Controlled Drugs Governance Policy

Policy information

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Summary of document:
This policy outlines the governance arrangements in place to ensure the safe review, recording and storage of controlled drugs within Hywel Dda University Health Board. It should be read in conjunction with the detailed guidance and advice contained in 268 Medicines Policy for Acute and Community Sectors

Scope:
This policy applies to all areas within the Health Board that use or handle Controlled Drugs. It is offered as guidance to the Independent Contractors to support the contracts that they hold with the Health Board.

All registered healthcare professionals and employees must follow this policy.

Independent contractors are advised to refer to this policy to support their contracts with the HB.

Controlled drugs (CDs) defined in this document are those substances contained within Schedules 1, 2, 3, 4 and 5 of the Misuse of Drugs Act 1971[4]. The Health Board, through the Medicines Management Operational Group and Medicines Policy, however, may extend this term to include other substances that are open to abuse, or are high risk medicines or 'controlled' for other reasons.

To be read in conjunction with:
268 Medicines Policy (Acute, Mental Health, Learning Disabilities and Community) (opens in a new tab)
Controlled Drugs Standard Operating Procedures (Acute Sector)
HDUHB Controlled Drugs: Standards of Practice (Primary Care)

Patient information: None required
Owning group:
Local Intelligence Network

Executive Director job title:
Medical Director as Accountable Officer for Controlled Drugs

Reviews and updates:
1 – new policy 31.4.2018
2 – three yearly review 25.8.2021
3 – three yearly review Addition of Appendix Application and Renewal of Home Office Controlled Drugs Licences (Supply and Possession) Standard Operating Procedure, Updated: Flowchart for the Management of LIN referrals. Restructured document so easier to read and checked compliance with the training course for CDAO and relevant legislation. Checked and updated all links.

Keywords
Controlled Drugs; opiates; accountable officer.

Glossary of terms
CD - Controlled Drug. Controlled Drugs are "dangerous or otherwise harmful drugs". This category of medicines is subject to additional requirements over and above those that apply to other categories of medicines (such as Pharmacy (P) medicines or Prescription Only Medicines (POMs). Controlled Drugs are covered by both the Medicines Act (1968) and the Misuse of Drugs Act (1971) with associated regulations.
LIN Local Intelligence Network: A statutory network in place to provide an overview on all aspects of use of controlled drugs and to enable the sharing of relevant information to reduce the risk of harm
CDAO – Accountable Officer for Controlled Drugs

Keypoints:
This policy outlines the actions taken by the Health Board to manage Controlled Drugs in line with legislation so that they are available for the timely, appropriate clinical treatment of patients while minimising the risks to patients, staff and the general public.

Contents

Introduction

In accordance with the Government's response to the Shipman Inquiry[1], NHS bodies and the private sector must have arrangements in place for the management of controlled drugs (CDs) by all healthcare professionals who they employ or with whom they contract.

NHS bodies are required to appoint an Accountable Officer to monitor the use of controlled drugs within their organisation and take appropriate action where necessary.

This policy takes key elements from the Misuse of Drugs Act 1971 (Revised 2015 Wales) and other legislation, the revised Duthie Report[2], and the Department of Health, Safer Management of Controlled Drugs: A guide to good practice in secondary care[3] and the guidance published by NICE in 2016 (NG46): Controlled Drugs: safe use and management[4].

Policy Statement

Hywel Dda University Health Board is committed to ensuring that the governance arrangements relating to the safe and secure handling and storage of controlled drugs within the Health Board are in place, comply with current legislation and good practice guidance and minimise the risk to patients, staff and visitors associated with the use and handling of Controlled Drugs.

Scope

This policy applies to all areas within the Health Board that use or handle controlled drugs. It is offered as guidance to the independent contractors to support the contracts that they hold with the Health Board.

All registered healthcare professionals and employees must follow this policy.

Independent contractors are advised to refer to this policy to support their contracts with the HB

Controlled drugs (CDs) defined in this document are those substances contained within Schedules 1, 2, 3, 4 and 5 of the Misuse of Drugs Act 1971[4]. The Health Board, through the Medicines Management Operational Group and Medicines Policy, however, may extend this term to include other substances that are open to abuse, or are high risk medicines or 'controlled' for other reasons.

Aim

The aim of this policy is to reduce the risk of harm to patients and staff from the inappropriate management and use of controlled drugs and to ensure compliance with current legislation.

It provides overarching assurance of governance measures in place for the safe management of controlled drugs.

Objectives

To achieve the policy aim, the objectives:

- Detail the role and responsibilities of the Accountable Officer for Controlled Drugs
- Direct that detailed standard operating procedures (SOPs) are developed for all areas which handle Controlled Drugs such that the risks associated with the incorrect handling and storage of controlled drugs are reduced to a minimum.

- Detail the monitoring of the Standard Operating Procedures for Controlled Drugs
- Detail the procedure for reporting incidents, identifying and investigating any trends involving Controlled Drugs
- Set out the function of the Local Intelligence Network

Controlled Drugs Governance

The Accountable Officer for Controlled Drugs
The Appointment of the Accountable Officer for Controlled Drugs

The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008[5], states that organisations are required to appoint accountable officers.

A designated body must nominate or appoint (or under regulation 5(2) or (4) jointly nominate or appoint with one or more other bodies) a fit and proper suitably experienced person as its accountable officer.

A designated body must notify the Chief Executive of Health Inspectorate Wales (HIW) in writing of:

- any nomination or appointment by it in under paragraph (1) as soon as practicable and
- the removal of an accountable officer by it (whether or not under regulation 6) as soon as practicable

HIW must publish, from time to time and in such manner as it sees fit, a list of accountable officers of designated bodies in Wales.

The Health Board Chief Executive may nominate senior staff as Accountable Officers who report directly to the Health Board Chief Executive and who have responsibility for Health and Safety Security or Risk Management matters in the Health Board.

The following are prescribed as designated bodies for the purposes of section 17 of the 2006 Act:

- Local Health Board
- An NHS Trust
- Local Health Body (merged Trust & LHB)
- the Welsh Ambulance Services NHS Trust
- a Welsh independent hospital.

