Controlled Drugs

Final Internal Audit Report

2025/26

Swansea Bay University Health Board

Reasonable Assurance

Contents

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Executive Sign Off	15 January 2026
Audit Committee	12 March 2026
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Executive Summary

Purpose

To review the health board's arrangements for ensuring compliance with the Controlled Drugs Regulations.

Overview

The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 place a statutory responsibility on Swansea Bay University Health Board ('the health board') and its Controlled Drug Accountable Officer (CDAO) to ensure the safe management and use of Controlled Drugs (CDs).

We have conducted three previous audits in this area (2020/21: Advisory, 2021/22: Advisory, and 2022/23: Reasonable Assurance). These reviews consistently highlighted issues relating to storage, administration, and the need to strengthen CD governance arrangements within Service Groups.

It is encouraging to note improvements in the ordering and administration of CDs, as well as the completion of pharmacy audits of CD registers. However, governance and reporting remain areas of weaknesses. A new governance structure has recently been introduced, but at the time of our audit fieldwork, it had not matured sufficiently to demonstrate compliance across all Service Groups.

For this review, we have concluded **reasonable** assurance. Overall, compliance with controlled drugs procedures was generally good across the areas reviewed, with the exception of Acute Medical Assessment Unit in Morriston, where significant issues were identified relating to cabinet security and segregation of Patient Own Medicines. These issues, while important, appear to be isolated rather than systemic. It should also be noted that our sample targeted areas with a higher number of reported CD stock discrepancies between March and May 2025. Key matters requiring management attention include:

- Controlled Drugs Order Book and Register Compliance: A number of areas of non-compliance with policy and standard operating procedures were noted.
- Ward Based Signature List: Good practice was observed in two areas that maintain ward-specific signature lists, making it easier to identify signatures. This approach should be adopted more widely, provided lists are complete and regularly updated.
- Secure Storage: One CD cabinet showed visible damage, compromising security of its contents.
- Patients Own Medication (POMs): POMs were found mixed with CD cabinet stock.
- Pharmacy audit outcomes are not reported within the Service Groups.
- Controlled Drug Management & Assurance Plans: Not all Service Groups are regularly reviewing and updating their plans.
- Corporate Reporting: A new governance and reporting structure has recently been implemented, including a quarterly reporting template for Service Groups to submit to the Quality & Safety Group (QSG). However, at the October meeting, only one Service Group submitted a report using the new template.

Additionally, Health Inspectorate Wales (HIW) undertook an unannounced inspection of Morriston Hospital Emergency Department in November 2024, identifying issues such as unaccounted controlled medication and incomplete temperature checks on drug fridges. The health board has since confirmed closure of the HIW action plan, with all actions completed.

Full details of matters arising are detailed within the Findings & Agreed Action Plan. Review of progress in implementing the recommendations raised (see Appendix A) within the previous internal audit report has identified one action which can be closed within the audit tracker; and for those which remain outstanding we have indicated where these are superseded by recommendations raised within this review.

Scope & Assurance Summary

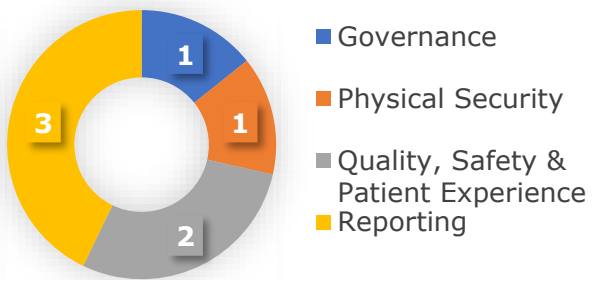
Objectives (The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.)		Related Findings	Assurance
1	Policies and procedures are in place that set out the arrangements and responsibilities for the management of controlled drugs, and these are available to staff on wards and theatres.	6	**Substantial**
2	The ordering, delivery and administration of controlled drugs is carried out in accordance with the policy and operating procedures, by authorised individuals, with records completed as required.	1 & 2	**Reasonable**
3	There are controlled drugs registers in place on each ward and theatre, which are completed accurately and reconcile to stock levels.	-	**Reasonable**
4	Controlled drugs are securely stored, with the keys held by an appropriate person.	3 & 4	**Reasonable**
5	Appropriate checks and audits are undertaken by health board staff in line with policy and acted upon accordingly.	5	**Reasonable**
6	There is appropriate oversight of controlled drugs within the health board, including incidents.	6 & 7	**Limited**
7	Recommendations raised in the recent Health Inspectorate Wales review are being actioned and monitored.	-	**Reasonable**

