this procedure, the word medicine describes any medication that the patient has already used or, with appropriate support would reasonably be expected to use at home.

Storage of medicines for self-administration on wards

Supplies of oral medication for all patients are kept in a locked cabinet attached to their bedside locker. Each cabinet will have a lock operated by a single key or key policy. A master key/ master policy system will be in place for nurse administration/ stock renewal etc.

It is the responsibility of the registered nurse to remove medicines no longer required from the patient's medicine cabinet.

Overall responsibility for the safety and security of patient medicines cabinets and medicine cupboard keys/procedures lies with the ward manager.

If keys are lost or the policy system is breached, every effort must be made to ensure the system remains secure. If this is not achievable this must be reported via the clinical incident process.

Staff Education

It is the responsibility of the Sister/Ward Manager, to ensure that the registered staff working in their ward have been appropriately trained to assess patients to self administer their own medicines. .

It is the responsibility of the registrant to identify to the Ward Sister/Charge Nurse/Clinical Lead if they require training or updates. A register of staff who have received training should

All patients who are identified as suitable to self administer must be assessed using the identified assessment chart.. The assessment process ensures that the patient is placed at the right level and this minimises risks associated with self administration.

- Level 2: Patient Administration under Supervision.
  The patient administers medicines but under the supervision of the registrant. The patient does not have access to the key. The registrant initials the drug chart as

appropriate at time of administration.

- Level 3: Patient Administration without Supervision.
  The patient is happy to self administer their medicines, signs consent and continues to administer their own medicines without supervision and is given a key to their cabinet. The registrant is responsible for checking that the patient is aware of any changes to regime and is compliant and happy to continue. The registrant is required to sign the prescription chart at least once in 24 hours to demonstrate this has been done.

The registrant is responsible for acting upon a patients changing condition and move the patient to the appropriate level – NB Patients can move up or down a level.

Patient Education

The NMC state that patient education is the professional responsibility of the nurse, in conjunction with the pharmacy and medical team. All patients must receive information regarding correct use of their medicines before commencing a self administration scheme and prior to discharge. Knowledge should be checked and reinforced throughout the process. The information can be verbal, written and where appropriate a combination of both, it should include

- The name of the medicine.
- The purpose of the medicine.
- The dose and frequency of the medicine.
- Any special instructions
- Possible side effects.
- Duration of treatment.

Transferring Patients

Lockers with medicines cabinets attached should not be transferred to another ward as the assigned master keys for the receiving ward may be different.

When a patient is moved to another ward please follow the following steps:-

- The registrant must remove all the medicines from the patient's medicine cabinet.

- The medicines should be placed in a pharmacy green bag and the nursing transfer checklist section on medicines completed.
- The medicines should be taken with the patient and given to the registrant receiving the patient on the new ward.
- The medicines should then be placed in the patient's medicine cabinet if a POMS ward, or in the ward medicines trolley.

The Self administration guidance can be found at :
http://howis.wales.nhs.uk/sitesplus/documents/862/Self%20administration%20Appendix%20J%202017%20Update.pdf and
http://howis.wales.nhs.uk/sitesplus/documents/862/Addendum%20Self-Administration%20Insulin%20v%201%20FInal.pdf

5.5 Non-availability of medicines

If the pharmacy department is advised by a supplier of the unavailability of a medicine it will communicate this information to medical and nursing staff as soon as possible. The pharmacy department will seek availability of any alternative that could be used. It is helpful to medicine users to know if the supply interruption is short or long term so that all avenues can be considered for temporary or long term therapeutic options.

Medication is an essential part of a patient's treatment and it is important that they receive their prescribed medication in a timely manner. This Policy also covers those instances when the medication is not on the ward for administration at that appropriate time.

5.5.1 Non availability during pharmacy department opening hours

When medicines are newly prescribed for any patient, ward staff should consider if the medicines are on the ward stock list or not. If not, then they should bring this fact to the attention of the pharmacy staff providing services to the ward. If the item is urgently required, and no pharmacy staff are available, then ward staff should order the medicine from the pharmacy dept by using the appropriate medicines requisition form or local hospital pharmacy ordering system.

Newly admitted patients should have their medicines reconciled by a member of the pharmacy staff, which will include an assessment of which medicines need to be supplied.

If any medicine is unavailable from the pharmacy department, then it is the responsibility of the

pharmacist to inform the ward staff of that fact, and to discuss the options e.g. wait for the original patient's medication to be brought into the hospital or arrange for a prescription change to a formulary medicine.

5.5.2 Non availability when pharmacy is closed

If a medicine to be administered to a patient is unavailable, then a decision must be made by the staff looking after that patient as to the urgency and necessity of the patient having that medication. If a decision is made that the medication is required to be given before pharmacy reopens, then the ward staff must ensure that every effort is made to find an alternative way of obtaining it. Medications which are likely to be urgent are:

- Intravenous Medicines
- Medicines to treat acute symptoms e.g. chest pain and agitation
- Antibiotics
- Steroids
- Anticonvulsants

In the event that a prescribed medicine is unavailable on the ward (non-stock item and/or individual patients' drugs unsuitable for re-use) the following should first be checked:

- patients individual medication locker
- nurse's station and treatment room to see if any patient's own medicine has not been put away

If the above is unsuccessful, then every effort must be made to obtain the medicine from an alternative source:

- emergency drug cupboard
- inter ward borrowing
- asking a relative to bring the item from home
- Emergency Duty pharmacy service

For the community hospitals a WP10HP can be written and dispensed locally, or in exceptional circumstances, the Emergency Duty pharmacist may be contacted in accordance with local arrangements.

5.5.2.1 Emergency Drug Cupboard

A range of emergency stock is held in Bronglais General Hospital, Glangwili General Hospital, Prince Philip Hospital, St David's Hospital & Withybush General Hospital. The contents of the emergency cupboard is determined locally and reviewed regularly by the hospital pharmacy based on ward stocks, common emergencies, and the antidote list for poisoning and previous out-of-hours requests. The stock can be accessed by the Site Nurse / Night Nurse Practitioner / On-call Pharmacist. Full packs are to be taken from the emergency medicines room/cupboard and a record of what has been taken is to be recorded in the Emergency Stock File (held in the emergency cupboard). For personal safety, the member of staff accessing the emergency cupboard must be accompanied by another employee, wherever possible.

5.5.2.2 Inter ward borrowing

If a medicine has to be obtained from another ward (outside normal pharmacy working hours only) the registered Healthcare Professional requiring the medicine must take the patient's prescription chart to the ward loaning the item and complete an Inter Ward Transfer Form. Accessed at:
http://howis.wales.nhs.uk/sitesplus/documents/862/Inter%20Ward%20Transfer%20Form.pdf
The form is then sent to the Pharmacy department for replacement of the stock borrowed. Pharmacy will retain the record.

5.6 Omitted Doses

All patients must receive their medication as prescribed. An omitted dose can potentially cause patients harm through deterioration of their condition, and must be acted upon as a priority. If a dose has already been missed without an appropriately documented reason ('unavailable' is not considered an appropriate reason) it should be considered a serious incident.
If a patient has an omitted dose after all the above has been followed then a code '5' ('drug not available') should be recorded in the patient notes, the relevant clinical team contacted and a Datix incident submitted.

Note: where the on-call pharmacist has been contacted and has advised the nurse that there is no clinical risk if the dose is omitted until supplies can be arranged (e.g. calcium and vitamin D over the weekend) then this does **not** require a Datix incident submission

Medication safety audits are carried out on every ward each month. The SOP for this process can be accessed here: http://howis.wales.nhs.uk/sitesplus/documents/862/268-AppS-MedicinesSafetyAuditSOP1.pdf

5.7 Administration error – see 9.2

If a medicine is administered in error, the person administering the medicine must report the incident to the medical team responsible for the patient's care so that the situation can be assessed and determine that any appropriate medical action is taken. The nursing or medical team will inform the patient of the incident. The person administering the medicine must report the incident to their line manager. A clinical incident entry on Datix must be completed.

5.8 Administration of Medication under Section 136 Mental Health Act in Sec136 suites

The administration of medicines to patients admitted under Section 136 of the Mental Health Act held in Sec 136 suites is detailed in Appendix: Guidance for Medication use in instances of Section 136 which can be found at: http://howis.wales.nhs.uk/sitesplus/documents/862/Section%20136%20document%20Final%20Nov%202019.pdf

5.9 Administration of Depot Antipsychotic Injections

Detailed guidance on the management and administration of depot antipsychotic injections both in Mental Health and Learning Disability wards and community and general medical or surgical wards can be found in the 868 Management and Administration of Depot Antipsychotic Injections Procedure

Part 6 - Administration of Intravenous Medicines

The National Patient Safety Agency (NPSA) issued guidelines to promote the safer use of injectable medicines resulting from reports made to NPSA of errors and incidents in the use of injectable medicines. Developments in intravenous medicines have introduced precise reconstitution and administration techniques to ensure maximum efficiency of the medicine and minimise harm to the patient. The essential theme of these guidelines is that all staff involved with intravenous medication should be trained and sufficiently knowledgeable and competent in dealing with intravenous medication. The staff should also have guidelines, information and support in respect of the medication to ensure the correct prescribing, preparation, administration and monitoring of injectable medication at all times.

