group policies and procedures

# medicines management policy

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| --- | --- |
| Category | CLINICAL GOVERNANCE |
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**Related policies and guidance**



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# aim

The aim of this policy is to promote the safe handling of medicines within all Castleman Healthcare Ltd places of work, for the benefit of patients and staff.

This policy applies to all Castleman Healthcare Ltd employees and subcontractors and aligns with the Medicines Management policies from other healthcare providers we are jointly delivering a service with.

# objectives

This policy outlines the best practice for procurement, storage, prescribing, dispensing and administration of medicines throughout Castleman Healthcare Ltd. This policy also outlines the legal requirements and professional responsibilities for all clinical staff when handling medicines and defines the legal categories of medicines. Reference sources can be found as an appendix to this policy.

These policies are based on current legal requirements, professional standards and professionally accepted best practice in UK healthcare as at April 2008, and have been produced in line with best practice guidance from the NPSA, NICE, MHRA and the Department of Health. It will be reviewed annually or in the light of any changes in legislation. In addition, Castleman Healthcare Ltd will also provide a specific policy for each separate service it delivers and will align with the Medicines Management Policy for each healthcare provider on jointly delivered services.

# Definition of a Medicine and legal Categories of Medicines

**Definition of a Medicine**

In the Medicines Management policy, the term ‘Medicine’ is defined as a substance, article or ingredient available for use by administration to human beings for a medical purpose. Instruments, apparatus and appliances are not classed as medicines; some substances may have a ‘CE’ classification.

**Legal Categories of Medicines for Human Use**

The Medicines Act 1968 defines three classes of medicines:

* 1. GSL - General Sales List Medicines
  2. P - Pharmacy Medicines
  3. POM - Prescription Only Medicines

GSL Medicines are available without the need for pharmacist supervision.

P Medicines can only be supplied under the supervision of a pharmacist.

POM Medicines can only be supplied on the written instruction (prescription) of a medical or dental practitioner, or a veterinary surgeon.

Under the Misuse of Drugs Act 1971, specific POMs are classified as Controlled Drugs. For the purposes of these policy documents all drugs listed in schedules 1,2, and 3 of the Act will be referred to as ‘Controlled Drugs’.[[1]](#footnote-1)

# Personal, Professional and Legal Responsibilities

Each professional group involved in the management of medicines in the healthcare environment has their own professional code of ethics and guidance on standards of professional conduct. This forms the basis of the standards required for any activity involving the management of medicines.

The Medicines Management policy applies to all clinical and medical staff within Castleman Healthcare Ltd organisations and other healthcare service provider we are jointly delivering a service with, and can mean a GP, clinician or any other prescriber e.g., nurse practitioner.

**Responsibilities**

1. The Clinical Governance Director is primarily responsible for safeguarding the quality of all clinical care within Castleman Healthcare Ltd.

2. All staff involved with the storage, ordering, supply and administration of medicines will comply with the Castleman Healthcare Ltd policy and their own GP practice policy. The Medicines Management GP is responsible for adoption of and adherence to this policy. All will adhere to the current GMC Code of Professional Conduct and Scope of Professional Practice.

# Dorset CCG Medicines Code policies

The Dorset CCG Medicines Code defines the policies and procedures to be followed to ensure the legal, safe and secure handling of medicines, including prescribing, ordering, dispensing, storage and administration. It aims to ensure the highest standards of medicines management, and thus minimise the risk of medicines errors.

The Medicines Code is presented as a series of chapters covering all aspects of the medicines use process and applies to all medical, nursing, pharmacy and allied health professions involved in medicines management activities in Dorset Clinical Commissioning Group. Castleman Healthcare Ltd and other service providers delivering joint services adhere and implement these policies and procedures as required.

Refer to Dorset CCG Policies at Dorset Formulary. <http://www.dorsetformulary.nhs.uk/>

# Storage of Medicines

All medicines should be stored in a secure and safe manner, with regard to appropriate environmental monitoring and the control of waste. All storage requirements are the responsibility of the Medicines Management GP/Service Lead Clinician, including custody of all drug cupboard keys.

Controlled Drugs require special storage arrangements; possession and safe storage is the responsibility by law of the Medicines Management GP/Service Lead Clinician and the designated Senior Nurse in each GP practice. (See section 9).

All departments where medicines are stored will have separate lockable facilities as detailed in each specific policy (see above).

The rooms where all these storage facilities are located must have daily max/min temperature recording in place which should be monitored by practice nurses. All the medicines cupboards must be kept locked when not in use.