Management Actions

1
High Priority

6
Medium Priority

Themes



Risk Types

Quality or Safety Issues

Legal & Regulatory Non-Compliance

Findings & Agreed Action Plan

Objective 1: Policies and procedures are in place that set out the arrangements and responsibilities for the management of controlled drugs, and these are available to staff on wards and theatres.	**Substantial**

The 'Policy for the Management of Controlled Drugs' and its supporting Standard Operating Procedures (SOPs), are available to all members of staff via the health board's SharePoint site. Both documents have recently been reviewed and updated (October 2025) and ratified by the Medicines Management Group.

The main update to the policy is the inclusion of section 1.8.2.2, which states that S*ervice Groups are responsible for developing and maintaining a Controlled Drug Management & Assurance Plan (CDMAP). The CDMAP should:*

- *Provide assurance against all aspects of the Health Board Controlled Drug Policy.*
- *Outline actions required to strengthen controlled drug governance within the Service Group.*
- *Be regularly reviewed at an appropriately senior level within the Service Group.*

The recent inclusion of this requirement in the policy has contributed to delays and challenges in strengthening governance arrangements. *(*See audit objective 6 for further details regarding compliance with this aspect of the policy.)

The accompanying SOP, titled *'Standing Operating Procedure to support the Policy for the management of Controlled Drugs in Swansea Bay University Health Board'*, was reviewed alongside the policy in October 2025 and is not due for further review until October 2027. The SOP has a wide scope, consisting of individual procedures covering key requirements for the management, storage and administration of CDs at both Ward (CDW) and Theatre (CDT) level, including:

- Ordering of CDs.
- Collection of CDs from Pharmacy.
- Receipting of CDs from Pharmacy – we note that this has been updated, as recommended in our previous Internal Audit (SBU-2223-019), to require witnessed receipt, with the order form signed and printed by the receiver and also countersigned by the witness.
- Administration of CDs to patients.
- Balance checking of CDs on wards and reconciliation in theatres.
- Management of CD cupboard keys.
- Completion of CD Registers.

The audit findings raised within this report primarily relate to operational non-compliance rather than deficiencies in the design of the policy of SOPs. Accordingly, our review did not identify any changes required to these documents, other than one amendment noted during the audit (see **Key Finding 6**).

Objective 2: The ordering, delivery and administration of controlled drugs is carried out in accordance with the policy and operating procedures, by authorised individuals, with records completed as required.	**Reasonable**

At the outset of the review, we were supplied with a report from the Controlled Drugs Accountable Officer (CDAO) and Pharmaceutical Advisor (Medicines Management) outlining CD stock count issues across all areas within the health board between March and May 2025. Based on this report, we selected areas with a higher number of CD stock issues, reviewing five wards and three theatres across the Neath Port Talbot Singleton and Morriston Service Groups.

Ordering Testing

We tested a sample of 40 CD orders, across the five wards and three theatres to assess compliance with the relevant SOPs (CDW 1-3 and CDT 1-4). The following exceptions were noted (see **Key Finding 1**):

- One instance where the order form (pink slip) had the 'Collected by' section unsigned by the employee collecting and checking the stock from Pharmacy.
- Six instances where the order form was not signed by the receiver at ward/theatre level, noting four of these incidents related to one area.
- Seven instances lacked a countersignature by a witness, as required by Standing Operating Procedures CDW 3 and CDT 3, with four relating to the same one area as above.
- Two instances where the CD order number was not recorded in the CD register.
- Two instances where receipt of CDs was not countersigned by a witness when updating the CD register.
- 17 signatures were illegible or unidentifiable across the ordering process, including entries in both the order book and CD register; this is an increase from 11 in our previous review.
- In all cases, only the 'Ordered by' section of the CD order book / CD register included printed names alongside signatures.