Epidural injections are clearly not for intravenous use, but the principles are also applied to training, prescribing, preparation, labeling and administration of IV medicines apply.

6.1 Professional responsibilities and accountability

Practitioners holding registration with their professional regulatory body are accountable for their actions and omissions. When administering intravenous medication staff must exercise their professional judgment as to their knowledge and experience in dealing with each individual medication. Where an individual member of staff is unfamiliar with a particular medicine, and/or has little or limited experience in administration of the medicine the individual must refer back to the prescriber or the pharmacy department for more detailed information. This information is also available from the electronic source The Injectable Medicines Guide (Medusa). Practice set out within this policy will apply to all practitioners/ staff who are involved in the prescribing, administration and safe handling of intravenous medication within the Health Board.

Each ward must ensure that all staff that are or may be involved in intravenous medication are:

- Able to access all policies, procedures and guidelines approved by HDUHB for the

use of intravenous medication.

- Given the appropriate level of training, retraining and competence assessment which must be recorded for their involvement with intravenous medication.
- Given information as to any medicine or device alert concerning intravenous medication, device or consumable which may be used in administering intravenous or parenteral medication within HDUHB.
- Staff that administer cytotoxic intravenous chemotherapy and cytotoxic medication by other routes must demonstrate that they have undertaken approved training.

6.2 Training and competency for IV and other routes of parenteral administration

All staff involved in the use of intravenous and other routes of parenteral medication must be trained and competent in all roles that they may undertake concerning parenteral medication. Within HDUHB training programmes are in place to ensure that all aspects of intravenous medication usage are covered to include:

- Prescribing
- Preparation (including calculations)
- Labeling
- Administration
- Checks involved throughout the process (who and when)
- Devices used for administration
- Monitoring requirements
- Disposal of waste material
- Risks of using intravenous medication and how to minimize them
- Standard information sources available to Health Board staff concerning intravenous medication.

HDUHB, through its Learning and Education Department, has set up a scheme to ensure that all staff involved in any aspect of intravenous medication has undergone the training and is deemed competent. The names of those deemed competent can be

recorded on a database, but as a minimum will be recorded in the staff member's personal file. As part of the All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal a review of competence will take place every three years and where there has been a practice gap of 12 months or more.

Competence for administration of adult chemotherapy will be set out in standard operational procedures of the HDUHB. Administration of intravenous chemotherapy is limited to professionals who have completed the identified training and demonstrated competence.

To achieve their training competencies Student Nurses may check, and prepare an intravenous medicine **under direct supervision at all times.** Student Nurses are not allowed to connect or administer an intravenous medicine**.** The registered nurse responsible for the patient receiving the medication retains the responsibility and accountability for the safe preparation and administration of the medicine. A second competent registrant is required to check the preparation, and where necessary the setup and patient checks in accordance with section 5.1.4 and 5.1.5

6.3 Prescribing intravenous medication

Medicines should only be given by the intravenous route when the practicality and appropriateness of other routes has been excluded. The use of this route should be regularly reviewed in favour of switching to oral administration (or another route) as soon as clinically appropriate. When two or more patient medication records (prescription charts) are in use, it is essential that they are cross referenced so that practitioners are aware of all prescribed medicines. To ensure safe practice prescriptions for intravenous medication must specify the following:

- The allergy status of the patient
- Patient's name
- Prescribers signature
- The medication using approved name (in certain circumstances the brand and formulation

- The dose and frequency
- Date of initiation and route of administration
- Concentration or total quantity of medication in the final infusion container or syringe
- Name and volume of diluents and/ or infusion fluid to be used
- Rate and duration of administration
- Stability information to determine expiry date of the final product
- Type of pump or device number being used
- For children the age and weight should be specified
- Date for treatment review
- What clinical monitoring should take place, how often and for how long, (See product characteristics and e- Injectable Medicines Guide)

The use of a flush (usually sodium chloride 0.9%), is considered an essential part of cannula care and intravenous medication/fluid administration and should be prescribed at the same time the prescription of intravenous medication/fluid is written.

6.4 Storage of intravenous medication

The storage of intravenous and other parenteral medication (except large volume infusions) stocked on a ward or department must be in the appropriate locked pharmacy cupboard or fridge. Any medication issued for individual patients that require special storage will have this highlighted on the pharmacy label.

6.5 Preparation of intravenous medication

Whenever possible ready prepared injections, infusions or Centralised Intravenous Additive Service products (CIVAS) should be used. If any extra manipulation or medication addition is required then the staff involved must ensure that they are familiar and competent to carry out the preparation of this particular intravenous medication. Preparation and administration requires two registrants, see section 5.1.3

- Read all the prescription details carefully and confirm that they relate to the patient to be treated
- Confirm that the details on the prescription are correct e.g. dosage, diluents/s. concentration rate of administration and that the patient is not allergic to the medicine or any of its components.
- Ensure that the area to be used for the preparation is clean and clear of clutter. Ideally this should be a dedicated area just for the preparation of intravenous medication
- Assemble all the equipment and infusion devices required including flushes if they are required. Process the preparation using a Aseptic Non-Touch Technique (ANTT), i.e. avoid touching areas where bacterial contamination may be introduced e.g. syringe tips, needles and vial tops.
- Prepare the label (see below)
- Beware of confusion due to similar names and/ or packaging, by reading the labels carefully.
- Check expiry date of all the materials and medication used
- Check for damage to containers, vials, ampoules and packaging
- Confirm that the materials have been stored correctly
- Complete any calculations. These should be written in the patient's notes and checked by an independent practitioner who is competent in the administration of that intravenous medication.
- Hands must be cleaned according to the control of infection guidelines
- If a giving set is required it should be attached using the technique appropriate for the type of container. The line must be primed in accordance with nursing procedures.

6.6 Labelling of intravenous medication

All injections and infusion additives must be labeled after preparation. Under no circumstances should a practitioner have in their possession or vicinity two or more unlabeled syringes at the same time. If the syringe is to be administered via a pump device then it must be labeled in a manner not to conceal the syringe calibrations or as to otherwise affect the function of the pump device.

In Line with NPSA Guidance Labels for intravenous medicines should clearly state the following information

- name of the medicine;
- strength;
- route of administration;
- diluent and final volume;
- patient's name;
- expiry date and time;
- name of the practitioners preparing the medicine.

6.7 Infusion devices for intravenous medication

All infusion devices in use within HDUHB must be of a type that has been approved; the Medical Devices Management Policy 467 gives guidance. Healthcare professionals who use a particular device must be familiar with the function and limitation of each device that they need to use and ensure that the device is suitable for administration of the medication or diluent that is being used. Additionally, staff must be aware of the compatible giving set/s which can be used safely with that device. All staff using infusion devices must have received appropriate training for use of that particular device and have been shown to be competent in the use of that device.

6.8 Administration of intravenous medication

Before administering any intravenous medication a practitioner should be aware of any monitoring of the patient that is necessary after the medication is administered, and then check the following:

- Patient's name and hospital/NHS number
- Prescriber's signature
- The medication using the approved name (in certain circumstances the brand and formulation)
- The dose and frequency
- Date and route of administration

- The allergy status of the patient
- Check that the medication is free of haziness, particles and discoloration.
- Concentration or total quantity of medication in the final infusion container or syringe.
- Name and volume of diluents and/ or infusion fluid to be used
- Rate and duration of administration
- Stability information to determine expiry date of the final product
- Type of pump to be used
- For children the age and weight should be specified
    - Date for review of treatment
    - That the medication is due at that time and has not already been administered.

The person administering the medication must record the administration as soon as possible after the event in the appropriate patient record. Ask the patient to report any soreness at the injection site or any change in their wellbeing. When an infusion is running, it should be regularly monitored by a competent member of staff who has undertaken the appropriate competence training. Administration of intravenous medication requires two registrants, see section 5.1.3.

6.9 Patient monitoring with intravenous medication

Prior to the administration of any intravenous medication the staff that will subsequently be looking after the patient must be made aware of any specific clinical requirements as to the monitoring of the patient; preferably this should be in the form of written details. Any of the results or findings from the monitoring must be documented within the patient's notes and the prescriber informed of any deviations from the expected findings. The patient should be involved in helping staff by being made aware that they should inform staff of any changes in their well being. The nurse who is looking after the patient will make frequent checks for:

- Signs of leakage from site or infusion bag
- Signs of infection or inflammation at the infusion site.
- Remaining contents of the infusion bag

- Rate of infusion.

Where particular risks are identified, these need to be clarified with the prescriber prior to administration of any intravenous medication.

6.10 Infection control and personal protective equipment

As parenteral medication is accessing the body directly, bypassing the normal infection barriers, it is imperative that the control of infection and the maintenance of the medicines sterility are made a high priority by staff that are undertaking the preparation and administration of the product.