The Delegated Accountable Officer for Controlled Drugs (CDAO) Hywel Dda University Health Board as of June 2025 is the Medical Director.

The CDAO will ensure that an annual report is submitted to the Board outlining the key trends, issues and concerns relating to the safe and secure handling, and storage of controlled drugs.

Roles and Responsibilities of the Accountable Officer for Controlled Drugs CDAO)

Responsibilities of the Accountable Officer (AO) for Hywel Dda University Health Board are

(i) The AO must ensure a policy and standard operating procedures (SOPs) for CDs are in place. SOPs must at least cover:

- Who has access to CDs and assigning responsibilities
- Where CDs are stored
- Security of storage and transport as per Misuse of Drugs legislation
- Disposal and destruction
- Who is alerted should an incident or complications arise
- Record keeping
- Maintaining CD registers according to Misuse of Drugs legislation.
- Maintaining record of CDs returned by patients.

(ii) Review and amendment of SOPs to reflect changes in the legislation and impending review dates.

(iii) Ensuring arrangements are in place for routinely monitoring the safe use and management of CDs in their Health Board. This includes:

- Ensuring all those working with CDs are appropriately trained, according to SOPs
- Ensuring that arrangements are in place for assessing and investigating concerns, and that the AO is alerted to any significant findings
- Defining the relationships between the AO and existing local performance structures
- Defining the relationship between the AO and existing local groups e.g. Medicines Management Operational Group, Clinical Governance Committees, Medicines Management Teams
- Ensuring suitable arrangements are in place for disposal of CDs
- Checking that systems are in place to identify and act on triggers (e.g. patient complaint, police intelligence or concern raised by a healthcare professional) which ensure the AO is informed
- That there is an incident reporting system and all such reports are analysed and actioned.

(iv) Ensuring the self-assessment (HB) declaration, requested by HIW, is completed and returned.

(v) Ensuring adequate records are kept of concerns, including at least:

- date concern made known to the Accountable Officer
- date matters of concern took place
- details of nature of concern
- details of relevant individual to whom concern expressed and of who made the concern known
- details of action taken by the designated body
- an assessment of whether information should be disclosed to another responsible body, and if so the name of this body and information given.

Hywel Dda University Health Board policies, guidelines and standard operating procedures for the governance of Controlled Drugs

The documents in place in this Health Board, which meet the legal and good practice guidance specified by the Department of Health and the General Pharmaceutical Council (GPhC) are as follows:

- This Health Board policy: 708 - Controlled Drugs Governance Policy
- Hywel Dda University Health Board 268 Medicines Policy (Acute, Mental Health, Learning Disabilities and Community) and associated documents (opens in a new tab)
- HDUHB Controlled Drugs Standard Operating Procedures (Acute Sector) (opens in a new tab)
- HDUHB 1260 Management of Controlled Drugs in General Practice Procedure (opens in a new tab)
- HDUHB 1261 Authorised Witnesses: Processes for destruction of Controlled Drugs Procedure (opens in a new tab)
- HDUHB 1138 Security Management Policy (opens in a new tab)
- HDUHB Suspected Illicit Substances Management Procedure
- Staff Process: Raising a Concern or Issue (opens in a new tab)
- The terms of reference of the Local Intelligence Network

The Health Board's Medicines Policy (268) provides detailed guidance for the ordering, prescribing, administration, recording and destruction of controlled drugs within the Health Board.

The Medicines Policy sets out the procedure for reporting and dealing with an incident that involves a controlled drug.

The development, review and amendments to the policy is the responsibility of the Health Board's Medicines Management Operational Group.

The review of the policies is undertaken in line with the Health Board's guidance on policies (190 - Written Control Document Policy (opens in a new tab)) every three years; amendments and legislative changes are made as required.

Standard Operating Procedures (SOP) for CDs (Acute Sector)

Standard Operating Procedures (SOPs) (see 6.2 above) have been introduced following the publication of the Safer Management of Controlled Drugs (CDs) in Secondary Care by the Department of Health. These were developed following the Shipman Inquiry. The SOPs are designed to ensure that CDs are readily available for use by registered healthcare professionals when clinically required by patients in the Health Board. They also aim to improve and clarify the governance of local arrangements for the safe management of CDs in wards by bringing current arrangements and practice in line with the (new) regulatory frameworks.

These SOPs form part of the Health Board's Medicines Policy, which also provides further advice and a link to the SOPs relating to CDs which have been approved by the Health Board. These Health Board SOPs include details of the ordering, collection/transport, receipt, storage, administration, handover of keys, returns, checking/audit trail, destruction and disposal, use of patient's own CDs, borrowing of CDs out of hours in an emergency, and dealing with patients/staff suspected of illicit drug usage.

The AO must ensure a policy and procedures for CDs are in place through the development of standard operating procedures (SOPs).

The CDAO will ensure that all SOPs are appropriately reviewed and approved through the agreed process in Appendix 2.

SOPs must at least cover:

- Who has access to CDs and assigning responsibilities
- Where CDs are stored
- Security of storage and transport as per Misuse of Drugs legislation
- Disposal and destruction
- Who is alerted should an incident or complications arise
- Record keeping
- Maintaining CD registers according to Misuse of Drugs legislation.
- Maintaining record of CDs returned by patients.

The CD SOPs will be reviewed as a minimum every 3 years or sooner, if changes in legislation, guidance or professional standards are made or following a serious incident.

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A list of the current SOPs relating to CDs is shown in Appendices.

Wholesaler Dealers Licence and Home Office CD licence SOPs

Wholesaler Dealers Licences are required by hospital pharmacies to supply/sell medicines (including Controlled Drugs) to organisations external to Hywel Dda University Health Board (for example, community pharmacies, WAST and other Health Boards and NHS Trusts). Currently, the Wholesalers Dealers Licence is held by the WDA based within the Glangwili Hospital Pharmacy.

The process for the application and renewal of Home Office Controlled Drugs Licences (Supply and Possession) is set out in the appendices.

Local Intelligence Network (LIN)

The Health Board will have in place a LIN that will meet on a quarterly basis. The key roles of the LIN as defined by the guidance can be seen in the appendices.