**Stock Management**

Each Practice/healthcare provider is responsible for checking and regularly inspecting the medicines storage areas, including checking:

1. The tidiness and cleanliness of the cupboards.

2. That cupboards used are appropriately sized, placed, secured and locked when not in use.

3. That there is no excess stock.

4. That stock rotation occurs (to use shortest dated stock first).

5. That stock medicines are kept in their appropriate environmental conditions.

6. That the CD register is properly maintained, and records of daily CD checks are kept in practices, healthcare settings where applicable.

7. That all stock is within its expiry date.

**Emergency Drugs**

It is the responsibility of the Medicines Management GP/Service Lead Clinician or Senior Nurse in each practice/healthcare setting to ensure that a pre-determined range of emergency/cardiac arrest drugs is kept in appropriate clinical areas. It is their responsibility to maintain these emergency drugs and replace them upon expiry or if used. (Section 15).

Refer to Dorset CCG - <https://www.dorsetccg.nhs.uk/wp-content/uploads/2018/04/Standard-E1-storage-safe-custody-of-medicines.pdf>

**Audit**

The Clinical Governance Director will request to see audits from each practice/healthcare setting where medicines on an annual basis, to ensure safe and appropriate storage arrangements are in place. Checks will include balances of CD’s, stock levels, and expiry dates of all medicine stocks.

**Pharmaceutical Waste**

All expired or otherwise used medicines will be removed from stock and segregated for disposal.

Pharmaceutical waste is classified as ‘special waste’ and will be disposed of according to legal and local authority regulations. (Section 21).

Refer to Dorset CCG: <https://www.dorsetccg.nhs.uk/wp-content/uploads/2018/04/Standard-B4-Waste-Management.pdf>

# Procurement

Procurement is the process of purchasing a medicinal product for dispensing and administering to a patient. A medicinal product in this case is defined as any raw material, container, closure, prescription ingredient, finished product, proprietary preparation or any other medicinal substance.

**Purchasing**

The purchasing of all medicinal products is the responsibility of the Medicines Management GP/Service Lead Clinician for the service being delivered. They must be satisfied that the supplier and the source of any medicine purchased are reputable, paying particular attention to storage conditions before purchase and to labelling, appearance origin and chain of supply of the medicine concerned.

All medicines purchased will carry a full UK Marketing Authorisation (product licence).

# Prescribing

Prescribing must conform to the advice given in the current British National Formulary (BNF) under “Guidance on Prescribing”. Medication records are not legally classed as prescriptions but are ‘written directions’ to supply and administer specific medicines for specific patients. They are exempt from the detailed requirements for prescription writing that exists for example under the Misuse of Drugs Act for controlled drugs, except in the case of prescribing discharge medication (TTO’s).

**Medication Records**

Each patient will have a medication record on which all medicines administered will be recorded.

Only one record should be used at any one time for each patient.

The patient’s details must be fully recorded on the documentation and the following information must be stated:

1. Patient’s name, address, DOB, age, NHS / Unit number.

2. Date of attendance.

3. Allergies/medicine sensitivities.

4. If pregnant, at what stage.

5. Current medication history, including any ‘alternative’ medicines.

**Prescribers**

Those persons allowed to prescribe for patients are doctors working within the units and those operating under the instructions of a ‘Patient Group Direction’. Their responsibility is to agree to ensure patient consent to treatment based on understanding and awareness, to identify the correct patient when prescribing, to record the prescription/written order clearly following the BNF “Guidance on Prescribing” and details within this policy.

**Patient Group Directions (PGD)**

A PGD is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. Each PGD is drawn up locally by doctors, pharmacists and other appropriate professionals. It must be approved by the Clinical Governance Group. PGDs apply to groups of patients who may not be individually named prior to presentation for treatment. Each facility must have PGDs in place where appropriate.

Refer to Dorset CCG Policies on prescribing <https://www.dorsetccg.nhs.uk/services/medicines-management/>

# Supply and Dispensing

The supply of medicines is the responsibility of the Clinical Governance Director with the Medicines Management GP/Clinical Service Lead and/or Senior Nurse being responsible for ensuring adequate supplies of ‘stock’ medicines are available.

**Supply of Stock**

A documented stock list of all medicines routinely held in each unit will be available at local level. This list should be reviewed regularly as practices change and at least annually. This list should be agreed by the Service Lead. Stock levels should be kept to a minimum manageable and safe level.

A local system will be in place for replenishment of stock on a regular basis by signed requisitions or a pharmacy top up service. All order and supply documents will be signed as correct by the clinical and pharmacy staff to provide a clear audit trail for the supply and receipt of stock medicines.