Guidance on Personal Protective Equipment is set out in the local Infection Prevention and Control Procedures.

6.11 Disposal of waste material

All waste must be disposed of in line with the HDUHB policy on waste which must meet the requirements of current environmental legislation. Any material that has been in contact with the patient should be classed as hazardous clinical waste and disposed of via the standard method for clinical waste. Any item deemed as ‘sharps’ should be disposed of by being placed in a ‘sharps’ bin even if they have a small amount of medication left inside them. Empty infusion sets can be placed in the yellow/orange clinical waste bags or in ‘sharps’ boxes.

For guidance on disposal of Controlled Drugs see Part 7.

6.12 Responsibilities of the pharmacist and the pharmacy department

The Pharmacist providing clinical services to a clinical area and its patients shall

- Ensure that a risk assessment is carried out on every new intravenous medication and, whenever possible a ready to use dosage formulation of the medicine is purchased in preference to any injection that needs manipulation prior to administration.
- Provide Information and advice is provided to all health care professionals on the administration of intravenous medication.

- Assist with the training of staff.
- Ensure that staff are aware of how to access the agreed standard references for intravenous medication.
- Ensure that all guidance produced for the prescribing and administration of any intravenous medication has been approved appropriately

6.13 Identifiable risks with intravenous medication

The following list is not exhaustive but includes some common general risks:

- Incomplete and unclear prescriptions that do not contain vital information concerning the dose, preparation or administration which can lead to possible errors and increased risk to patients
- Administration of medication by the wrong parenteral route i.e. giving medication by the epidural route when the correct route should be intravenous.
- Absence of relevant and accurate information concerning intravenous medication
- Complex calculations needed for prescribing the correct dose, infusion rate or preparation of dilution for intravenous medication. Calculations should be independently double checked by a second registrant.
- Involvement of inexperienced staff (e.g. registrant or students in training) in some parts of the process.
- Selection of wrong medication or diluent.
- Use of expired items.
- Unsafe handling of toxic medication or non aseptic technique leading to infection.
- Failure to correctly identify and confirm identification of intended patient incompatibilities between medication, diluents, other medication and infusion sets or devices.

Part 7 - Controlled Drugs

This chapter will ensure that the UHB has a robust framework in place for the management of controlled drugs (CDs) in secondary care.

7.1 Accountability

HDUHB has identified the Medical Director as Accountable Officer to be responsible for all aspects of the safe and secure management of CDs. For further information, consult the HB Controlled Drugs Governance Policy.

7.2 Roles and responsibilities

It is the responsibility of the Directorates to ensure that their staff are trained and competent to carry out the tasks required of them in the management of CDs.

The registered nurse, midwife or clinical lead in charge of a ward or department is responsible for the safe and appropriate management of CDs in that area.

The practitioner in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another registered nurse; however, legal responsibility remains with the practitioner in charge. Whilst the task can be delegated, the responsibility cannot.

The key for the Controlled Drugs cupboard and general keys must be kept on two distinct separate bunches. The Controlled Drug cupboard must be kept locked when not in use. The Controlled Drug cupboard keys will be kept on the person in charge of a specified area, or their designated deputy (e.g. this may be the nurse in charge of a team).

On occasions, for the purpose of stock checking, the CD key may be handed to a pharmacist or pharmacy technician on production of a current UHB ID badge.

If the CD keys go missing, urgent efforts must be made to contact staff who have just gone off duty. The senior nurse on duty must be informed immediately and the pharmacy department when they next open if the keys are not located.

In the event that a set of keys goes missing and cannot be located the practitioner in charge should contact the pharmacy department or on-call pharmacist for advice.
If the original keys are not found, the locks must be changed as soon as practical.
An entry of the incident should be completed on Datix.

An authorised signatory for ordering CDs is a qualified nurse, midwife or operating department practitioner (ODP) whose signature has been provided to pharmacy.

There may be additional medicines (including mifepristone) for which the Health Board follows the full or partial Controlled Drug regulations. This list will be approved and updated by the Medicines Management Operational Group. The list can be accessed at: http://howis.wales.nhs.uk/sitesplus/documents/862/Local%20Requirements%20for%20CDs.pdf

7.3. Controlled Drug Stationary

All stationery which is used to order, return or distribute controlled drugs must be stored securely and access to it must be restricted.
CD stationery (i.e. requisition books and registers) will be issued from pharmacy against a requisition that will be written by an authorised signatory from that ward or department. Stationery will not be issued against a signature that is not on the authorised signatory list.

A record will be made of CD stationery supplied by pharmacy.
The record will include:

- Date
- Ward/department
- Name of person ordering the stationery

- Type of stationery issued
- Quantity
- The serial numbers of the stationery – to be added at the time of issue
- Signature of the member of pharmacy staff making the supply
- Signature of the member of ward staff receiving the stationery

Loss of any CD requisition books must be reported to the pharmacy and a Datix incident form, Datix completed by the area responsible for the loss of the requisition book as soon as possible following recognition of the incident.

When a new CD register is started, the balance of CDs in stock must be written into the new book promptly by a registered nurse and witnessed by a second nurse or another registered health professional. It is good practice to write the start date on the front cover.

Completed ward requisition books and CD registers must be retained for a minimum of two years from the date of the last entry in a locked place by the ward or department. When the CD register is complete, write on the cover a date 2 years on from the last entry. This is the date that the register can be appropriately disposed of as confidential waste.

Other requirements for the retention of CD records are listed below:

- Aseptic Worksheets (paediatric) – 26 years
- Aseptic Worksheets (Adult) – 13 years
- Clinical trials – 5 years
- Destruction of CDs – 7 years
- External Orders and delivery notes – 2 years
- Extemporaneous preparation worksheets 13 years
- Prescriptions (inpatients and outpatients) 2 years

7.4 Storage of Controlled Drugs

7.4.1 Wards and Departments

Ward CD cupboards must comply with the Misuse of Drugs (Safe Custody Regulations) 1973 and British Standard reference BS2881 or be otherwise approved by the pharmacy department. 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 should be used (www.soldsecure.com).

Where a ward or department is to be closed for greater than 5 days, Controlled Drugs, requisition books, registers and keys must be removed from the ward and stored in pharmacy. The stock should be reconciled against the levels in the register by 2 qualified members of staff. Either 2 ward staff or a member of ward staff and a pharmacist or pharmacy technician can undertake this role. A record stating “Number returned to pharmacy XX” for each drug held in stock. The CDs will be stored in a sealed box securely in the pharmacy. When the ward or department reopens the stock will be returned and reconciled immediately against the register and an entry made in the register “Number returned to ward XX”.

The measures below must be observed for the storage of CDs:

- Cupboards 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 available.
- The cupboard must be dedicated to the storage of CDs.

7.4.2 Pharmacy

It is acceptable for the Pharmacy department to store Controlled Drugs within the automated robot providing:

- a joint risk assessment with the police has been undertaken of the premises and robot.

- approval is given by the relevant Local Intelligence Network to store CDs in the automated robot.
- regular audit is undertaken to ensure robust procedures are in place and implemented.

7.4.3 Community

In the patient's home Controlled Drugs should be stored within a plastic lidded box as advised by the community nursing staff. The Controlled Drugs remain the patient's property. A stock balance must be kept and checked at each visit. Any discrepancies should be reported to the prescriber and the relevant Community Service Manager and the police prior to investigating the loss.

7.5. Ordering and Delivery of Controlled Drugs

Controlled drugs must be requisitioned using the controlled drug order book and the requisition must be signed in full by the nurse who is an authorised signatory for that ward or department. The name of the nurse must also be printed on the requisition. A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Ward or department managers will be responsible for ensuring that new members of staff provide a specimen signature to pharmacy and inform pharmacy when members of staff leave in order that their names can be removed from the approved list. Pharmacy will co-ordinate an annual update of the records held.

Senior pharmacists (Band 8a or above in permanent posts) may order CDs for clinical areas providing they are named on the ward or departmental list for "Persons Authorised to Order Controlled Drugs". The CD order is to be dispensed and checked according to Hywel Dda Health Board Policy in line with an approved SOP. The Senior Pharmacist involved in completing the CD requisition ***must not*** be involved in the dispensing or checking process or receipt by the ward.

Each order must be in duplicate, with the white page as the top copy and one item ordered per page.

Requisitions must contain the following:

- Name of the hospital
- Ward/department
- Drug name, form, strength, ampoule size if more than one is available
- Total quantity required e.g. 5, 10 etc – not a number of boxes (i.e. one box). When quantities ordered do not correspond to a complete box the quantity will be altered by pharmacy to the nearest appropriate number.
- Signature and printed name of the registered nurse
- Date
- Signature of the person issuing from the pharmacy

The order book must be kept in a locked cupboard or drawer when not in use. Spare CD stationery must also be kept secure.

Each ward/department should only have one order book in use at any given time. If a ward/department has more than one controlled drug cupboard then a separate book may be used for each cupboard.