The function of this group is to provide an oversight and enable communication of concerns and issues associated with CDs across a range of organisations.

The LIN will operate under an approved information sharing protocol (ISP).

Incidents involving CDs will be investigated by the operational team in line with the Health Board's existing policies. The findings will be shared through the operational service and with the LIN to ensure that a clear oversight is achieved and learning from the incident can be shared.

The LIN will review all Datix reports submitted within an agreed timeframe. It will identify any trends and concerns through the analysis of Datix reports and communicate these through direct communication from the CDAO to the relevant directorate requesting for assurances of actions.

Incidents and Concerns relating to Controlled Drugs

The Health Board's Medicines Policy (Section 6.2.8) sets out the procedure for reporting incidents relating to CDs. To ensure that incidents are reviewed, identified actions implemented and learning is shared across the Health Board additional safeguards are in place.

Health Board employees, GP practices and Community Pharmacies report through Datix

The link to report an incident via Datix can be accessed here: Datix Cymru (opens in a new tab)

External bodies who wish to report an incident and inform the CDAO do so via email to the LIN generic email account (LIN.HDD@wales.nhs.uk)

The HB Whistleblowing process is also available to individuals who wish to raise concerns anonymously.

Patients, relatives and carers can raise concerns via the Patient Support Services (PALS)

All concerns and incidents reports will be investigated following the HB Concerns investigation and management process (link (opens in a new tab)). This includes information about which Root Cause Analysis tools should be used.

Through the overview of the Senior Management Leads, LIN and the Medicines Event Review Group (MERG) all incidents identified that involve a controlled drug will be reviewed within an agreed timeframe to ensure that:

a) Appropriate actions have been implemented by the operational leads where the incident has occurred.
b) There is shared learning from the incidents across the Health Board
c) Datix reports are reviewed and completed in a timely manner
d) Where trends and/or concerns are raised then the relevant service will be alerted and assurances of actions to address requested by the CDAO
e) Data from the Medication Safety Dashboard is regularly monitored for compliance with aspects relating to controlled drugs.

Suspicion of theft or misuse of Controlled Drugs

Where an incident has occurred and is thought to be due to either theft or misuse of controlled drugs then the police must be informed as soon as possible as this is potentially a criminal offence.

The Health Board's security team must also be notified of the incident along with senior management including the Accountable Officer for CDs (CDAO).

Where fraud is suspected e.g. through falsification of records, the Health Board's Local Counter Fraud Specialist must also be notified

The scope and time scales of a review that involves controlled drugs should be approved by the Accountable Officer and the outcome shared directly with the CDAO

Learning from such review will be shared through the operational site/service leads for local actions. While the implementation of actions is the responsibility of the operational service the LIN will maintain oversight, identify if actions are not being progressed and identify where learning needs to be shared across the HB.

Training

Authorised witness training

The CDAO is responsible for ensuring that the organisation has enough Authorised Witnesses (AW) to ensure that timely destruction of expired CDs can take place. (This also ensures compliance with the Waste Legislation Section 28 exemptions). The AWs work under the HDUHB 1261 Authorised Witnesses: Processes for destruction of Controlled Drugs Procedure (opens in a new tab)

Continuous Professional development for LIN members and AOCD.

LIN circulates reports and shares useful resources (e.g. CQC, NHS England alerts and relevant websites)

The Health Board commissions the Santus 2 day initial and update training for the CDAO and other members of LIN when required.

Controlled Drugs Monitoring and Audit Programmes

Secondary Care

- Daily CD stock check by nursing staff
- 3-6 month stock checks & audit by pharmacy
- Quarterly report to LIN for medicines prone to misuse based on the Monthly Usage for co-codamol, diazepam, lorazepam, gabapentin, pregabalin, zopiclone, morphine sulphate 10mg in 5ml oral solution.
- Site Quarterly Occurrence Report to LIN
- Clinical appropriateness of CD prescribing:
    - Routine clinical pharmacy interventions
    - Guidelines for prescribing (Pain guidelines)
    - Specialist pain team (acute/chronic and palliative)

- Training for trainee doctors

Primary Care

- Quarterly Occurrence Report to LIN
- Annual self-declaration by GP practices to LIN
- Community Pharmacies good practice recommendation to complete weekly CD stock balance checks
- Clinical appropriateness of CD prescribing:
  - National Prescribing Indicators scrutinised at GP practice level by Medicines Optimisation Team
  - Chronic Pain Team support high prescribing practices
  - Any outlining NPIs are escalated via the HB Risk Register

Outside Agencies

The membership of the LIN can be found in Appendix 1 (Local Intelligence Network Terms of Reference). Contact details are kept in the LIN generic email account which can be accessed through the Personal Assistant to the Primary Care Medicines Optimisation Team or Senior Pharmacists.

Information Sharing Arrangements

An Information Sharing Protocol has been drawn up and has been quality assured by WASPI and can be found in LIN SharePoint folder.

When referrals or concerns are received (usually via the LIN generic email) they must be screened and managed following the Flowchart for the Management of LIN referrals (appendices) and Screening Arrangements for LIN referrals and recorded on the LIN tracker.

Private Prescribers for CDs

All Schedule 2 and 3 CD private prescriptions must be on WP10 PCD forms.

CDAOs are responsible for the authorisation of PIN (Prescriber Identification Number) numbers for private prescribers of Controlled Drugs which enables them to obtain WP10 PCD forms from NHS Wales Shared Services.

The responsibility for the monitoring and governance of GMC registered medical prescribers of CDs is with Health Inspectorate Wales.

HIW does not currently register and monitor private clinics run by non-medical independent prescribers (including Controlled Drugs) so the CDAO is responsible for issuing PIN numbers and must establish and operate appropriate arrangements for the periodic inspection of these premises not subject to inspections by Health Inspection Wales, Care Inspectorate Wales or the General Pharmaceutical Council.

Responsibilities

Chief Executive and Board

The Chief Executive and Board are responsible for the provision of resources to implement processes to ensure that the management and governance of controlled drugs complies with legislation and good practice guidance and for the appointment of an Accountable Officer for Controlled Drugs (CDAO).