Cardiac arrest emergency medicines will be supplied to appropriate areas and a system put in place to check expiry dates of this stock and replace when necessary.

Medicines will be transported in a secure manner from the contract pharmacy to the individual units.

**Supply of controlled drugs**

Each practice/healthcare setting (where applicable), will hold agreed stock levels of a number of controlled drugs, which shall be ordered in accordance with legal requirements. They will be supplied by the pharmacy service, delivered by the pharmacist/collected by a nurse and received by the nurse-in-charge who will sign for their receipt. (See section 9).

# Controlled Drugs

For the purpose of this policy all medicines listed in schedule 1, 2 and 3 of the Misuse of Drugs Act will be considered as Controlled Drugs (CDs).

In addition, the new strengthened governance arrangements for CDs and legislative changes that flow from the Government’s response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations.

CDs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

The Health Act 2006 is primary legislation and applies to the whole of the UK. In England, the CDs (Supervision of Management and Use) Regulations 2006 (SI 2006 No. 3148) [http://www.opsi.gov.uk/si/si2006/20063148.htm] came into force in January 2007.

It aims to set out robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of CDs, whilst at the same time helping to ensure appropriate and convenient access for those patients who require them.

It is now a statutory requirement to appoint an Accountable Officer (AO) in every healthcare organisation, who will have responsibility for the safe use and management of CDs within that setting.

# Preparation of medicines for administration

All medicines will only be prepared for administration immediately before they are required. Each service delivered will have its own specific policy/guidelines for administering medicines.

**Other medicines**

When preparing medicines for administration:

1. Some medicines should be considered as ‘single patient use’ items and should only be used for one patient and then any excess discarded. These include

1. Inhalers
2. Single dose ampoules/vials
3. IV infusions

2. Multi-dose preparations

• Multi-dose vials used for more than one patient will be discarded 28 days after opening, or as stated in the product information. The date and time of opening must be recorded on the vial.

• Bottles of oral liquid medicines kept as stock must be discarded six months after opening (or sooner if the expiry date is reached). The date of opening must be recorded on the bottle.

When preparing any medicines for administration all of the above criteria must be adhered to, to ensure safe practice and aseptic technique must be used at all times.

The UKCC Standards for Administration of Medicines, Oct 1992 and the Scope of Professional Practice, June 1992 must be adhered to at all times.

# Administration of medicines

Medicines are administered by doctors and registered nurses. An up-to-date list of specimen signatures and initials for all clinical staff who administer medicines will be kept by Castleman Healthcare Ltd for each specific service delivered.

Registered nurses who administer medicines will be conversant with the UKCC Standards for Administration of Medicines (Oct 1992). This policy outlines who can administer medicines by the various routes available and what the procedures are to maintain good and safe practice during administration.

# Patients own medicines and self administration

**Patient’s own medicines**

To ensure patient safety and to ensure correct care of patients own property, patients will keep their medicines with them at all times.

**Self-Administration**

Patients with their own medicines are deemed suitable to self-administer their medicines, and should be given the privacy and support necessary to do so. If patients find that they are unable to administer their own medication this will be recorded on the patient’s records and arrangements will be made for an appropriately trained member of staff to administer the drug.

# COSHH

Records will be kept for all ‘hazardous substances’ kept within each unit. A pro forma record sheet is attached for information (Appendix 3). These records will be reviewed and updated as product or usage changes or at least once a year if no change is noted.

# Emergency drugs

**Cardiac Emergency Drugs**

Each Castleman Healthcare Ltd and healthcare service provider we are jointly delivering a service with will provide and maintain cardiac arrest/emergency drugs boxes. The contents of these boxes are to be agreed at local level in line with local CCG policy. Provision will be made to keep these boxes in date and ready for use.

**Anaphylaxis/Allergy/Adverse Reactions**

Each area will ensure a supply of appropriate medicines for the treatment of allergic reactions. The Lead Nurse will ensure that procedures are in place to control allergies and adverse reactions to medicines to include:

1. Documenting known allergies on patients’ medication records and in their nursing notes.
2. Use of red allergy bands.
3. Reporting any adverse reactions to the patients GP.
4. Reporting of adverse incidents to the MHRA (yellow card system) if necessary.

# Following Death

If a patient were to suffer a fatal cardiac arrest or die from any other means whilst within the care of Castleman Healthcare Ltd and any healthcare service provider we are jointly delivering a service with, this would be deemed an unexpected event and procedures will be followed out as set out Castleman Healthcare’s ‘Death of a service user’ policy.