Orders for stock controlled drugs from the agreed ward stock list must be sent to the pharmacy before 10:00a.m. Controlled drugs for departments or wards may be collected by a messenger who must be a member of UHB staff and bring an official organisational ID badge for identification. The messenger need not be a qualified nurse.
The messenger or porter transporting the controlled drug to the ward/department is responsible for the safe custody of the drug until signed for by the qualified member of staff.

Controlled drugs delivered by a messenger or porter must be checked immediately on arrival at the ward/department by a qualified member of staff. The pink copy of the requisition must be signed to accept the CDs onto the ward. On receipt the CDs must be entered into the controlled drug (CD) register immediately.

The following details should be recorded on the appropriate page in the CD register:

- Date of entry
- Name and signature of nurse making the entry
- Name and signature of the witness
- Balance in stock
- The serial number of the requisition
- Quantity received

7.6. Emergency Supply of Controlled Drugs

Under normal circumstances all supplies of CDs must be through the pharmacy department. If a controlled drug is required urgently for a patient when the relevant pharmacy is closed, the drug is not available on the ward and no other drug is a suitable alternative, then one dose may be obtained from another ward. The duty manager must be contacted.

The ward requiring the dose must take the patient's prescription and their CD register to the ward providing the dose. The dose of the drug required should be signed out of the CD register on the providing ward and into the CD register of the receiving ward by 2 qualified members of nursing staff. The following must be recorded in both CD registers:

- Date and time when dose is transferred
- Name of patient
- Names & signatures of nurses who transferred the dose
- Quantity transferred
- Balance in stock in both CD registers

7.7. Return of Controlled Drugs to Pharmacy

Controlled drugs are returned to pharmacy for two purposes, safe destruction or recycling and re-use. The following must be recorded in the ward CD register when CDs are returned to the pharmacy

- Date
- Name and Signature of the nurse.

- The name and signature of the pharmacist or pharmacy technician accepting the CDs for return.
- The quantity of drug being returned.
- Reason for return e.g. out of date, excess stock
- Balance remaining.

On return to the pharmacy, the pharmacist or technician who accepted the CDs for return and re-use must enter the CDs into the appropriate page in the pharmacy CD register immediately. The stock must be booked back into the computer stock balance and a reconciliation of the balance on the shelf, the balance in the register and the balance on the computer be made. All 3 levels must tally. Any discrepancy must be investigated immediately.

The following details must be recorded on the relevant page of the pharmacy CD register:

- Date
- Ward from which the return is being made.
- The amount of preparation being returned
- The name and signature of the pharmacist or technician making the return.
- Balance in stock.

If the CDs are for destruction an entry must be made in the appropriate destruction register in the pharmacy - i.e. patient's own or returned stock registers.

Patient's own returns can be destroyed without the presence of an Authorised Person. The details required in the register are:

- Date
- The ward & the name of patient, if appropriate
- The preparation and quantity being returned
- The name & signature of the pharmacist/technician making the return
- The next reference number for destruction

If the CD is "date expired stock" for destruction it must be entered in the destruction register for this purpose and the above details recorded as appropriate

7.8. Prescribing Controlled Drugs

There are additional requirements for the prescribing of Controlled Drugs in accordance with the Misuse of Drugs Regulations 2001 (as set out in the BNF: Controlled Drugs and drug dependence).

Prescribers can only prescribe or administer any Controlled Drugs to registered patients. Prescribers should also refer to the following Health Board Guidance: The Prescribing, Dispensing and Administration of Opioid Medicines in Adults.

The prescribing and supply of Schedule 1 Controlled Drugs (drugs not used medically e.g.lysergide) requires specific Home Office authority which the Health Board does not currently hold.

7.8.1 Inpatient Prescribing

For hospital inpatients, CDs can be prescribed on the inpatient medicines chart or the anaesthetics card in line with local policies and procedures.

The written requirements for controlled drugs on these charts are the same as for other medicines: if prescribed “when required” e.g. for breakthrough pain, a minimum interval for administration should be specified e.g. every six hours; and a total quantity to be administered in 24 hours.

7.8.2 Prescribing for Outpatients or discharge prescribing (TTH’s)

Prescriptions for CDs for outpatients or discharge must comply with all the requirements of the Misuse of Drugs Act. Prescriptions must be written on a discharge form or an outpatient form. Doctors who have not achieved full registration with the GMC are permitted to prescribe CDs for patients on discharge but not for out patients. Under normal circumstances a maximum of 30 days only should be prescribed. If there are compelling circumstances for the prescription of more than this duration then the reasons must be documented in the patient’s notes. A prescription for a controlled drug is valid for a period of 28 days from the date of issue.

7.8.3 Documentation and Prescription

The prescription must be indelible i.e. written by hand, typed or computer generated. Addressographs may be used. If an addressograph is used, it must be tamper evident.

Prescribers should also sign across a corner of the addressograph. This is a further safeguard to ensure addressographs are not tampered with or another addressograph is not placed on top of the one that the prescriber signed for.

The prescription must include the following details:

- The patient's full name, address and, where appropriate age
- The patient's hospital number
- The name and form of the drug e.g. tablets, capsules even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation (liquids) or the number of dosage units (tablets, capsules, ampoule, patches) to be supplied in both words and figures

The prescription must be signed by the prescriber with their usual signature, in their own handwriting (this must be handwritten) and dated by them (the date does not have to be handwritten).

A pharmacist is authorised to dispense a prescription for a Schedule 2 or 3 controlled drug if it specifies the total quantity only in words or in figures, or if it contains minor typographical errors, provided that any amendments are indelible and clearly attributable to the pharmacist dispensing.

7.8.4 Independent Prescribers

Nurse and pharmacist Independent prescribers can prescribe, supply or administer, or direct any person to administer any Controlled Drug in schedule 2 to 5 of the Misuse of Drugs regulations. Physiotherapist and podiatrist independent prescribers can prescribe, administer and supply a limited number of Controlled Drugs. Refer to the HDUHB Non- Medical Independent Prescribers Policy for full details: http://howis.wales.nhs.uk/sitesplus/documents/862/176PolicyOnNonMedicalPrescribingV2.pdf

7.9 Administration of Controlled Drugs

Controlled drugs must only be administered against a prescription signed by an appropriately qualified prescriber, or in the case of midwives a relevant drug protocol.

Two practitioners must be involved in the administration of CDs; one of them must be a registered nurse, midwife, ODP or doctor. Both practitioners must be present during the whole of the administration procedure. They should both witness:

- The preparation of the CDs to be administered
- The CD being administered to the patient (except in the administration of CDs by midwives attending a home birth where a midwife has collected the CD from the Midwifery Led Unit, and single nurse practitioners in the community)
- The destruction of any surplus drug e.g. part of an ampoule not required
- A record must be made in the ward or department CD register when a CD is removed from the CD cupboard. The following details must be recorded on the relevant page in the CD register:
- Date and time when dose administered
- Name of patient
- Quantity administered
- Name and signature of nurse who administered the dose
- Name and signature of the witness
- Balance in stock

If part of a vial is administered to the patient, the registered nurse must record the amount given and the amount wasted 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 waste*". Specific Controlled Drug Registers are being introduced for theatres (and other areas where CD administration is titrated and wastage occurs) and the instructions for recording in these registers must be followed. [MMG Feb 2018]. This must be witnessed by a second registered nurse who must also sign the record. If a second registered nurse is not available, the administration can be witnessed by any of the staff listed as appropriate checkers

Individual doses of CDs which have been prepared for immediate administration 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 who can be another registered nurse, doctor, pharmacist or pharmacy technician. The reason must be documented and signed in the CD register by the practitioner and the witness.

7.10. Disposal/destruction of Controlled Drugs

CDs must be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or reused. Where denaturing is carried out on the wards, the methods used should be those currently recommended by the Royal Pharmaceutical Society. Any pharmacy held stock of obsolete, expired or unwanted Schedule 2 CDs, other than those returned by patients, which require destruction, may only be destroyed in the presence of an authorised person (witness). Authorised witnesses currently include inspectors of the Royal Pharmaceutical Society, police constables, the Accountable Officer and the Chief Pharmaceutical Officer to Welsh Government. The Accountable Officer for the UHB can also appoint appropriate individuals as authorised witnesses within the organisation to witness destruction.

Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, must be kept segregated from other CDs in the CD cupboard. Stock CDs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent re-issue or administration.

Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, must be rendered irretrievable by emptying into a yellow top sharps bin. The emptied vial or ampoule must then be placed in the sharps bin. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Larger quantities of CDs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes, are also disposed of in a sharps bin.

All destruction must be documented in the appropriate section of the CD register. It must be witnessed by a second professional such as a registered nurse, midwife or ODP. If any of the previously listed staff are not available to witness the destruction then a doctor or pharmacist may witness it. Both persons must sign the CD register.

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 register. Controlled drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) or are excess stock must be returned to the pharmacy for safe destruction.

If it is necessary to destroy the contents of a PCA/PCEA syringe that has been transferred to the ward, the destruction must be recorded in the CD register

7.11. Controlled Drug Registers and Reconciliation of balances

The CD register must be bound with sequentially numbered pages and it should have separate pages for each drug, formulation and strength of formulation, so that a running balance can be easily kept. Entries must be made in chronological order, in ink or be otherwise indelible.

