

Policy to determine the requirement for Home Office Controlled Drug Licences

1. Introduction

1.1. This policy is intended to ensure that Swansea Bay University Health Board holds the correct licences in relation to Controlled Drugs and that an up to date register is kept detailing the status of such licences.

2. Definitions

2.1. Abbreviations used in this policy

- CD – Controlled Drugs
- CDAT – Community Drug and Alcohol Team
- C&VHB – Cardiff and Vale University Health Board
- EMRTS – Emergency Medical Retrieval and Transfer Service
- GPOOH – GP Out of Hours
- HB – Health Board
- MHRA – Medicines and Healthcare products Regulatory Agency
- SBUHB – Swansea Bay University Health Board
- WAST – Welsh Ambulance Services NHS Trust
- WDA – Wholesaler Dealer Authority
- WFI – Welsh Fertility Institute

3. Policy Statement

- 3.1. This policy responds to the requirements and responsibilities to hold Home Office controlled drug (CD) licences for the supply and possession of CDs in accordance with the relevant legislation including the Medicines Act 1968, the Misuse of Drugs Act 1971 and specifically the Misuse of Drugs Regulations 2001. This policy has also relied upon the guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA) February 2014 and the Welsh Government Circular (CPhO (2014))¹ issued in July 2014.
- 3.2. Legislative changes in recent years requires that the Health Board evaluates current CD management against this policy as well as future intention.
- 3.3. There are two types of CD license. A license to enable supply of CDs and a license to enable possession of CDs.
- 3.4. The Health Board is required to hold a Wholesaler Dealer Authority (WDA) Licence issued by the MHRA for the supply of CDs, wherever a WDA licence is required the Health Board will also need to hold a Home Office Licence for the supply of CDs.
- 3.5. As a Health Board the organisation is exempt from the need of a Home Office License for the possession of CDs (providing the CDs are in Schedules 2-5).
- 3.6. A limited supply of CDs between different organisations to meet an individually named patient's needs on a very occasional basis is permissible without a Wholesaler Dealer Licence or Home Office CD license (the supply must be on a not-for-profit basis). This provision is intended to ensure patient care is not compromised, supply of CDs without a licence would be in **exceptional circumstances only**.

3.7. This policy applies to CD stock only. Neither Home Office CD licenses, or a MHRA WDL are required for the supply of CDs dispensed for individual patients, or for the holding of such CDs providing they are held by the person for whom they were dispensed.

4. Scope of the Policy

4.1. This policy applies to all staff employed by or working under the supervision of the Health Board (including all staff employed via an agency, working under SLAs and honorary contracts or within a hosted service) hereafter referred to as HB staff.

5. Aims and Objectives of this Policy

5.1. The objective of this policy is to ensure the Health Board is compliant with:

- The Home Office requirements with regards to controlled drugs licencing
- The MHRA requirements to hold a WDL (specifically in relation to CDs)

5.2. The policy aims to provide clear and unambiguous guidance, along with examples, on the licencing requirements for all services covered by the scope of this policy.

5.3. Note, this policy does not cover manufacturing, assembly or importing of medicinal products for which additional licences would be required.

6. Responsibilities

6.1. Management and staff are required to ensure adherence to this policy.

7. The legal principles

7.1. There are two legal principles which need to be applied in every scenario where CDs are managed by the HB in order to determine if a Home Office CD license (and in the case of supply whether a MHRA WDL) is required. These are:

- Is the HB supplying CDs to a different legal entity?
- Does the HB have and maintain complete management and control of the CDs at all times?

8. Legal entities

8.1. A different legal entity to the HB can be defined as a completely separate organisation (including other Health Boards and Trusts e.g. Welsh Ambulance Service Trust (WAST). However, it can also be defined as an individual (who is entitled to be in possession of CDs) providing medical services (see examples C1, C2, D2 and F1).

8.2. Where HB CDs are used for the treatment of private patients receiving such treatment under arrangements made directly with the HB i.e. private treatment provided by the HB, this constitutes use within the same legal entity (see example F2).