Accountable Officer for Controlled Drugs

The Accountable Office for Controlled Drugs has delegated responsibility from the Chief Executive to develop and monitor the systems in place to reduce the risk of misuse of controlled drugs through sub-optimal processes, to review any incidents involving controlled drugs and to share 'lessons learnt' information across organisations

Medical Director, Director of Primary Care, Clinical Director of Pharmacy & Medicines Management, Director of Nursing, Quality & Patient Experience

The Medical Director, the Director of Primary Care and the Clinical Director of Pharmacy & Medicines Management jointly have responsibility for the implementation of this policy and the Medicines Policy and to have systems in place to ensure appropriate sharing and learning from incidents and events.

Senior Management Leads
(Senior Nurse Managers, Heads of Service, Hospital Directors and Professional Heads of Departments)

The Senior Management Leads have responsibility to ensure all staff working within their directorate are appropriately trained and comply with the guidance within this policy, relevant CD SOPs and the Medicines Policy.

Ward and Department Managers

The Ward and Department Managers are responsible for ensuring that all staff are aware of the Medicines Policy and CD SOPs and the need to ensure appropriate governance around CDs including the reporting of any incidents of concern involving CDs to the CDAO.

Pharmacy & Medicines Management staff

The Pharmacy staff are responsible for ensuring that the laws relating to the safe and secure handling and storage of Controlled Drugs are complied with and to assist with training of Health Board staff (and contracted registered healthcare professionals) on the storage and handling of controlled drugs.

Nurse/Midwife/Operating Department Practitioner (ODP) in charge

The nurse/midwife/ODP in charge is responsible for the safe and secure handling and storage of all controlled drugs held on the ward/department whilst in charge. In the event of discrepancies or apparent loss they are responsible for ensuring pharmacy is informed and an incident report completed.

Operating Department Practitioners (ODPs)

Operating Department Practitioners (ODPs) who are registered with the Health Professions Council are legally entitled to order, possess and supply CDs for administration to patients in accordance with the directions of a doctor, dentist or supplementary or independent prescribers in the department within which they work. Responsibility stays with the senior registered practitioner in charge even if they are not the theatre manager.

Individual staff (registered healthcare professionals and employees)

Individual staff are responsible for making themselves aware of and implementing this policy (including any updates), following the standard operating procedures and guidelines included and referring to other Health Board policies for further information. Staff must report any incidents where this policy is not adhered to.

References

1. Learning from tragedy, keeping patients safe. Overview of the Government's action programme in response to the recommendations of the Shipman Inquiry (Feb 2007) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228886/7014.pdf (opens in a new tab)

2. Hospital Pharmacists: The Safe and Secure Handling of Medicines: A Team Approach (The Revised Duthie Report 2005) London: Royal Pharmaceutical Society https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Publications/Safe%20and%20Secure%20Handling%20of%20Medicines%202005.pdf (opens in a new tab)

3. Department of Health, Safer Management of Controlled Drugs: A guide to good practice in secondary care (May 2007) http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_074511.pdf (opens in a new tab)

4. NICE Guidelines (2016) NG46 Controlled Drug: Safe use and management - Overview | Controlled drugs: safe use and management | Guidance | NICE (opens in a new tab)

5. UK Government: Misuse of Drugs Act 1971 and The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 (http://www.legislation.gov.uk/uksi/2015/891/contents/made (opens in a new tab)

The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008. Wales Statutory Instruments 2008 No. 3239 (W. 286). https://www.legislation.gov.uk/wsi/2008/3239/contents (opens in a new tab)

Home Office/CPhO/qA1354623 Compliance with licencing requirements for controlled drugs 24th February 2025 (Available from Pharmacy & Medicines Management on request)

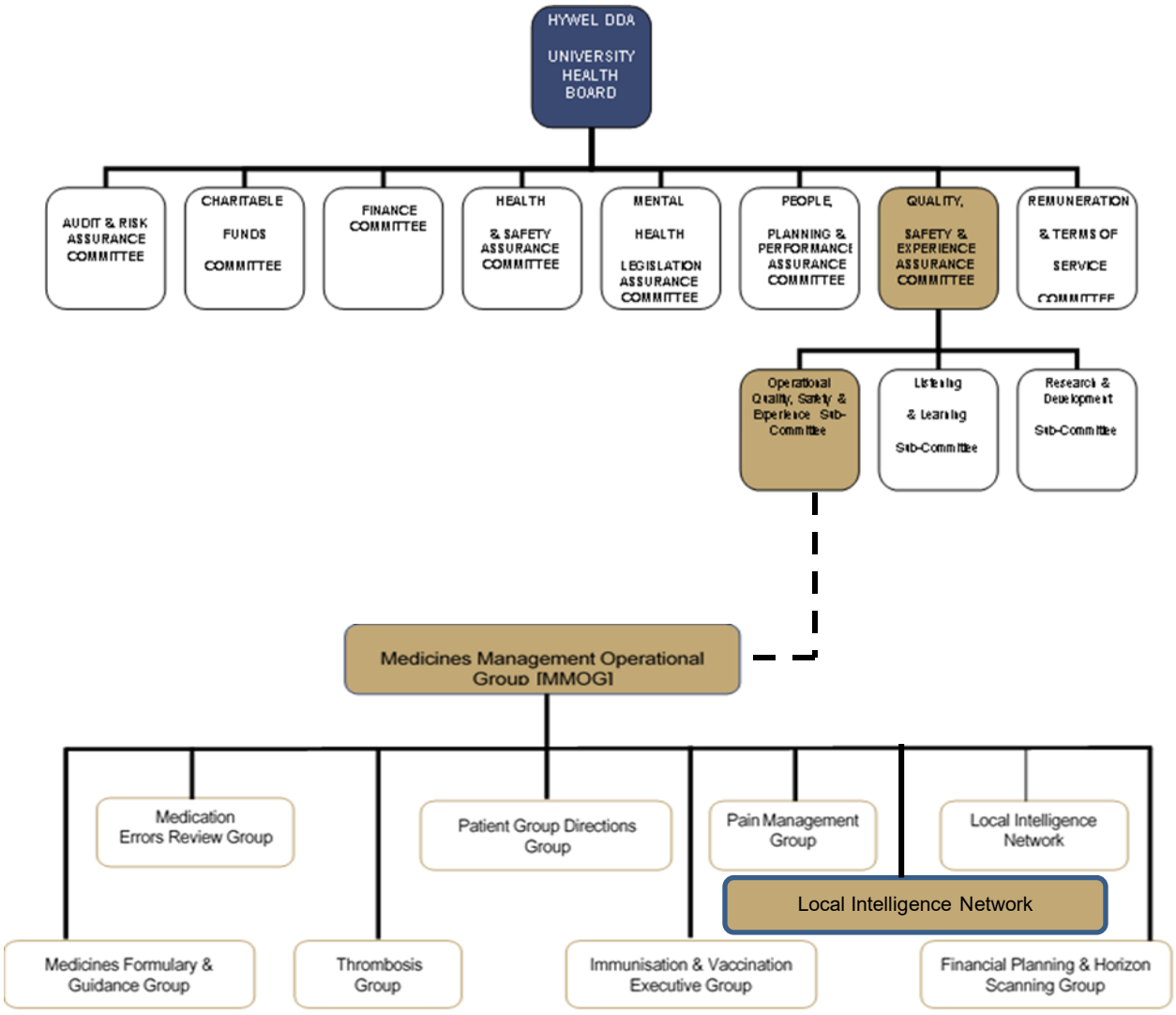
Domestic controlled drug licensing in healthcare settings (opens in a new tab)