Good practice was identified with some areas displaying posters on the CD cabinets reminding staff that all orders require a witness countersignature when receiving CD stock, on both the CD order form and CD register.

Administration Testing

Further substantive testing was undertaken on the administration of CDs to patients, assessing compliance with SOPs CDW 4 (Ward Administration of) and CDT 3 (Theatre Administration). Reviewing a sample of 40 administrations, the following exceptions were identified: (see **Key Finding 1**)

- Only four of the eight areas recorded both patient name and Hospital / NHS number; others recorded either a name or a patient number.
- One instance where the person administering the drug also countersigned as the witness.
- 15 signatures were illegible or unidentifiable (seven administrator, eight witness) an increase from the 11 reported in our previous review.

We also noted that two areas maintained a ward-based signature list; however, in both cases, the lists incomplete and not regularly updated to reflect current staff (see **Key Finding 2**).

Key Findings		Risk & Impact	Agreed Management Action
1	**Compliance with Controlled Drugs Order Book and Register Requirements** Substantive testing of 40 orders across eight areas (five wards and three theatres) identified the following exceptions: <u>Missing signatures in the CD order book:</u> • One instance where the 'Collected by' section was not signed. • Six instances where the 'Receiver' signature was absent; and • Seven instances where the required witness countersignature was missing. <u>CD register discrepancies:</u> • Two instances where receipt of CDs was not countersigned when updating CD stock levels. • Two cases where the CD order number was not recorded in the register. <u>Illegible or unidentifiable signatures:</u> • 17 signatures across order books and the CD registers were illegible or could not be attributed to an individual. Further review of CD administration entries noted: • 15 illegible or unidentifiable signatures (seven administrator, eight witness). • One instance where the same individual signed both administrator and witness. • Four areas did not record both patient name and NHS number as required by SOP CDW4 (4.3) and CDT6 (5.3)	Loss or misappropriation of CDs may go undetected, increasing the risk of diversion, regulatory non-compliance, and potential harm to patients	**Agreed Action:** 1. Establish task and finish group to set up a programme and timetable of refresher training for all staff involved in CD ordering, receipt and administration, emphasising the importance of legibility and accountability in signatures. 2. Delivery of refresher training by service groups 3. Routine spot checks and audits of CD order books and registers to be introduced; with escalation to an appropriate forum for repeated non-compliance. **Expected Evidence of Implementation:** 1. Creation and dissemination of training materials and associated attendance records. 2. Report training delivery compliance to QSG (two per service group). 3. Completed spot check reports / audit checklists; governance meeting minutes discussing monitoring outcomes and summary provided in QSG report (two per service group).
		Medium Priority	**Officer:** (1) Controlled Drugs Accountable Officer; (2&3) Controlled Drugs Leads **Target Implementation Date:** (1) 30 September 2026; (2&3) 31 March 2027 (reports are quarterly)
	Theme: Quality, Safety & Patient Experience	Control Operation	
2	**Maintenance of Ward Based Signature Lists** During substantive testing, we observed two wards-maintained ward-based signature lists. These lists provided a useful mechanism for identifying individuals involved in the ordering,	Incomplete or outdated signature lists reduce the effectiveness of this	**Agreed Action:** 1. Revise CD policy to mandate signature and printed name. This will be emphasised as part of the refresher training referred to at Key Finding 1.