- If a mistake is made it must be bracketed in such a way that the original entry is still clearly legible. No crossings out or alterations are allowed. The entry must be signed, dated and witnessed by a second registered nurse, midwife or other registered professional. The witness must also sign the correction.
- On reaching the end of a page in the CD register, 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.
- Stock levels of Controlled Drugs must be checked once every 24 hours by two registered Healthcare Professionals to ensure stock levels are correct against the Controlled Drugs Register.
- This is the responsibility of the Ward Manager.
- The following information must be recorded for every daily check:
  - date and time of check
  - that the stock balances are correct.
  - the signature of the two registered Healthcare Professionals undertaking the checks

- Original packs of CDs with intact tamper evident seals do not need to be opened for checking purposes.

- If stock reconciliations do not balance, the matter must be reported immediately to the appropriate senior nurse manager who will inform the Site Lead Pharmacist or deputy at the earliest convenient opportunity. An investigation to confirm the loss will be undertaken by the senior nurse in conjunction with the ward pharmacist if necessary. A formal Datix incident form must be completed with advice to the Accountable Officer on escalation.
- The pharmacy department will carry out a full stock reconciliation on the wards and departments at a minimum of every three to six months with a ward nurse. The quality of record keeping will also be assessed at that time and feedback on the quality of record keeping will be discussed with the nurse in charge. If necessary, recommendations for improvements will be agreed.
- All controlled drugs in the pharmacy must be checked every three to six months. This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for CDs or a suitable deputy approved by the Site Lead Pharmacist.
- This check is in addition to the rolling checks on the CD register.

7.12 Use of a Patient's Own Controlled Drug on the ward

A patient's own Controlled Drugs can be used for their treatment only while they are a patient (Day Case or inpatient)

. In this situation, they must be placed in the CD cupboard but should be marked and kept separate from ward stock. An entry detailing the patient's CD must be made on the Patients Own page of the ward CD register and a record of the administration of doses must be documented.

Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home

If patients' own CDs are not required for use during the patient's admission then one of the following actions should be followed and recorded in the CD register:

- If the patient or the patient's representative agrees, medicines may be sent to the pharmacy for safe destruction. The pharmacist must take responsibility for destruction. Document the agreement to destroy the drugs in the patient's notes.
- If the patient wishes, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult and this action documented in the patient's notes. If the medicines are not safe and/or appropriate for use, then the patient and/or patient's representative should be advised and they should be encouraged to send them to the pharmacy for safe destruction. This must be documented as for any other CD returned to pharmacy.
- Just In Case (JIC) bags should be stored in the ward CD cupboard and recorded on the Patients Own page of the ward CD register. If the patient requires a syringe driver to be set up, ward stock should be used. If the ward does not stock the required medicines then the JIC medicines can be used only for the patient who brought them in and the administration recorded in the ward CD register. If the JIC box is no longer required it must be returned to the hospital pharmacy for destruction.

7.13. Controlled Drug Discharge Medicines (TTHs) and Receipt of CDs by Outpatients

When Schedule 2 CD TTHs are collected from the pharmacy, the person collecting them will be asked to sign for receipt. They may be signed for by a healthcare professional, porter or a healthcare assistant.

The following details will be recorded in the CD collection register:

- The date, the name, form and strength of the drug and the patient's name
- The name and address of the healthcare professional collecting the CDs
- The form of identification provided by the healthcare professional e.g. identity badge or whether the messenger is known to the dispenser.
- The name of the member of pharmacy staff handing out the prescription

When an outpatient prescription is being given to the patient or their representative or relative the following details must be recorded:

- 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 (as above)
- 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.

7.14. Transfers between Clinical Wards or Departments

When a patient on a PCA/PCEA containing a CD transfers between 2 clinical areas the following steps must be taken:

- The nurse/practitioner transferring the patient must make an entry on the PCA/PCEA Infusion Monitoring Chart detailing the amount left in the syringe. They must sign and date the entry.
- A second practitioner must sign and date the entry as a witness.
- The nurse/practitioner accepting the patient in the new clinical area must check the contents of the syringe on receiving the patient and sign and date an entry on the PCA/PCEA Infusion Monitoring Chart which must be countersigned by the nurse/practitioner transferring the patient.
- A patient transferring between 2 clinical areas on a subcutaneous syringe driver containing a CD must have a similar record of the amount remaining in the syringe made on the Subcutaneous Syringe Driver Chart.
- Patients' own CDs stored in a ward CD cupboard should be transferred with the patient. The CDs must be signed out of the first CD register by two registered practitioners and into the second CD register by two registered practitioners.

7.15. Controlled Drug use by Midwives

Midwives working in the on HB sites must follow all the elements of this policy.

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

Midwives providing care for women during a home birth where pethidine is required will acquire the pethidine from the Midwifery Led Units (MLU) where stock for community use is stored. The procedures for administration will be followed. Midwives will carry the pethidine in a locked box on route to the woman's home. If the pethidine is not used the midwife will return it to the MLU stock and record this in the relevant CD register.

7.16. Receipt and Handling of CDs by Pharmacy

The Clinical Director of Pharmacy and Medicines Management is responsible for the safe and appropriate management of CDs in the pharmacy. Day-to-day management of CDs 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 Clinical Director of Pharmacy and Medicines Management.

On receipt of a CD order from a wholesaler, the CDs must be brought to the member of staff in the purchasing section with responsibility for processing CD orders. They will take the following action:

- The delivery will be checked against the order and delivery note for accuracy.
- The delivery will be locked in the CD cupboard/room at the first opportunity.
- The quantity delivered will be checked against the delivery note and added to the balance in the register. The new total must be reconciled with the CD register and pharmacy computer system balance. All balances must be reconciled.
- When the balance is reconciled, the CD delivery must be entered into the CD register and onto the pharmacy computer system balance.
- If there is a discrepancy between the order and the delivery, the delivery should be locked in the CD room/cupboard until the discrepancy has been investigated. This should be done within 24 hours when practical but at the earliest opportunity at times such as weekends or Bank Holidays.

7.17. Transfer of Controlled Drugs using messengers

A person who conveys CDs between sites is acting as a messenger and is responsible for delivering a sealed or locked container. The seals or locks used must be tamper evident. The messenger is responsible for the delivery of a sealed intact container.

A transport log will be used to provide an audit trail for the transport of CDs and will require a signature at each point of transfer.

The procedure below will be followed:

- The CDs will be sealed in the container for transport along with the CD requisition book.
- The white copy of the CD requisition will be annotated with “Into bag/container” rather than being signed and if a numbered seal is being used the number of the seal will be recorded on the white copy.
- The sealed bag/Envopak/box will be signed for on the transport log by the messenger.
- On delivery to the receiving ward the transport log will be signed by a member of staff who is qualified to handle CDs.
- This member of staff will break the seal and verify the contents of the bag and match it the order. They will enter the CDs into their CD register in the normal way.
- Any discrepancies must be reported to the duty pharmacist immediately
- The white copy of the CD requisition and the transport log will be returned to the issuing pharmacy as soon as possible by the receiving clinical area.
- All members of UHB staff signing for CDs to transport must show a valid ID badge.
- If taxis are being used to transport CDs, a record of the taxi-drivers’ car registration or taxi licence number must be obtained.
- If, at any site, the sealed bag is to be left for collection, a signature from a member of UHB staff (e.g. a porter at the porters lodge or switchboard) must be obtained on the transport log. Also if the driver is required to leave the sealed bag at a porter’s lodge for onward delivery to the ward it must be signed for. The person signing to accept the bag for onward delivery must also obtain a signature from the destination ward/department staff on the transport log when they deliver the bag.

7.18. Controlled Drugs within Anaesthetic Rooms

A specific controlled drug record book is available for use in Theatres/Anaesthetic rooms within the HB.

Controlled drug supplies may be received directly from pharmacy.

Receipt of controlled drugs may be undertaken and witnessed by a registered nurse or registered ODP

The quantity supplied to a doctor for a specific patient must be recorded against that specific patient name in the controlled drug record book, signed for by that doctor and the registered nurse or ODP as witness. The quantity administered to the patient must be recorded and signed for by the doctor. The quantity destroyed must be recorded, signed for by the doctor and the registered nurse or ODP as witness.

The doctor is responsible for this supply whilst in their possession.

The stock balance must be confirmed at the end of each transaction i.e. receipt, issued to doctor and recorded in the relevant column.

The stock balance must be checked at the beginning and end of each operating list. Stock reconciliation should be recorded in the stock checks section at the back of the controlled drug record book, which the checker and witness must sign.

Part 8 – Return, Disposal and Destruction of Medicines

Medicines that are no longer needed retain their legal status as medicines until such time as they are assessed and destroyed when their legal status becomes controlled under Waste Regulations. It follows that the management and handling of excess or unwanted medicines requires equal diligence to the management and handling of other medicines in current use.