Appendices

Terms of Reference for the Local Intelligence Network

LOCAL INTELLIGENCE NETWORK

TERMS OF REFERENCE



Version	Issued to	Date	Comments
v.1	Medicines Management Group	13/07/2016	
v.2	Medicines Management Sub-Committee	09/05/2019	
v.4	Medicines Management Sub-Committee	03/07/2019	
v.5	Medicines Management Sub-Committee	30/01/2020	
v.6	Medicines Management Operational Group	18/05/2021	
v.7	Medicines Management Operational Group	July 2025	

LOCAL INTELLIGENCE NETWORK

1. Constitution

1.1. The Network will be chaired by the Accountable Officer for Controlled Drugs for Hywel Dda University Health Board (HDUHB) and activity will be reported, via the Medicines Management Operational Group (MMOG) to the Quality, Safety and Experience Committee (QSEC), to the Health Board, and monitored by Health Inspectorate Wales (HIW).

1.2. The Network will cover all health care providers within the geographic area of Hywel Dda, such as, primary care contractors, out of hours providers, all hospitals, private hospitals, hospices and care homes in Hywel Dda, as well as other services such as Mountain Rescue, etc., where controlled drugs are held.

2. Membership

2.1 The membership of the group shall comprise:

2.2

- Accountable Officer for Controlled Drugs, HDUHB (Chair)
- Clinical Director of Pharmacy and Medicines Management (Vice Chair)
- Head of Clinical Governance or Incident manager
- Head of Health, Safety and Security, HDUHB
- Primary Care MM/Pharmacy representative
- Secondary Care MM/Pharmacy representative
- Senior Nurse Medicines Management
- Police Pharmacy Liaison Officer, Dyfed-Powys Police
- Substance Misuse Service Lead
- Head of Quality and Governance
- NHS Counter Fraud Officer
- General Pharmaceutical Council, Local Inspector
- Local Authority Representative (Domiciliary Carers, Care Homes Lead)
- Independent Sector Representative
- Ambulance Service Representative
- Health Care Inspectorate Wales
- Member of Substance Misuse Commissioning Team

Membership of the group will be reviewed on an annual basis.

2.3 Organisations required to have an Accountable Officer will normally be represented by that person. Representatives from Contractor Bodies will be invited as required (LMC, LDC). Other possible members include:

- GP (to provide GP perspective, NOT representative of all GPs)
- Community Pharmacist (to provide perspective from their profession)
- Independent hospitals and hospices representative
- Child Protection team member
- POVA member

3. Quorum and Attendance

3.1 A quorum shall consist of six members and must include as a minimum the Chair or Vice-Chair of the group. If the meeting is not quorate, it will continue as a working meeting with subsequent ratification of decisions made by Chair's Action.

3.2 Any senior officer of the UHB or partner organisation may, where appropriate, be invited to attend, for either all or part of the meeting, to assist with discussions on a particular matter.

3.3 The group may also co-opt additional independent 'external' experts from outside the organisation to provide specialist skills.

3.4 Should any officer member be unavailable to attend, they may nominate a deputy, with full voting rights, to attend in their place subject to the agreement of the Chair.

3.5 Those that have not attended for the last 2 meetings will be contacted to request attendance (at a minimum of 2 meetings per annum) and/or send a representative.

3.6 The group may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

4. Purpose

4.1 To share intelligence regarding the use and potential abuse of controlled drugs (CDs) that are purchased or ordered, prescribed, dispensed, handled and administered within Hywel Dda University Health Board geographic area.

5. Operational Responsibilities

5.1 Develop an information sharing code based on agreed principles for sharing controlled drug (CD) intelligence between agencies.

5.2 Receive and review intelligence on the patterns of purchasing, ordering, prescribing, dispensing, handling and administration of controlled drugs.

5.3 Actively share intelligence regarding use and potential abuse of CDs.

5.4 Agree how to report concerns.

5.5 Agree procedures for investigation and participate in incident panels.

5.6 Agree on the handling of incidents affecting more than one agency.

5.7 Review the 'Log of Incidents' or concerns that have been raised and any action taken by each of the organisations within the network.

5.8 Hear reports from an investigation subgroup/Incident Panel and decisions of the Network Chair.

5.9 Advise on monitoring processes and audits of CD management.

5.10 Advise on training requirements for CD handling and undertake joint training.

5.11 Advise on policy requirements.

5.12 Update its membership as required.

6. Agenda and Papers

6.1 The agenda will be agreed by the Accountable Officer for Controlled Drugs for HDUHB with the Clinical Director of Pharmacy and Medicines Management.