Key Findings	Risk & Impact	Agreed Management Action
receipt, countersigning (witnessing), and administration of Controlled Drugs. While not mandated by policy, this approach represents good practice and could be replicated across all areas. However, in both instances, the lists were incomplete and not consistently updated to reflect current authorised staff.	control, limiting the ability to verify authorised staff involvement and increasing the risk of unauthorised access or errors in the controlled drugs process.	**Expected Evidence of Implementation:** 1. Amended wording agreed by Pharmacy Governance Group and revised policy ratified by health board's policy group 2. Content of refresher training materials and completed spot checks (as per Key Finding 1).
	Medium Priority	**Officer:** Controlled Drugs Accountable Officer
Theme: Governance	Control Operation	**Target Implementation Date:** 30 September 2026

Objective 3: There are controlled drugs registers in place on each ward and theatre, which are completed accurately and reconcile to stock levels.	**Reasonable**

To assess compliance with SOPs CDW 11 (Controlled Drugs Register) and CDT 13 (Procedure for the completion of Controlled Drugs Register), we reviewed CD registers in our sampled wards and theatres and noted:

- All registers were in the prescribed format (hardback standard stationery issued by the Pharmacy Department).
- Each drug type has a separate page within the CD register.
- CD orders and administration were recorded on the correct page by drug type and evidenced by two staff signatures, subject to exceptions identified under audit objective 2.
- Dispensing entries recorded unused quantities, with wastage disposed of in sharps bins and countersigned as witnessed.
- Drug balances were updated after each entry and carried forward when a page was complete.
- Periodic CD balance checks (every 3 to 6 months) were conducted by hospital pharmacy teams and recorded in the register (see audit objective 5).

We also assessed compliance with SOPs: CDW 5 (Ward Balance Checks) and CDT 8 (Theatre Reconciliation), which stipulate physical stock levels are checked against register balances every 24 hours on wards and at each transfer of custody or handover of keys in theatres.

All eight areas consistently completed these checks, documented at the back of the register with two signatures. For one area (Morriston Acute Medical Assessment Unit - AMAU) there were a few gaps for the daily checks completed in September 2025 which was brought to management's attention at the date of the site visit.

Finally, independent balance checks conducted during fieldwork confirmed no discrepancies between register records and the physical CD cabinet stock levels.

Objective 4: Controlled drugs are securely stored, with the keys held by an appropriate person.	**Reasonable**

SOPs CDW6 and CDT9 set out the requirements for the security of CD cabinets and the management, recording and safe keeping of CD cabinet keys including:

- CD keys are kept separate from other general keys and always held by a designated person / person in charge.
- CD cabinets must be located in a secure location and remain locked.
- No other drugs should be stored in the cabinet apart from CDs.
- If Patient Own Medication (POMs) are stored within the cabinet, they are on a separate shelf and clearly identifiable.

Controlled Drugs Cabinet Keys

- Wards: staff confirmed that CD cabinet keys were kept separately from general keys and held by a designated person in charge when not in use. Only Registered Nurses were permitted access, which was visibly confirmed during site visits.
- Theatres: Key logbooks were maintained to record the staff member holding the CD key at any point in time, with countersignatures required. Separate logs were in operation for both the master key to the safe (which holds the CD keys for all Theatres within the department) and for each individual CD cabinet. Logs recorded key issue at the beginning of theatre lists, handovers during the day, and return to the safe or cabinet at close.

Controlled Drugs Cabinet & POMs

All CD cabinets were located in secure, locked rooms and were in good condition, except for the cabinet located at AMAU Morriston was visibly damage and evidence of forced entry identified (see **Key Finding 3**). Only CDs were stored within the cabinets, and where POMs were present, these were kept on a separate shelf and recorded within a separate POMs register. However, again at AMAU Morriston. POMs were mixed with CD stock, causing confusion during balance reconciliation, as both were included in the stock count (see **Key Finding 4**). Theatres do not store POMs.