# Errors and Adverse reactions policy

An open reporting system will be promoted at all times. All medicine errors will be reported using the adverse incident reporting system. A senior clinical member of staff will investigate all medicine errors and will apply professional judgement to each error to reduce future incidents.

# Drug alerts and the MCA (MEDICINES Control Agency)

MHRA drug alerts are received into each unit via email from the Project Director the alerts are classified as follows:

• Class 1 - Action now (including out of hours)

• Class 2 - Action within 48 hours

• Class 3 - Action within 5 days

• Class 4 - Caution in use

All drug alerts received into the organisation will be passed on without delay to the Lead Nurse. Each drug alert is classified (i.e. graded for importance/urgency) and has a serial number, and upon receipt of each drug alert appropriate action must be undertaken as requested and fed back to the Project Director

# Signature records

To fulfil the requirements for effective recordkeeping in all Castleman Healthcare Ltd areas a full record of the signatures and initials signatures of all clinical staff will be held in a secure environment by the Medicines Management GP and/or Senior Nurse and the pharmacy Contractor. This must include all Nursing Staff including HCSW

These records will be updated regularly and for each change in clinical staff.

# Disposal of Pharmaceutical Waste

All expired, damaged or unwanted medicines will be returned to the pharmacy contractor for prompt and efficient disposal.

Any group B pharmaceutical waste (discarded syringes and needles, cartridges, broken glass, contaminated disposable sharp instruments or items) will be collected for incineration in a rigid sharps receptacle which complies with BS7320.

These must only ever be 75% filled and have a secure seal.

Expired or no longer required controlled drugs will be destroyed and disposed of according to legal requirements, by the contract pharmacist, witnessed by either a member of the police service, or a locally designated member of staff. (See section 9).

# Appendix  - references & resoruces

1. GMC Code of Professional Conduct
2. Standards for the Administration of Medicines
3. Royal Pharmaceutical Society of Great Britain
   1. Code of Ethics
   2. Standards for Professional Practice
4. DOH (2007) Safer management of controlled Drugs: *A guide to good practice in secondary care (England)*
5. Health Act (2006) Part 3: *Drugs, Medicines and Pharmacies*; Chapter 1:*Supervision and Management of Controlled Drugs*
6. National Prescribing Centre(2005) Monitoring and Inspecting the management of controlled drugs: *A competency framework*(England)1st Edition Sept 2005
7. Statutory Instrument 2006 No.3148 The controlled drugs (Supervision of Management and Use) Regulations 200

# Appendix - Template for Controlled Drug Incident - Accountable Officer (AO) Record.

|  |  |
| --- | --- |
| **Date on which concern**  **made known to AO:** |  |
| **Date on which the matters that lead to the concern took place:** |  |
| **Details regarding the nature of the concern:** |  |
| **Details of individual in relation to whom concern was expressed:** |  |
| **Details of who expressed the concern e.g. person or supplier:** |  |
| **AO assessment of whether information in relation to the concern should be disclosed (yes/no and reason for decision):** |  |
| **If ‘Yes’ above – details of to whom the disclosure was made and the details disclosed:** |  |
| **Recommendations made by person/body to whom information is disclosed:** |  |
| **Date and details of any actions taken as a result of disclosure:** |  |

**AO Name** (print)**: ………………………… AO signature: ……………………… Date: ……….**

# Appendix 2 – CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH REGULATIONS 1999 (COSHH) SUBSTANCE IDENTIFICATION AND COSHH ASSESSMENT RECORD

|  |  |  |
| --- | --- | --- |
| Substance Name: | Trade Name: | |
| Ingredients: | Date of Issue: | Record Number: |
| Nature of Hazard  🞏 🞏 🞏 🞏 🞏 🞏 🞏  Very Toxic Toxic Harmful Corrosive Irritant Biohazard Sensitiser | | |
| Potential Exposure Points  🞏 🞏 🞏 🞏 🞏  Inhalation Ingestion Skin Eyes Injection | | |
| Physical Properties  🞏 🞏 🞏 🞏 🞏 🞏  Solid Pellet Powder Dust Resin Fibrous  🞏 🞏 🞏 🞏 🞏 🞏  Liquid Gas Vapour Explosive Flammable Flash point | | |
| Max exposure limit (MEL)………………………………………  Occupational exposure standard (OES) :…………………….. | | |
| Where substance is used: Quantities supplied in: | | |
| What it is used for and quantities used at any one time: | | |
| Where and how it is stored | | |
| Where and how it is handled (including PPE used) | | |
| Manufacturers recommended precautions | | |
| Manufacturers name: Contact telephone number:  Manufacturers address: | | |