6.2 All papers must be approved by the Chair of the Local Intelligence Network.

6.3 The agenda and papers for meetings will be distributed **seven** days in advance of the meeting.

6.4 The minutes and action log will be circulated to members within **ten** days to check the accuracy.

6.5 Members must forward amendments to the Local Intelligence Network (LIN) Secretary within the next **seven** days. The LIN Secretary will then forward the final version to the Chair for approval.

7. Frequency of Meetings

7.1 The LIN will meet quarterly and shall agree its schedule of meetings for the anticipated 12 month duration. Any additional meetings will be arranged as determined by the Chair of the LIN.

7.2 The Chair of the LIN, in discussion with the LIN Secretary, shall determine the time and the place of meetings of the LIN and procedures of such meetings.

8. Accountability, Responsibility and Authority

8.1 The LIN will be accountable to the Medicines Management Operational Group, which reports directly to the Quality, Safety and Experience Assurance Committee for its performance in exercising the functions set out in these Terms of Reference.

8.2 The LIN shall embed the UHB's vision, corporate standards, priorities and requirements, e.g. equality and human rights, through the conduct of its business.

8.3 The requirements for the conduct of business as set out in the UHB's Standing Orders are equally applicable to the operation of the group.

9. Reporting

9.1 The LIN through its Chair and members shall work closely with the Chair and members of the Medicines Management Operational Group and the Medication Event Review Group (MERG). With MERG, LIN will scrutinise Datix reports and Risk Registers involving Controlled Drugs.

9.2 In doing so, the LIN shall contribute to the integration of good governance across the organisation, ensuring that all sources of assurance are incorporated into the Board's overall risk and assurance framework.

9.3 Bring to the Medicines Management Operational Group's specific attention any significant matters under consideration by the group.

10. Secretarial Support

10.1 The LIN Secretary role will be undertaken by the administration support for the Accountable Officer for Controlled Drugs.

11. Review Date

11.1 These Terms of Reference and operating arrangements shall be reviewed on an annual basis.

Process for Approval of Controlled Drugs Standard Operating Procedures (Acute Sector) by the Accountable Officer for Controlled Drugs

The Local Intelligence Network (LIN) will be the approval committee that makes a recommendation to the Accountable Officer (currently the Health Board's Medical Director) to approve the Controlled Drugs Standard Operating Procedures (Acute Sector) (CD SOPs).

As part of the recommendation LIN gives the Accountable Officer assurance that the appropriate research/references/guidance has been consulted, the work has been checked/quality assured, stakeholders have been actively involved in the review and an audit trail of any amendments and rejected comments has been kept.

The CD SOPs will be reviewed as a minimum every 3 years or sooner, if changes in legislation, guidance or professional standards are made or following a serious incident.

The responsibility for leading the review and updating the CD SOPs will be as follows:

- Ward CD SOPs - Senior Nurse Medicines Management with the appropriate nurse managers and directors and a nominated Lead Clinical Pharmacist or Lead Site Pharmacist.

- Theatre CD SOPs - Senior Nurse Medicines Management with the nursing leads for theatre, Senior ODA, nominated Consultant Anaesthetist and nominated Lead Clinical Pharmacist or Lead Site Pharmacist.

- Pharmacy CD SOPs - A Lead Site Pharmacist working with the Dispensary Managers Group.

- Primary Care CD and Community Nurses and Community Midwives CD SOPs - Lead Pharmacist Primary Care in conjunction with relevant Primary Care representatives.

The current format of the CD SOPs will be maintained as they are an appendix to the HDUHB Medicines Policy with version control, issue and expiry date information added.

The LIN will receive annually the list of current CD SOPs relating to controlled drugs.

The LIN will receive any amendments to any CD SOP due to legislation or changes in practice that are updated within the time between the annual reviews.

The CDAO will sign off the agreed list of CD SOPs.

Current SOPs in place for the Management of Controlled Drugs

The current SOPs for CDs (Acute Sector) can be accessed via:

- Hywel_Dda_University_Health_Board_Ward_and_Department_Controlled_Drugs_SOP-s_Jan2024 (opens in a new tab)

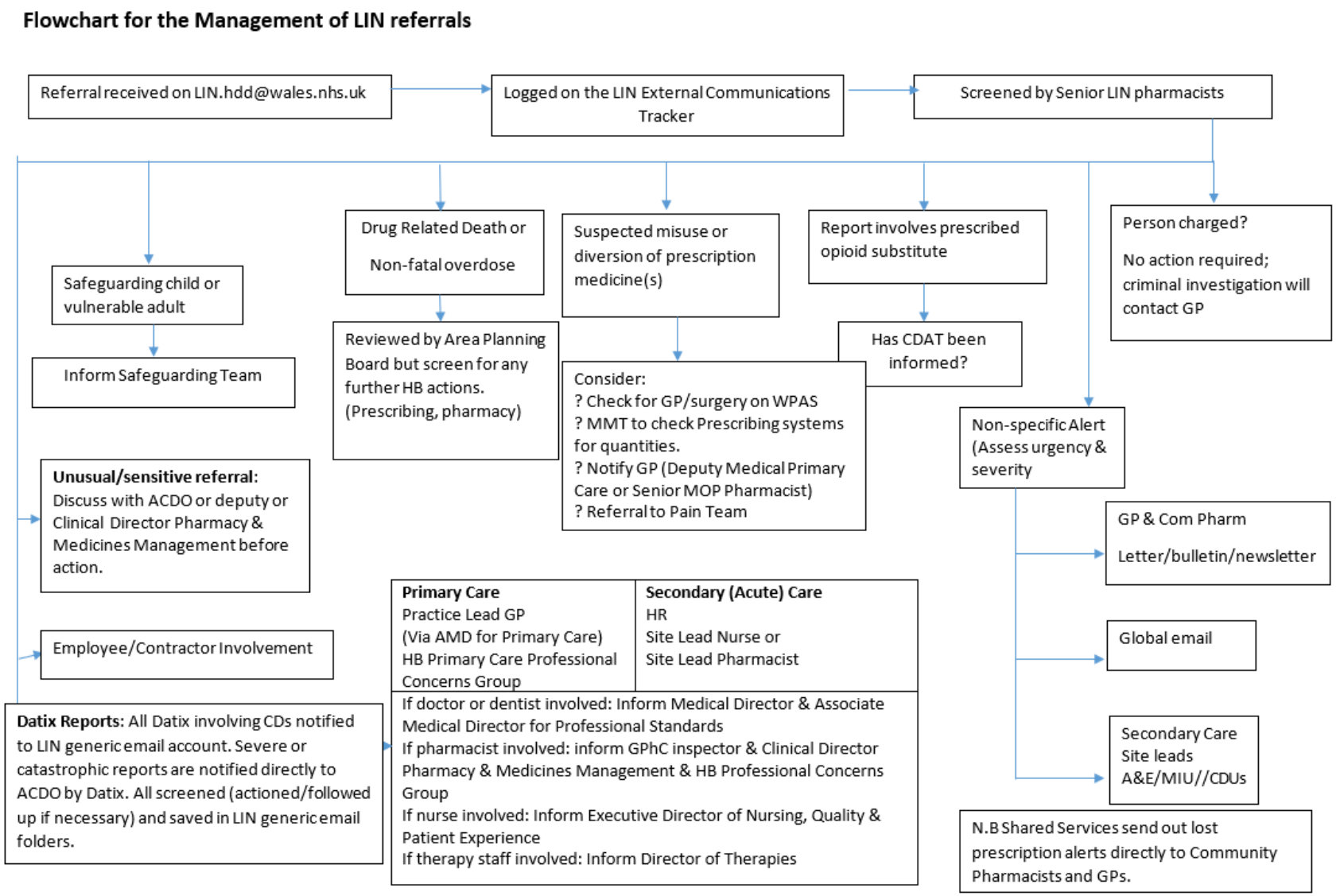
The current SOPs for CDs (Primary Care) can be accessed via:

- HDUHB 1260 Management of Controlled Drugs in General Practice Procedure (opens in a new tab)

SOPs for authorised witness destruction

- HDUHB 1261 Authorised Witnesses: Processes for destruction of Controlled Drugs Procedure (opens in a new tab)

Flowchart for the Management of LIN referrals



Application and Renewal of Home Office Controlled Drugs Licences (Supply and Possession) Standard Operating Procedure

Introduction

The Misuse of Drugs Act 1971 (opens in a new tab) imposes prohibitions on the possession, supply, manufacture, import and export of CDs.

However, The Misuse of Drugs Regulations 2001 (opens in a new tab) permits pharmacists, doctors and dentists, when acting in these capacities, under a general authority to possess, supply and procure Schedule 2, 3, 4 and 5 CDs. In summary, it enables these groups to use CDs in healthcare settings for the treatment of patients without breaking the Misuse of Drugs Act 1971.

Other mechanisms for the lawful possession of CDs (opens in a new tab) include persons who have an applicable Home Office licence can possess and supply CDs in accordance with the terms of the licence under licence from the Secretary of State (Home Office). These mechanisms are listed in the Misuse of Drugs Regulations 2001.

The last previous clarification of the requirements for CD possession and supply licences was made in 2014 (Welsh Government Circular (CPhO (2014))1 issued 18th July 2014). It appears that some HBs have only held one supply and possession licence for their whole HB (as a single legal entity) and, only applying for a separate possession and supply licence alongside their Wholesaler Dealer Licence (WDL), when they are supplying other organisations (e.g. WAST).

Finally, the Home Office and Welsh Chief Pharmaceutical Officer issued a joint letter on the 24th February 2023 (CPhO-HO-Letter-to-HBs-HMP-CD-Licensing-Requirements-v3-24-Feb-2023.pdf (opens in a new tab)) to clarify which Controlled Drug (CD) licences all Health Boards now need in place to either possess or supply CDs legally and the possession licences that need to be held by the clinics, community hospitals and other services that the hospital pharmacy supplies with **stock** CDs. There are some exemptions to the requirement for a licence and these are described in Domestic Controlled Drug Licensing in Healthcare Settings (opens in a new tab). ('Domestic' in this context refers to 'within the UK'). This document enables Health Boards to assess the current need for licences.

Information about the process to apply for Controlled Drug Licences can be found here: Controlled drugs: domestic licences - GOV.UK (www.gov.uk) https://www.gov.uk/guidance/controlled-drugs-domestic-licences (opens in a new tab)

Controlled drugs: domestic licences - GOV.UK (www.gov.uk) https://www.gov.uk/guidance/controlled-drugs-domestic-licences#apply-for-a-domestic-licence (opens in a new tab)

Retail pharmacies that wholesale or supply

If you are a pharmacist undertaking a retail pharmacy business, you do not need a controlled drugs licence because certain limited licence exemptions exist in the Misuse of Drugs Regulations 2001.

If you need a wholesale dealer's licence from the Medicines and Healthcare products Regulatory Authority (MHRA) for your business, you will also need a controlled drugs domestic licence. You can contact the MHRA on info@mhra.gov.uk to find out if you need a wholesale dealer's licence.

Application Process

1. **Determine if a Home Office Controlled Drugs (CD) Licence is required for the service/premise**

   a. Check Domestic Controlled Drug Licensing in Healthcare Settings (opens in a new tab) for possible exemptions
   b. CD Licences only apply to Controlled Drugs issued as **STOCK**. Controlled Drugs dispensed for individual patients (from a prescription) can be stored in the CD cupboard for use/collection at a later date without the need for a CD Licence.
   c. Consider if an alternative supply route can be used (for example, patient specific prescriptions)
   d. Consider if alternative non-CD medicines can be used to treat the conditions the clinic/service commonly see (for example, Penthrox for dislocations, NSAIDs instead of opioid analgesics).
   e. Can the service/clinic be provided from a hospital site?
   f. Discuss with local Site Lead Pharmacist and Pharmacy Service Manager

2. **If a CD Licence is required**

   a. Discuss with local Site Lead Pharmacist and Pharmacy Service Manager

   b. Anticipate that a new application will require about 9 months to be granted and make alternative arrangements for the service in the meantime. A renewal takes up to 16 weeks if a visit is required. However, as long as the application is submitted before the previous one expires, the service is covered legally and can continue to operate.

   c. Complete the paper/electronic template (Prep Sheet for CD licence Applications.odt (opens in a new tab))

   d. Determine these positions for the application:
      - Overall person in charge
      - Person responsible for the site security
      - Person responsible for legal compliance and regulatory affairs at the site.