Key Findings		Risk & Impact	Agreed Management Action
3	**Physical Security of Controlled Drugs Cabinets – AMAU Morriston** Physical verification confirmed that all CD cabinets were located within secure, locked rooms and were generally in good condition. However, at AMAU Morriston, the CD cabinet showed visible damage and evidence of forced entry. Staff subsequently confirmed that the damage occurred when the Estates team gained access after the lock was broken. Although access was obtained, there is no evidence that the remaining damage was escalated or that a request for a replacement cabinet was made, thereby compromising the security of the contents.	Compromise CD security, increasing the risk of unauthorised access, theft, misuse, and non-compliance.	**Agreed Action:** 1. Arrange repair or replacement of the damaged cabinet to meet security standards. 2. Reinforce staff awareness of reporting damage promptly **Expected Evidence of Implementation:** 1. Confirmation of arrangements for damaged cabinet. 2. Staff communication for reporting of damage.

Key Findings		Risk & Impact	Agreed Management Action
	We have been advised that the drugs have since been moved to an alternative cabinet.	**High Priority**	**Officer:** (1&2) Head of Nursing, Acute & Emergency Care and Hospital Operations (AECHO) Morriston **Target Implementation Date:** (1&2) 31 March 2026
	Theme: Physical Security	Control Operation	
4	**Segregation of Patients Own Medicine (POMs)** Policy expects POMs to be stored separately from CDs. Where POMs need to be held in the CD cabinet, they should be held on a separate shelf with a separate record being maintained. While this was generally observed, at AMAU Morriston, there was a lack of segregation which led to discrepancies in the reconciliation of CD cabinet stock levels with the CD register.	Failure to segregate POMs from CDs may lead to stock errors, medicine mismanagement, SOP breaches and compromised governance and patient safety.	**Agreed Action:** 1. Clarify segregation requirements in policy 2. Recommunicate storage requirements to all staff handling CDs and POMs – this will include AMAU. *3.* Segregation checks in routine audits
			Expected Evidence of Implementation: 1. Amended wording agreed by Pharmacy Governance Group and revised policy ratified by health board's policy group 2. Communication to staff 3. Spot check reports and audit findings showing compliance.
		Medium Priority	**Officer:** (1) Controlled Drugs Accountable Officer; (2&3) Controlled Drugs Leads **Target Implementation Date:** (1) 30 September 2026; (2) 31 October 2026; (3) 31 March 2027
	Theme: Quality, Safety & Patient Experience	Control Operation	

Objective 5: Appropriate checks and audits are undertaken by health board staff in line with policy and acted upon accordingly.	**Reasonable**

Daily CD balance checks are conducted by ward and theatre staff, and we confirmed this practice across the sampled locations visited during audit fieldwork (see audit objective 3).

The *Management of Controlled Drugs* policy specifies that the Pharmacy department is responsible for conducting checks on wards and departments in collaboration with the relevant ward or department managers. These checks include audits on the safe handling and storage of CDs, review of CD registers and verification of current stock lists. Audits are required every three to six months, and template documents are provided to record these activities. Standard practice is to document within the CD register that a balance check and/or audit has been completed, as well as record the audit in AMaT and, previously, the CD Dashboard.

In August 2025, the Pharmacy department implemented the AMaT for recording all audits undertaken at ward and theatre level. This replaced the CD Dashboard and introduced a revised audit cycle, which now runs from October–March and April–September, rather than the previous January–June and July–December schedule. Overview reports provided to us from AMaT and the CD Dashboard, highlighted a high level of compliance for undertaking Pharmacy reviews across the Service Groups. The AMaT system records each review undertaken, highlighting compliance levels against each section of the audit template held within the Appendix of the CD Policy.

To evidence that audits had been undertaken, we reviewed an overview report from the previous CD Dashboard (up to September 2025), which confirmed that regular audits were being carried out across the Service Groups. We also examined supporting documentation for the two most recent audits in each sampled area, confirming compliance with the required frequency (every 3 - 6 months).