8.3. Where HB CDs are used for the treatment of private patients receiving such treatment under arrangements made independently between the patient and a third party registrant, this constitutes use of CDs between different legal entities. This may occur where the third party registrant is substantively employed by the HB but for this episode of care is providing separate private treatment albeit with financial reimbursement to the HB for staff providing supporting services/consumables/medication/facilities etc. (see example F1).

8.4. Where the HB hosts a service (i.e. a service that provides healthcare to a population wider than its resident population such as services that are provided on an 'all Wales' basis) that is part of the same legal entity as the HB it is important to consider where

the service receives CD supplies from. Often a hosted service will hold CDs at sites remote from the host HB and supply of CDs from SBUHB may not be practical. This may necessitate a supply of CDs from other organisations which would result in CDs being supplied between legal entities (see examples D1, D2 and D3).

9. Management and Control

- 9.1. Sufficient management and control can be defined as a situation where only HB staff have access to the CDs. In its simplest form this is management and control of the cupboard/cabinet in which the CDs are stored and not necessarily the wider area.
- 9.2. In a situation where non HB staff have access to a room where HB CDs are stored (e.g. premises shared with other organisations) but without access to the CDs which are located in a locked cupboard (only accessible to HB staff) within the room; there is deemed to be sufficient control and management of the CDs by the HB (see examples A1, A2, D1 and D2).

10. Legal Ownership of Premises

- 10.1. The requirement for either a Home Office CD licence or MHRA WDL is not affected by the legal ownership status of the individual premises as this does not materially affect either of the two legal principles outlined in paragraph 6 above.

11. Transporting CDs

- 11.1. Couriers or carriers do not require a CD licence provided that the CDs are not handled (i.e. unpacked, checked, stored, repacked etc.) or stored at a single location for more than 24 hours. The Health Board remains responsible for the CDs while in transit until they have been received and accepted. The Health Board is responsible for ensuring a 'fit and proper' courier/carrier is used (see example G1).

12. Due Diligence

- 12.1. The HB has a duty to apply due diligence in ensuring that any organisation/individual to which it supplies CDs is legally entitled to be in possession of CDs and where applicable holds the appropriate licence. To fulfil this duty, whenever the HB is considering supplying CDs to another legal entity, it must receive written assurance from the CEO/CDAO of that organisation that they are legally entitled to be in possession of CDs and that they have assessed the requirements for a Home Office CD possession licence and satisfied themselves of compliance (see examples C1, C2 and F1).

13. Swansea Bay University Health Board Examples

- 13.1. Below is a series of example situations that could occur within the HB setting. Note, not all of the situations are currently taking place within SBUHB.

Situation A:	Co-located sites: Where the HB provides healthcare services at sites where other organisations also provide services.
Example A1:	A prison where healthcare services (which involve the supply/administration of CDs) are provided by the HB. The Prison receives CD stock from a licensed wholesaler of medicines. The Prison Governor and other prison employees have access to the medical rooms where the CDs are stored, however they do not have access to the individual cupboards housing the CDs. Only staff employed by the HB have access to the CDs.
Test 1: Is the HB supplying CDs to a different legal entity?	NO - in this case the HB is not supplying any CDs as they are received from a wholesaler. The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	YES - Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs
Example A2:	The Community Drug and Alcohol Team (CDAT) provide healthcare services (which involve the supply/administration of CDs) from a number of community settings co-located with third sector organisations. CDAT is part of the same legal entity as the HB and operated by HB staff. CDAT receive CD stock for these sites from HB pharmacy departments. The building owners and their caretaking staff have access to the rooms where the CDs are stored, however they do not have access to the individual cupboards housing the CDs. Only staff employed by the HB have access to the CDs.
Test 1: Is the HB supplying CDs to a different legal entity?	NO – CDAT are part of the same legal entity as the HB. The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	YES – Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

Situation B:	Out of hours services
Example B1:	GP Out of Hours (GPOOH) services are operated from a number of sites across the Health Board and receive CD stock from HB hospital pharmacy departments. The GPOOH service is part of the same legal entity as the HB and operated by HB staff. CDs used in this service are only accessible by HB staff.
Test 1: Is the HB supplying CDs to a different legal entity?	NO – Both the hospital pharmacy departments and the GPOOH service are part of the same legal entity (the HB). The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	YES – Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