      (They can be the same person but all people will need a Home Office approved Disclosure & Barring Service (DBS) check by the Home Office nominated company even **if they already hold an NHS DBS check)**

   e. Home Office DBS checks take **an average of 5 weeks to complete** and need to be renewed every 3 years. See Information for DBS applications for CD Licences (current 2025) below.

   f. There is a fee for CD Licences depending on the type, whether it is an initial application or a renewal (with/without a renewal compliance visit which are undertaken every 1-5 years

determined on a case-by case basis). These fees are payable by the service requiring the licence. Current fees can be found here: Controlled drugs and precursor chemicals: licence fees - GOV.UK (opens in a new tab).

g. The Authorised Witnesses for the destruction of expired and unused Controlled Drugs are appointed by the Health Board and their details can be obtained from the Pharmacy Service Manager.

h. Activity: on the application contains an Excel Spreadsheet (opens in a new tab) where the activity (which is a list of the Controlled Drugs, their Schedule and whether the service processes (i.e. use in the clinic/service) or supplies Controlled Drugs (usually only by pharmacy departments). This needs to be completed, saved and uploaded with the application.

i. The application needs to be completed on-line using the information gathered on the paper/electronic template. Currently there is only one Home Office account for the Health Board, please obtain login details from the Pharmacy Service Manager. The information in the application is only retained for a limited amount of time (5 days) so aim to complete the application in 1 session (or within 5 working days).

j. At the end of the application process, **print a PDF of the application** (and save to files) and then click the 'Submit' button. Record the application reference number before exiting the website.

k. The Home Office will send an acknowledgement but not always immediately.

l. The Home Office may request additional information via email.

m. The Home Office will then arrange a mutually convenient compliance visit date.

n. On the day of the visit all the persons named on application need to be present.

o. After the compliance visit, additional actions may be requested and evidenced.

p. The CD Licence is granted when the invoice has been issued and **paid**.

q. Ensure that there is a robust alerting system in the department for upcoming renewals including DBS checks for staff.

Renewal of CD licences

Please note that the CD licence is only valid from **one year** from the date granted.

The application for renewal is the same process as above and must be completed and submitted before the current CD licence expires. The Home Office advice is to submit 16 weeks before expiry in case an inspection visit is required.

Information for DBS applications for CD Licences (current 2025)

Thank you for contacting eBulkPlus at Security Watchdog to apply for a DBS Enhanced Disclosure in support of your application for a Controlled Drug domestic licence, Precursor Chemical Category 1 licence or Category 2 and 3 registrations.

The Drug Licensing and Compliance Unit (DLCU) have contracted Security Watchdog, to assist you in obtaining your DBS check. Security Watchdog will provide you with the expertise and administrative support to guide you through the whole Disclosure application process. This will start from your initial registration with our service and continue through the entire process to the Disclosure outcome, ensuring that at all stages the DBS Policy and Codes of Practice are strictly adhered to.

There are 3 stages of the application process which must be followed:

Stage One: Online Application

Please complete your online DBS application by using the link below and clicking 'Start Application' on Standard/Enhanced.

https://disclosure.capitarvs.co.uk/cheqs (opens in a new tab)

You will be asked to enter the following information:

Organisation Reference: DLCU
Organisation Code: licence

The application form is a simple 5 page process. Please follow the on screen instructions and complete all the fields provided. Mandatory fields are denoted by (*)

Stage Two: Payment

At the point of entering your application online you will be prompted to make this payment online via our secure Sagepay system. The total cost of your application will be £56.09. This includes the cost of the DBS Disclosure and Security Watchdog's administration fee.

Failure to make payment will result in your application not being submitted

Stage Three: Identification Verification

In line with the DBS Code of Practice all applicants requiring a DBS check must have their identity verified. If you are currently remotely working from home due to the covid situation and cannot go to the post office but do have a HR department who can verify the documents then you can do this with them via Video Call. Please do not call us to do a video call for verification.

Please send your HR team/manager scans of your documentation, ensuring the full document is scanned clearly. They will need to print the document, and add the following "I [name] confirm this document is a true likeness of the original." They must then include their signature, job title and contact information, and date the document. A video call would be required to confirm your likeness with the photographs on your passport/driving licence or other photographic ID.

If you are not able to have your documents checked in this method, attached is a Post Office Checking Service form which allows you have your identification checked. The Post Office charge over the counter to use this service. Please check which Post Offices offer the Document Certification Service by going to http://www.postoffice.co.uk/branch-finder (opens in a new tab). Once selected, look under the Identity & Licenses section and tick Document Certification Service.

You will need to take:
Three items of original ID **(please note all documents such as proof address statements/utility bills must be the originals received in the post as we cannot accept online statements/bills as per the DBS Guidance)**
A good quality photocopy of each document
The attached Checking Service Form

Whichever method of ID checking you use, you will need to send us the verified copies of your ID documents as well as your application reference number, a mixture of numbers and letters.

Please can you no longer now post the id documents and only send them to this email through scan or clear photographs of the verified ID documents at dbs.enquiries@capita.co.uk using the subject DLCU Application. We would advise keeping copies or scans of the documentation should further copies be required.

If you require further advice or information, please do not hesitate to contact us on 01420 558 752.

Please note: When replying to queries please email us and not leave notes on the eBulk system. We do not receive a notification when you leave a note and as such we will not be aware of your response.

dbs.enquiries@capita.co.uk

Post Office Identify Services – Document Certification Service (opens in a new tab)

Schedule of Controlled Drugs

A useful source for information relating to controlled drug schedules may be found at https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation (opens in a new tab)

The HDUHB Medicines Policy link to Local Requirements for the Storage, Administration & Prescription for Controlled Drugs in Hywel Dda UHB (Acute sector wards, clinics & departments) (opens in a new tab). The Medicines Management Operational Group agreed the storage, administration and prescription requirements for certain CD medicines listed which may be in excess of the minimum legal requirements. N.B: This guidance covers commonly used CDs. Please check the requirements for any other CDs not listed with Pharmacy.