8.1 Return of excess or unwanted medicines

8.1.1 Acute and community hospitals

All excess or unwanted medicines must be held within the ward or clinical area until such time as safe arrangements has been made for their disposal. Wards receiving stock control by pharmacy staff must not make returns without prior agreement with the pharmacy. Pharmacy staff will return stock to pharmacy at the time of stock control. Wards who order their own stock should notify pharmacy of any excess or unwanted medicines. Safe arrangements should be made for the return of these excess or unwanted medicines to pharmacy during normal pharmacy opening hours, using hospital transport or a porter with an auditable record of dispatch. It would be considered good practice for wards to have a record of items returned.

Medicines returned which are suitable for reuse should be handled according to the All Wales Policy for the Reuse and Management of Waste Medicines in Hospitals.

8.1.2 Community

Under no circumstances must community Healthcare Professionals take surplus medicinal products into their possession from patients/carers or next-of-kin or make any further use of them.

It is the duty of community Healthcare Professionals to advise the patients and relatives on the correct destruction/disposal of unwanted medicinal products. **Unwanted medicinal products must be returned to the community pharmacist for destruction.** It is not the

responsibility of the community Healthcare Professional to return the medicinal products to the community pharmacy. However Community Healthcare Professionals may hold temporary possession of medicines, in exceptional circumstances (for example, acting in the best interest of the patient/relative/carer or public interest and the action should be reasonable and in accordance with peer professional practice) in order to return them to the Community Pharmacy for destruction. It would be sensible to seek and document the agreement of the patient, carers or next-of-kin. If there is not a carer or relative, the Healthcare Professional's line manager should be informed.

All residual contents of ampoules or vials must be sent for disposal in the appropriate container in accordance with HB Policy.

8.1.3 Medicines brought into hospital by patients

For medicinal products brought into hospital by the patient, which will not be required on discharge, consent must be sought from the patient or next of kin to destroy the products.

In the case of children, the legal guardian may give authority for the disposal of medicinal products.

Medicinal products for disposal must be sent to the Pharmacy department in a sealed container.

Where a patient refuses to agree to the destruction of such products, or refuses to hand over medicinal products which are contra-indicated, the risk must be explained to the patient and the responsible doctor informed. This must be documented in the patient's records and further advice sought from the Senior Nurse, Consultant or Senior Pharmacist.
In respect of patients who lack mental capacity, it may be necessary to remove drugs which, although not unlawful for the patient to possess, could be dangerous to the patient. For further advice contact the Mental Capacity Act Lead Officer.

In the event of patients bringing illicit drugs (or substances suspected of being illegal drugs) with them into hospital or any Health Board premises, the appropriate procedure must be followed (see 4.1.4).Contact the Pharmacy department for further advice.

8.2 Disposal of cytotoxic medicines

Arrangements for the disposal of cytotoxic medicines should be in accordance with the recommendations contained in the current policy on the disposal of clinical waste.

8.3 Disposal of Controlled Drugs

Excess or unwanted CDs must be returned and disposed of in accordance with the Medicines Policy Part 7.

8.4 Disposal of part used syringes and injections

Syringes that are not fully discharged and partly used infusion bags containing prescription only medicines (POMs) should be disposed of using an appropriate 'sharps' container. They must not be returned to pharmacy.

8.5 Disposal of medicines by the pharmacy

All disposal and destruction of medicines within the pharmacy must be in accordance with departmental procedures and meet the requirements of the current waste legislation, regulations and guidelines from the Professional Regulatory body for pharmacy and the All Wales Chief Pharmacists Group.

Part 9 – Discrepancies, Incidents Involving Medicines, Defects, Hazards, and Adverse Drug Reactions

9.1 Losses and discrepancies

Loss or suspected loss or misuse of medicines should be reported to the Ward Manager/Clinical lead and the Site Lead Pharmacist (or deputy) who can then decide on a further course of action. A Datix entry must be submitted. Refer to Part 1.

9.2 Management of medication errors

In order to prevent medication errors, it is in the individual responsibility of all practitioners to adhere to their Professional Code of Practice, Regulatory Guidance, National and Local Policy and Procedures and to the HDUHB Medicines Policy at all times. Adhering to this guidance will maximise patient safety and minimise risk.

The HB Multi-disciplinary Medication Errors Policy should be referred to for further information.

A medication error can be defined as a preventable error that may cause or lead to inappropriate medication use or patient harm while medication is in control of the health care professional or patient. Such events may be related to professional practice, health care products, procedures and systems including prescribing, order communication, product labeling, packaging and nomenclature, compounding; dispensing, administration, counseling and monitoring. Healthcare professionals should learn from any medication error, near miss or adverse outcome in order to prevent repetition. A balanced approach is required to protect patients and staff alike. Staff must be given adequate support by their line manager determined by the individual circumstances specific to the medication error.

The over-riding priority when a medication error is discovered is to protect the patient and provide any immediate clinical action that may be required to reverse or negate any adverse clinical consequences.

9.2.1 Action to be taken in event of medication error

When a medication error (prescribing, dispensing or administration) that has led to the inappropriate administration of a medicine to a patient is discovered, action must be taken. Patient safety must be the priority and action taken to maintain their safety. The patient's medical (or on-call) team must be informed of the error immediately.

The patient must be reviewed and a medical action plan produced specific to the nature of the medication error.

The Ward Manager/Clinical Lead in charge must be informed.

In the event of a dispensing error that has led to inappropriate medication administration, inform the Site Lead Pharmacist (or deputy) or on-call pharmacist.

9.2.2 Reporting a medication error

All incidents involving medicines that have led to inappropriate medication administration must be reported via Datix. For further information, please refer to the medication incident 'trigger list' poster, displayed in clinical areas (http://howis.wales.nhs.uk/sitesplus/documents/862/Incident%20Near%20Miss%20Hazard%20Reporting%20Medicines.pdf)

This is to ensure that the Assurance Safety and Improvement (ASI) Team is informed of all incidents in a timely manner. The Datix report should not be delayed until all proposed actions have been carried out; it is sufficient to specify the actions proposed.

When completing the report, the staff member involved in, or witnessing an incident must ensure that the details recorded are concise and a true and complete version of events. An appropriate record must also be made in the patient's clinical record, medical and nursing. This is not duplication since all events relating to the patient need to be clearly stated because Datix incident report does not form part of the medical record. It is important for the person reporting the incident to confine

themselves absolutely to the facts. There is no place for an expression of opinion however well meant. No reason for events is required, even if the person reporting the incident is implicated. Merely state the facts as they are. Further information may be required at investigation, statements from staff, number of patients, dependency, staffing levels, time of day and any other circumstances which might impact on the issues.

A senior member of the multi-disciplinary team must inform the patient / relative and this should be recorded in the patient's clinical records.

Where equipment is involved in the medication error, staff must ensure that the item is removed from use immediately and defects are reported to the Biomedical Engineering; guidance is given in the Medical Devices Management Policy 467

9.2.3 Serious medication errors

A serious medication error is when patient harm occurs or is anticipated. In the event of a serious error the consultant must be informed as soon as possible. If this is outside normal working hours, the Site Manager must be contacted via switchboard. They will then contact the HB on-call General Manager and the Consultant as appropriate.

It is important that the Medical Director, the Director of Nursing and the Head of the ASI Team are informed of the error and the relevant circumstances at the earliest opportunity. Serious incidents may be deemed notifiable to the Welsh Government and this is required within 24 hours of the incident or the next working day.

In the event of a serious medication error, the ASI Team will facilitate the preliminary investigation under the guidance of the Medical Director.

All serious medication errors along with patient related incidents will be reported to the National Recording and Learning System (NRLS) via the ASI Team.

Error analysis and recommendations will be conducted in accordance with local

procedures.

9.3 Near misses

Any event that would have led to an error but did not actually happen due to last minute intervention should be reported as a 'near miss' on Datix. In clinical risk management terms, reporting a near miss is just as important as reporting an actual error. Medication errors are rarely the 'fault' of individual practitioners and are commonly the result of poor processes/systems. The collation of information on near misses can provide valuable data that may indicate poor system design.

It is important that the continued reporting of errors and near misses is seen as a means of learning in order to minimise future risk.

9.4 Medicine Event Review Group (reporting to Medicines Management Operational GroupSub-Committee)

Will review medication errors and pharmacy intervention data and undertake trend and root cause analysis. The group will co-ordinate actions required in the event of national safety alerts and produce and issue to the clinical areas any local safety alerts deemed appropriate. The group has the authority to initiate action, which may involve system redesign and improvement and/or education, training and competency assessment of healthcare professionals on any aspect of medicines use.

9.5 Management of staff involved in medication errors.

All medication errors should be investigated locally to determine whether the incident is due to a system failure or inappropriate action(s) by a member of staff.

The HDUHB Multi-disciplinary Medication Errors Policy details the process to be followed.

Procedures need to be in place to identify if this is the first or subsequent time the individual/individuals have been involved in such an incident and the time span over which the incidents have occurred. Consideration should be given to the

circumstances surrounding the incident and the individual's previous practice and performance.

Each profession will need to interpret this guidance according to their Professional Code of Practice.