Situation C:	The HB supplies CDs to other organisations (i.e. organisations that are part of a different legal entity to the Health Board)
Example C1:	The HB supplies stock CDs to the Welsh Ambulance Services NHS Trust (WAST) from a single HB pharmacy department.
Test 1: Is the HB supplying CDs to a different legal entity?	YES – The HB is supplying CDs to an organisation that is a different legal entity to the HB and therefore needs a Home Office CD license to supply these CDs. The HB also needs a MHRA WDL license to supply the medication. The licenses are specific to the pharmacy department making the supply.*
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	NO – The supplied CDs are outside of the control of the HB once supplied. Licenses required as detailed above.
Example C2:	The HB supplies stock CDs to St John's Ambulance from a single HB pharmacy department.
Test 1: Is the HB supplying CDs to a different legal entity?	YES – The HB is supplying CDs to an organisation that is a different legal entity to the HB and therefore needs a Home Office CD license to supply these CDs. The HB also needs a MHRA WDL license to supply the medication. The licenses are specific to the pharmacy department making the supply.*
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	NO – The supplied CDs are outside of the control of the HB once supplied. Licenses required as detailed above.

Example C3:	The HB Pharmacy Pre-Packing Unit (located in pharmacy department A of the HB) packs down manufacturer's packs of schedule 4 and 5 CDs into smaller quantities (typically from packs of 28 tablets/capsules to packs of 7 or 14 tablets/capsules). These are then labelled with instructions for use by the patient with a blank space to add the patient's name, and other relevant particulars e.g. quantity to be taken per dose, duration of use etc. This work is carried out under the appropriate MHRA manufacturer's license. The finished product is commonly referred to as a 'pre-pack'. At the point of dispensing, an appropriate registrant will add any additional information on the label and supply the 'pre-pack' to a patient. Some of these 'pre-packs' are sent internally within the HB to a pharmacy at a different site (Pharmacy department B of the HB) to be sold by wholesale to the Welsh Ambulance Services NHS Trust (WAST). Some of the 'pre-packs' are used internally within SBUHB for SBUHB patients.
Test 1: Is the HB supplying CDs to a different legal entity?	YES – The HB is supplying CDs to an organisation that is a different legal entity to the HB and therefore needs a Home Office CD license to supply these CDs. The HB also needs a MHRA WDL license to supply the medication. The licenses are specific to the pharmacy department making the wholesale supply (Pharmacy department B). [*] However, whilst pharmacy department B requires both a MHRA WDL license and a Home Office CD license, pharmacy department A (in which the Pre-Packing Unit is located) does not require either of these licenses. This is because the pre-packs are not sold <i>directly</i> to a different legal entity from the Pre-Packing Unit and pharmacy departments A and B are both part of the same legal entity of the HB.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	NO – The supplied CDs are outside of the control of the HB once supplied. Licenses required as detailed above.

^{*}Consider due diligence - see paragraph 12 above for more information

Situation D:	Services provided outside of the geographical boundary of the HB e.g. hosted services
Example D1:	The Emergency Medical Retrieval and Transfer Service (EMRTS) is an All-Wales service hosted by the HB. It holds CD stock for supply/administration to patients at several sites across Wales e.g. airfields etc. EMRTS is part of the same legal entity as the HB and operated by HB staff. EMRTS receive CD stock for these sites from HB pharmacy departments. The site owners have access to the rooms where the CDs are stored e.g. for maintenance etc, however they do not have access to the individual cupboards housing the CDs. Only staff employed by the HB have access to the CDs.