**Health risks:**

* Inhalation
* Skin Contact
* Ingestion
* Irritant to eyes
* Neurological damage
* Carcinogenic
* Foetal Damage
* Other (please specify)

Spillage and Disposal

* Ventilate area
* Eliminate all sources of ignition
* Absorb in sand or inert absorbent material
* Collect into container and close lid
* Do not allow spillage to enter drains/ sewers/ water courses
* Dispose of in accordance with local authority regulations
* Wear protective overalls and chemical/ safety footwear
* Wear suitable hand protection
* Wear respiratory protection if spill is in poorly ventilated area
* Spillage kit required
* Other (please specify)

**First Aid**

* Inhalation – remove to fresh air and rest
* Ingestion – do not induce vomiting
* Ingestion – give plenty of water to drink
* Significant exposure – call for medical assistance immediately
* Eye – irrigate with water for at least 15 minutes
* Skin – wash with plenty of water
* If irritation persists, consult a doctor
* Other (please specify)…………………………………………

**Fire Fighting**

* Powder, foam, carbon dioxide (CO2), water
* Toxic fumes produced when substance is involved in a fire
* Wear self-contained breathing apparatus
* Not applicable
* Other (please specify)…………………………………………

Information obtained from Supply label Hazard data sheet

Assessment required? Yes /No

Name *(please print)*:…………… Signature ………………………………… Date:…………….

# APPENDIX - COSHH ASSESSMENT RECORD

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Process Identification/Process Location: Record Number:  Date of Assessment: | | | | | | | | | | | |
| Who performs task? Review Date: | | | | | | | | | | | |
| Brief description of task/frequency/duration: | | | | | | | | | | | |
| Hazardous substances/activity | | | | Hazard | | | | | | Exposure Limit (if applicable) | |
| 1. | | | |  | | | | | |  | |
| 2. | | | |  | | | | | |  | |
| 3. | | | |  | | | | | |  | |
| 4. | | | |  | | | | | |  | |
| 5. | | | |  | | | | | |  | |
| Secondary emissions | | | | | | | | | | | |
| **POTENTIAL EXPOSURE POINTS DURING SUBSTANCE(S) USE** | | | | | | | | | | | |
| Substance/Trade name/Activity | | Lungs | Mouth | | Skin | | Eyes | Quant used | Frequency of Exposure | Duration of Exposure | Numbers Exposed |
|  | |  |  | |  | |  |  |  |  |  |
|  | |  |  | |  | |  |  |  |  |  |
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|  | |  |  | |  | |  |  |  |  |  |
| **CONTROL MEASURES IN PLACE** | | | | | | | | | | | |
| Substance/Activity | Local Exhaust ventilation | | | | | General Ventilation | | | Type of PPE being used | | |
|  |  | | | | |  | | |  | | |
|  |  | | | | |  | | |  | | |
|  |  | | | | |  | | |  | | |
| Control measures regularly checked? Yes No | | | | | | | | | | | |
| Control measure record kept? Yes No | | | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| CONCLUSION FOR ALL SUBSTANCES  NA = not applicable S = satisfactory DK = don’t know US = unsatisfactory | | | |
| NA S DK US | COMMENTS AND NOTES | | |
| Labelling |  | | |
| Storage |  | | |
| Transport |  | | |
| System of Work |  | | |
| Local Ventilation |  | | |
| General Ventilation |  | | |
| Waste Disposal |  | | |
| Provision of PPE |  | | |
| Training |  | | |
| Health Surveillance |  | | |
| Air Monitoring |  | | |
| Welfare Facilities |  | | |
| Emergency Procedures |  | | |
| Other |  | | |
| Foreseeable changes to working practices/materials: | | | |
| Having considered the information on this form, I am/we are of the opinion that:  Risks to health are unlikely 🞏  Risk is significant but adequate controls are in operation 🞏 | | | |
| Risk is significant and controls need to be as follows 🞏 | | Responsibility | Action Date |
|  | |  |  |
|  | |  |  |
|  | |  |  |
| Risk is unknown, the following action is recommended 🞏 | |  |  |
|  | |  |  |
|  | |  |  |
|  | |  |  |
| **This assessment should be reviewed:**  When the above actions are implemented 🞏 Annually 🞏 When circumstances change  Recommended date:………………………………..  Assessor(s) name:…………………………………. Job Title:………………………….  Signature(s):……………………………………………………………………………… | | | |

1. *Current British National Formulary (BNF)*  [↑](#footnote-ref-1)