If a HB bank member of staff makes a drug error they may be limited to where they can work until such time that training has been instigated and assessed.

If an agency member of staff makes an error they will be referred to their manager for training. Evidence of that training will be required by the HB. If any subsequent errors are made, consideration will be given as to whether placement within the HB is appropriate.

9.6 Reporting and recording adverse drug reactions and defective medicinal products

9.6.1 Adverse drug reactions

Immediate action must be taken to reduce the effect of the ADR (e.g. stopping IV fluid). Where appropriate (e.g. serious ADR or clinical incidence, potential defective product) the vial/original pack must be bagged and labelled accordingly where safe to do so or record the product details (e.g. manufacturer, batch number and expiry).

Any ADR must be reported to the prescriber or another appropriate medical/dental officer, pharmacist and the senior nurse/sister and an entry made in the patient's medical notes.

The prescribing doctor / pharmacist / nurse should report ADRs using the Yellow Card Scheme to the MHRA (https://yellowcard.mhra.gov.uk/). Paper copies of the Yellow Card Report can be found at the back of a BNF. Guidance on which ADRs should be reported can be found at: https://yellowcard.mhra.gov.uk/_assets/files/HCP-leaflet-072013.pdf .

A competent patient must be informed if they have suffered an adverse drug reaction. Where a patient lacks capacity, the patient and the patient's family and/or carers and in case of a child the parent/guardian must be informed that an adverse reaction has

occurred and has been documented.
For anaphylaxis or **significant** adverse reactions in community the patient would be admitted to the acute sector for 24 hours' observation.

The nature of the adverse reactions and the medicine involved should be accurately recorded in the patients' case notes. A clearly visible statement to the effect that the patient has suffered an actual or suspected adverse reaction to a given medicine should be permanently imprinted inside the front of the case notes and/or the electronic patient record and also on the in-patient chart (patient medication record) and out-patient and discharge prescriptions, either in large lettering or using specially prepared label.

9.6.2 Defective medicinal products

The Medicines and Healthcare products Regulatory Agency (MHRA) investigates all reports of defective medicines. Where the results of investigations have implications for other patients or users, the MHRA will issue a Hazard or Medicines Alert, which advises of hazardous products or unsafe practices.
Healthcare staff must report their concerns to the Site Lead Pharmacist (or deputy) pharmacist or on-call pharmacist (if out of normal working hours) if a defective or potentially defective medicine is suspected. Examples of defective medicines include the products themselves (e.g. particulate contamination, wrong products contained in outer packaging, poor or incorrect product labeling, poor or incorrect patient or product information (e.g. instructions for use). The pharmacy department is responsible for informing the MHRA of defective or potentially defective products. Details should be discussed with the Quality Assurance Lead Pharmacist prior to transmission of details to the MHRA.

Outside of normal working hours the on-call pharmacist should contact the Clinical Director of Pharmacy and Medicines Management or a senior pharmacist prior to a decision to inform the MHRA. When a decision has been made to inform the MHRA, the Clinical Director of Pharmacy and Medicines Management or other senior pharmacist should complete the Medicinal Product – Suspected Defect Report Form

available online at https://yellowcard.mhra.gov.uk/defective-products/.

Part 10 - Unlicensed Medicines and Unlicensed Indications

Note: Hywel Dda University Health Board's procedure for the use of unlicensed medicines and medicines outside their product licence, and the Welsh Risk Pool Services' Technical note on prescribing of unlicensed drugs or using drugs for unlicensed indications are under review. The information contained in this chapter will be updated in line with any changes in the above guidance when available.

10.1 What is a product licence?

A medicine must be granted a product licence or marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) before it can be widely used within the UK. Licences are granted only if acceptable standards of efficacy, safety and quality are met.

The product licence defines the medicine's terms of use and is detailed in the manufacturers Summary of Product Characteristics (SPC). Information is provided on the indication(s), recommended dose(s), contraindications, special warnings and precautions for use. SPCs can be found at: eMC (https://www.medicines.org.uk/emc/) and the MHRA (http://www.mhra.gov.uk/spc-pil/) or the company's website.

The licensing process therefore reduces risk in using medicines. Occasionally there may be a clinical need for a patient to be treated with an unlicensed medicine (a medicine with no UK product licence) e.g. mexilitine; or with a licensed medicine outside the terms of the licence ("off-label") (e.g. Konakion MM 10mg/mL injection administered orally to adults for the reversal of over anticoagulation in warfarinised patients.). Certain patient groups (e.g. paediatrics) regularly use licensed medicines 'off label' supported by peer reviewed evidence (for example paracetamol is not licensed under 2 months of age for oral use or 3 months for rectal use but paracetamol is used in a newborn who has a sore head following instrumental delivery).

The use of unlicensed medicines or medicines outside their product licence is

indemnified by the All Wales Risk Pool only if supported by an appropriate policy. HDUHB requires that this Procedure for the Use of Unlicensed Medicines and Medicines Used Outside their Product Licence is followed so that they may take vicarious liability for healthcare staff involved in any aspect of unlicensed medicines procurement, prescribing, supply or administration.

10.2 Healthcare professionals' responsibilities in prescribing, supplying and administering unlicensed or 'off-label' medicines

The responsibility that falls on healthcare professionals when using an unlicensed medicine or a medicine off-label may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers have a duty to ensure they are aware of the legal status of the medicines they prescribe. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions; product quality; or discrepant product information or labeling (e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use).

At present, the following healthcare professionals can prescribe an unlicensed medicine: doctors; dentists; independent nurse and pharmacist prescribers and, in some circumstances, supplementary prescribers (who can be a pharmacist, nurse, midwife, community nurse, optometrist, physiotherapist, radiographer, or chiropodist/podiatrist). These health professional groups listed above can prescribe a licensed medicine off-label. In addition, optometrist, physiotherapist, radiographer, or chiropodist/podiatrist and paramedic independent prescribers can prescribe a licensed medicine off-label.

The General Medical Council's Good Practice in Prescribing Medicines (2021) document provides guidance on prescribing unlicensed medicines and prescribing medicines for use outside the terms of their licence (off-label). In either situation the prescriber must:

- Be satisfied that an alternative, licensed medicine would not meet the patient's needs.
- Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy.
- Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment, or arrange for another prescriber to do so.
- Make a clear, accurate and legible record of all medicines prescribed and, where common practice is not followed, give reasons for prescribing the medicine.
- Give patients (or their parents or carers) sufficient information about the medicine to allow them to make an informed decision. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.
- Answer questions from patients (or their parents or carers) about medicines fully and honestly.

Where an unlicensed medicine or a medicine used for an unlicensed indication is prescribed the prescriber is to inform the nurse administering the medicine (where appropriate) and the patient/carer of the unlicensed use. Pharmacists supplying the medicine must consider the need to ensure the prescriber, the nurse administering the medicine (where appropriate) and the patient/carer concerned are aware of the risks of such use.

The methods used for the administration of licensed medicines may in some circumstances lie outside the product licence. It is important to note that, for example the crushing or dispersing of a licensed solid dosage form for ease of administration, may mean that the use of the medicine becomes unlicensed. In situations where the

medicine is manipulated in a way that is not covered by the product licence prior to administration there should be discussion and agreement between the prescriber and the person who will administer the medicine. Discussion should also take place with the pharmacist to check the administration method is appropriate and that the efficacy of the medication is not changed as a result. The patient/carer should also be involved in the decision to use the medicine in this way.

Medicinal products covered by this procedure include:

1. **Medicines which do not have a UK product licence (an unlicensed medicine).** These may include medicines manufactured by a licensed manufacturer but which are awaiting a UK product licence, are manufactured for export, have been withdrawn from the UK market or where the manufacturer does not intend to apply for a UK licence. These products are usually obtained on a "named patient basis". The pharmacy will purchase such products, usually on a named patient basis, on receipt of a written request from a consultant. In an emergency this may be supplied retrospectively. Acceptance of liability by the UHB will also depend on "peer group support" as above

2. **Unlicensed medicines prepared by a manufacturer with a Specials Manufacturing Licence.** These are widely referred to as "specials". They are not usually obtained for a named patient. The responsibility for establishing the quality of the product lies with the pharmacist. A certificate of analysis will be obtained where appropriate. Where the quality of the product is judged to be unsuitable or cannot be established the prescriber will be informed.

3. **Use of licensed products outside their product licence**. The indication may be unlicensed, the dose range or age of the patient may be outside the licence, the route or method of administration may be unlicensed. In some circumstances the product may require unlicensed reformulation before administration. The UHB will accept liability for problems associated with such use if the use would have "peer group support". Peer group support for the use of unlicensed medicines or

medicines outside of product licences will be determined by a variety of means for example by reference to literature which contains evidence, standard texts, specialist texts, and that which is currently accepted as reasonable clinical practice.

Prescribers have a duty to ensure that they are aware of the legal status of a medicine that they are prescribing (i.e. licensed, unlicensed or 'off label') for a specific indication. Where pharmacists are aware of unlicensed use they must consider the need to ensure that the prescriber is aware of the risks and benefits of such use.