Test 1: Is the HB supplying CDs to a different legal entity?	NO – EMRTS and the HB pharmacy departments are part of the same legal entity (the HB). The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	YES – Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.
Example D2:	The Welsh Fertility Institute (WFI) is an All-Wales service hosted by Swansea Bay University (SBUHB) Health Board. It holds CD stock for supply/administration to patients at two sites in Wales. The first is within a SB HB hospital site. The second is within a hospital operated by Cardiff and Vale (C&V) University Health Board, a separate legal entity. CD stock is held for supply/administration to patients at both of these sites. WFI is part of the same legal entity as SBUHB and operated by SBUHB staff at both sites. WFI receive CD stock for the SBUHB site from a SBUHB pharmacy department. However WFI receive CD stock for the site located within the C&VUHB hospital from a pharmacy department in C&VUHB. The WFI medical facilities located in C&VUHB are accessible by C&VUHB staff for maintenance, cleaning etc, however C&VUHB do not have access to the individual cupboards housing the CDs. Only staff employed by SBUHB have access to the CDs.
Test 1: Is the HB supplying CDs to a different legal entity?	NO – The SBUHB pharmacy department and WFI are part of the same legal entity (SBUHB). SBUHB does not therefore require any licenses to supply CDs. It is outside the scope of this policy to comment on the supply of CDs by C&VUHB to the SBUHB WFI site located in the C&VUHB hospital. C&VUHB, as a separate legal entity will need to assess their need for the appropriate licenses to supply CDs in this way.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	Yes - Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

Example D3:	The HB provides specialist learning disability services (which involve the supply/administration of CDs) at residential units based in a community setting across South Wales. The geographical spread of these units spans several HB areas. All of these units receive CD stock from HB hospital pharmacy departments. The service is part of the same legal entity as the HB and operated by HB staff. CDs used in this service are only accessible by HB staff.
Test 1: Is the HB supplying CDs to a different legal entity?	NO – Both the hospital pharmacy departments and the residential units are part of the same legal entity (the HB). The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	Yes - Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

Situation E:	Community Hospitals
Example E1:	The HB operate a number of community hospitals, some for general rehabilitation and others for specialist care e.g. mental health. These sites are too small to have their own pharmacy department. All of these community hospitals receive CD stock from HB hospital pharmacy departments located on other hospital sites. The community hospitals are all part of the same legal entity as the HB and operated by HB staff . CDs used in this service are only accessible by HB staff.
Test 1: Is the HB supplying CDs to a different legal entity?	NO – Both the hospital pharmacy departments and the community hospitals are part of the same legal entity (the HB). The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	Yes - Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

Situation F:	Private Healthcare Services
Example F1:	HB facilities are hired by private healthcare providers to undertake private healthcare services. As part of this arrangement the HB supplies CD stock from their pharmacy department and support staff to the private providers. N.B. In this example the private healthcare providers may be clinicians employed substantively by the HB but in this instance are working in their own time under separate contractual arrangements i.e. not HB paid time and not waiting list initiatives.
Test 1: Is the HB supplying CDs to a different legal entity?	Yes – even though the CDs are under the control of staff who maybe substantively employed by the HB, in this instance they are undertaking non-HB related work as a private healthcare provider which constitutes a different legal entity. The HB therefore needs a Home Office CD license to supply these CDs to the private healthcare provider. The HB also needs a MHRA WDL license to supply the medication. The licenses are specific to the pharmacy department making the supply.*
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	No – the CDs are under the control and management of the private healthcare provider who will need to liaise with the Home Office regarding whether they require a Home Office CD license to hold the CDs.
Example F2:	The HB provides private healthcare services as an income generation activity. The HB does this using its own facilities, staff and stock of CDs (supplied by its own pharmacy departments) to undertake this private service. No other legal entity is involved and CDs used in this service are only accessible by HB staff (working in their capacity for the HB).
Test 1: Is the HB supplying CDs to a different legal entity?	No – whilst the HB is providing private healthcare services it is doing so as the HB with no involvement of any other legal entity. The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	Yes - Only HB staff have access to these CDs (and all staff are acting in their capacity as HB employees). Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

*Consider due diligence - see paragraph 12 above for more information.