10.3 Monitoring and Recording

Supplies of unlicensed medicines ordered at the request of a consultant will be recorded by the pharmacy. Supplies made to individual patients will be recorded manually and on the pharmacy computer system. The issue of "specials" will be recorded on the pharmacy computer system.

The pharmacy will report on the purchase and issue of unlicensed drugs annually to the Medicines Management Operational Group.

10.4 Unlicensed Medicines Risk Assessment & Request Form

Prescribers wishing to use an unlicensed medicine or a medicine outside of the terms of its product licence must complete an unlicensed medicines form giving details of the product and purpose for its use. The Prescriber/Consultant should complete the form, providing evidence from standard texts/publications or "peer support". The completed form should be returned to Pharmacy, who will complete the rest of the purchasing details. The form will be entered into the Unlicensed Medicines database and a summary report presented to MMOG each year.

10.5 Non-Medical Prescribing

Nurse or pharmacist prescribers may prescribe outside the terms of the manufacturer's product licence ("off-label") as either independent or supplementary prescribers. Since December 2009 Pharmacist IP's and Nurse IP's can prescribe unlicensed medicines

for their patients on the same basis as doctors and provided they are competent and take responsibility for doing so.

10.6 Packaging

On receipt of the medication, pharmacy will confirm that the pack is appropriately labeled with an English generic drug name, form, strength, expiry date and has an English version of the SPC. Where necessary the pack will be over labeled and an English SPC will be sourced to reduce the risk of dispensing errors and errors during administration.

10.7 Prescribing interface with GPs for unlicensed medicines and medicines outside of licence

Hospital prescribers wishing to transfer the care of a patient for whom they prescribe an unlicensed medicine or a medicine outside of its product licence must first seek agreement from the patient's GP. The GP may refuse to undertake ongoing prescribing. Information supporting the prescribing of the unlicensed medicine concerned must be provided where appropriate.

Part 11 - Medicines in Clinical Trials

11.1 Clinical Trial Medicines

All clinical trials involving Investigational Medicinal Products (IMPs) are governance reviewed and a pharmacy assessment forms part of this service.

Before a clinical involving medicines can commence, the pharmacy clinical trials team should be provided with copies of Research Ethics Committee, Medicines and Healthcare Products Regulatory Agency (MHRA) and UHB Research and Development Department approvals.

11.2 Clinical trial storage, prescribing, supply and administration

All medicines used in clinical trials within HDUHB should be received and supplied by the Pharmacy department and managed to the same standards as other medicines used therapeutically.

- IMP must not be stored in offices, clinics or ward areas unless by prior arrangement with pharmacy and only where appropriate risk management processes and standard operating procedures (SOPs) are in place.
- IMP must only be used in patients recruited to the trial.
- All IMP deliveries will be correctly received and recorded by a trained member of the pharmacy team.
- Temperature records will be maintained for all IMP storage locations as specified by the trial sponsor.

A prescription for a clinical trial medicine must be signed by a member of the investigational team or an approved prescriber. Following the trial protocol and sponsor approval, IMP can be prescribed on a trial specific prescription form, health board clinical trial prescription form, chemocare prescription form (if applicable) or inpatient medication administration chart (if applicable)

If clinical trials labelling and dispensing is required, the IMP will be dispensed following a trial specific pharmacy dispensing procedure and accurate accountability records will be kept. All record keeping will be detailed in the clinical trial protocol and must be followed.

The clinical trial prescription will be retained in the pharmacy site file which will be stored in the clinical trials designated storage area of the pharmacy site.

The administration of IMPs must be undertaken as for the policy for administration of routine drugs. Vigilance must be exercised to ensure that the IMP is being used according

to the clinical trial protocol and that each individual involved in conducting a trial is qualified by education, training and experience to perform a specific task. All registered Healthcare Professionals administering medication within a clinical trial must check the medical records for further information.

11.3 Unblinding a clinical trial medication

Pharmacy will ensure that a trial specific emergency unblinding procedure is written for all blinded trials before the trial commences.

Copies of the unblinding policy breaks or trial randomisation policies will be kept in pharmacy. Pharmacy will ensure that the blind is maintained throughout the trial. Policy break envelopes or copies of policies will be returned to the sponsor or investigator at the end of the trial. Policy break envelopes or randomisation lists will only be released to the trial sponsor (or investigator) when written evidence from the sponsor has been provided to the clinical trials pharmacist that the final locked dataset has been verified.

11.4 Disposal or return of clinical trial medicines

Following the clinical trial protocol, unused clinical trial study medication must be returned to the hospital pharmacy. Returned clinical trial study medication should be reconciled and recorded as set out by the clinical trial sponsor. Returned clinical trial medicines or any un-issued clinical trial medication must be returned to the sponsor or disposed of in accordance with the clinical trial sponsors instructions.

This procedure is not applicable to clinical trials involving blood products or wound healing products.

Part 12 - Strong Potassium Injections, Ordering, Storing, Prescribing and Administration

The information in this chapter reflects the requirements set out by the National Patient Safety Agency in an alert (NRLS-1051A_2002) aimed to minimise the risk of accidental overdose of intravenous (IV) Potassium. This information recognises the need to ensure that seriously ill patients in critical care areas who require intravenous Strong Potassium as part of their treatment continue to receive it promptly

The definition of Strong Potassium injections includes:

- Solutions of potassium chloride of 10% or more (i.e. 1gram of potassium in 10ml)
- Solutions of potassium hydrogen phosphate and potassium dihydrogen phosphate in ampoules and vials.

Prescribing.

IV treatment of hypokalaemia should only be instigated when the oral/enteral route is unavailable or will not achieve the required increase of serum Potassium within the clinically acceptable time.

Wherever possible prescribed ready mixed infusions. Prescriptions must be expressed as mmols of potassium and must include rate of infusion and carrier fluid.

The rate of administration in adults should not normally exceed 10mmols/hour. ECG monitoring is recommended for higher rates.

Further guidance on dosing of potassium is given in specific guidelines and/or your ward Pharmacist will be able to provide information on the ready mixed preparations available.

Ordering and Storage

Strong potassium injections as defined above will be treated as a controlled drug. Ordering, supply, storage and administration must follow the procedural guidance set out in Part 4.

Wards that are permitted to keep a supply of strong Potassium injection are:

PPH ITU
Bronglais ICU CMU Meurig Angharad A&E
GGH ICU HDU Theatres Theatre Recovery CCU
WGH ICU CCU Theatres

Wards other than those named above will only be provided with a supply of strong Potassium chloride on receipt of a prescription chart for the individual patient, it is likely that the pharmacist will wish to discuss this individual prescription with the prescriber. If authorised, the ward will again need to follow the CD process.

<u>Administration</u>

A two registered person independent whole process check (preparation and administration) is required for the administration of Strong Potassium in accordance with the procedure for CDs in Part 7.

Infusions prepared with Strong Potassium must be thoroughly mixed with repeated inversion and agitation of the container.

NB Wards must not obtain supplies of Strong Potassium from other wards. In normal working hours supplies should be obtained from pharmacy. Outside

normal hours supplies must be facilitated via the Site Manager.

Part 13 Storage of Records Relating to Medicines

Delivery notes accompanying ward/department stock deliveries

Once items delivered have been checked against the delivery note, and there are no apparent discrepancies by way of delivery error or costing error, the delivery note is to be kept on the receiving ward for 3 months and then may be destroyed.

Controlled Drug order book

These are to be kept on the ward/department for 2 years after the date of the last order entry in the book. The CD order book can then be destroyed.

Controlled Drug record book

These are to be kept on the ward/department for 2 years after the date of the last entry of receipt or administration, whichever is the later. The CD record book can then be destroyed.

If the CD Controlled Drug Record Book contains a record of destruction it must be retained for 7 years.

Medicines transit records

Upon completion of signature of the receipt, the delivery driver/ porter must return the record of receipt to the dispatching pharmacy as soon as possible. The delivery record will be kept for 3 months and then may be destroyed.

Pharmacy records

The pharmacy will retain records of orders, receipt and supply as set out in WHC (2000)/71 which details document retention as follows:

3 months	Picking records/ delivery notes to wards & departments
1 year	Stock-take reports plus current year Worksheets for resuscitation boxes (one year after expiry of longest dated item)
2 years	Orders/requisitions for medicinal products supplied by the pharmacy including all dispensing Top Copy of Discharge Prescription (TTH) Controlled Drug Registers and Requisitions (2 years after last date

	of entry) Hazard Warnings
5 years	Unlicensed medication requests and issues Worksheets for chemotherapy, aseptic and total parenteral nutrition, repackaging Certificates of analysis Recall Documentation Clinical trials records (5 years after end of trial)
6 years	Orders Financial records including invoices Disposal of waste records
7 years	Records of Controlled Drug destruction (Hospital stock or patient's own)
8 years	Medicines Information questions and answers (25 years in case of a child or Obstetrics & Gynaecology)
13 years:	Production records including extemporaneous Controlled Drug products and radiopharmacy