Situation G:	Transferring and Transporting CDs
Example G1:	The HB transfers/supplies CDs between one area of the HB and another (i.e. within the same legal entity) e.g. between HB pharmacy departments, between a HB pharmacy department and a HB community hospital or HB community clinic etc. The CDs are only accessible by HB staff at both the supplying and recipient areas. The courier used to transport the CDs has a Service Level Agreement with the HB that states that the CDs are not to be handled (i.e. unpacked, checked, stored, repacked etc.) or stored at a single location for more than 24 hours. Due diligence has been undertaken by the HB to ensure the courier is 'fit and proper' i.e. wherever possible the courier is part of the NHS but where occasionally a taxi company is used, that this is an established and reputable company and there is a SLA in place that describes the requirements for transport of CDs
Test 1: Is the HB supplying CDs to a different legal entity?	No – This represents a transfer of CDs within the same legal entity i.e. the HB. The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	Yes - Only HB staff have access to these CDs at both the supplying and recipient areas and an appropriate Service Level Agreement is in place with the courier. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

Situation H:	Using CDs within a laboratory setting i.e. not for administration to patients
Example H1:	The HB pathology department requires CDs for use as chemical calibrants in the validation and verification of instrumentation within the laboratory i.e. the CDs are used to compare with samples from patients to see if the same drug is present. The HB pathology department is part of the same legal entity as the HB and is operated by HB staff. The pathology department receives stock of CDs from a HB hospital pharmacy department.
Test 1: Is the HB supplying CDs to a different legal entity?	NO - Both the hospital pharmacy department and the pathology department are part of the same legal entity (the HB). The HB does not therefore require any licenses to supply CDs.
Test 2: Does the HB have and maintain complete control and management of CDs at all times?	YES - Only HB staff have access to these CDs. Therefore the HB can rely on its exemption as a HB under the relevant Regulations and does not require a license to possess CDs.

14. Confiscated Controlled Drugs

- 14.1. Where controlled drugs are confiscated from a patient the HB is not required to hold a Home Office CD licence. The HB is expected to hold the CDs securely and arrange for police collection at the very earliest opportunity i.e. there should be no unnecessary delay in transferring the CDs to the police.

15. Process for obtaining Controlled Drug Licence

- 15.1. Where a Delivery Unit believes a Home Office CD license is required the Delivery Unit Director must seek the approval of the Controlled Drug Accountable Officer to proceed with the application process.
- 15.2. Following approval of the Controlled Drug Accountable Officer, the Delivery Unit Director will apply for the license directly from the Home Office.
- 15.3. On successful attainment of a Home Office CD license, the Delivery Unit Director is responsible for notifying the corporate governance team who will record this in the Health Board register of CD licenses. The Delivery unit Director must also inform the Accountable Officer for controlled drugs.

16. Relinquishing a Home Office CD license

- 16.1. Where the Delivery Unit no longer believes they require a Home Office CD license the Delivery Unit Director must seek the approval of the Controlled Drug Accountable Officer to notify the Home Office.
- 16.2. Following approval of the Controlled Drug Accountable Officer, the Delivery Unit Director will inform the Home Office directly of the change of circumstance and that they wish to relinquish the CD license.
- 16.3. The Delivery Unit Director is responsible for notifying the corporate governance team who will record this in the Health Board register of CD licenses. The Delivery Unit must also inform the Accountable Officer for Controlled Drugs.

17. Maintenance of Licence Register

- 17.1. The Corporate governance team will maintain a register of all controlled drugs licences held by the health board.
- 17.2. The corporate will provide a list of current licences and their expiry date to the CDAO on an annual basis. The Unit Director will manage the licence renewal process.
- 17.3. It is the responsibility of the Delivery Unit Director to ensure licenses held by the unit are maintained appropriately including:
- Complying with all Home Office requirements including inspection requests and periodic declarations.
 - Ensuring ongoing appropriateness in line with controlled drug management activity within the Delivery Unit.
 - Ensuing continued validity of the license.

18. Policy Compliance

- 18.1. All staff are required to adhere to this policy.

19. Equality Impact Assessment

- 19.1. This policy has been screened for relevance to equality. No potential negative impact has been identified so a full equality impact assessment is not required **however confirmation of this is yet to be received.**

20. Further Information

- 20.1. For further information and advice regarding the requirement for a controlled drugs licence please email: sbu.cdao@wales.nhs.uk