During our review of CD registers, we identified one instance where it was not possible to confirm whether a Pharmacy audit had taken place, within the previous 6 months. This represents an improvement from the 2022/23 review, where six of eight CD registers lacked evidence of Pharmacy audits. Pharmacy subsequently provided audit documentation from June and July, confirming that recent audits in that area were completed within the required timeframes.

Discussion with Service Group Pharmacists confirmed that feedback on audits is provided by Pharmacy upon completion, highlighting any identified non-compliance. Progress against these non-compliances is only monitored when the area undergoes re-audit within the 3-6 month cycle. There is currently no formal reporting of Pharmacy review outcomes at Service Group level (see **Key Finding 5**)

Key Findings		Risk & Impact	Agreed Management Action
5	**Audits of Controlled Drugs** While feedback on audits is provided by Pharmacy upon completion, highlighting any identified non-compliance, progress against these non-compliances is only monitored when the area undergoes re-audit within the 3–6 month cycle. There is currently no formal reporting of Pharmacy audit outcomes at Service Group level, limiting oversight and assurance.	Lack of formal reporting of Pharmacy audit outcomes at Service Group level limits oversight and assurance, increasing the risk that non-compliance	**Agreed Action:** 1. AMaT audits and actions plans to be standing agenda item for service group governance structure for oversight of delivery. 2. Individual action plans to be reported until completed. 3. Compliance to be reported through QSG report.

Key Findings	Risk & Impact	Agreed Management Action
	persists and Controlled Drug governance weaknesses remain unresolved.	**Expected Evidence of Implementation:** 1. Agenda and minutes for service group Governance meeting minutes and sample audit summary reports showing audit outcomes. 2. Reports to QSG.
	Medium Priority	**Officer:** Controlled Drugs leads
Theme: Reporting	Control Operation	**Target Implementation Date:** 31 December 2026

Objective 6: There is appropriate oversight of controlled drugs within the health board, including incidents.	**Limited**

Service Group Oversight

Each Service Group oversee management of CDs through local monitoring arrangements. Governance structures vary but typically comprise a CD Management Group and a Quality and Safety Group, meeting monthly, bi-monthly or quarterly.. We were unable to undertake detailed testing into CD reporting, due to insufficient information provided by the Service Groups.

CD Management and Assurance Plans (CDMAPs) within the Service Groups are intended to align CD governance activity with the statutory requirements under *The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008*. CDMAPs record weaknesses in CD management practices and include action plans to address them. Our 2021/22 audit highlighted a high-priority finding that CDMAPS were not routinely reviewed and updated at Service Group Level, nor checked or compliance with legislation. During this review, we received updated CDMAPs for all Service Groups except for Primary Care, where we informed that the document was managed as a standing agenda item in the 'Controlled Drugs and High-Risk Medicines Group'. However, for the three months supplied, no updates or documents were presented (see **Key Finding 6**). The other CDMAPs appear to be live documents with regular updates evidenced at appropriate the Service Group meetings, with the documents now including a RAG (Red, Amber, Green) ratings to easily identify areas of compliance and those requiring additional resource. Compared to the previous review, the CDMAPS show greater maturity, with clearly documented actions, both completed and outstanding.

Previously (2022/23) Service Groups CD Leads met with the CDAO bi-annually to discuss emerging concerns regarding CD governance and to provide updates on CDMAP progress and associated actions. This responsibility is outlined in the *Management of Controlled Drugs Policy*. During our discussions with the CDAO, we were informed that these bi-annual meetings, as defined in the policy, are no longer in operation.

Corporate Oversight

The health board has revised its CD governance structure following recommendations from our 2022/23 report. Revised reporting arrangements were introduced in October 2025 to strengthen governance and assurance, support Service Group CD Leads, and ensure a consistent approach across Service Groups. These changes aim to enhance oversight, promote best practice, and provide assurance to the CDAO and the health board that CDs are managed safely and in compliance with regulations. A new reporting template requires Service Groups to submit quarterly, biannual, and annual reports to the Quality & Safety Group. However, at the October meeting, only two Service Groups submitted reports, and one used the outdated CDMAP instead of the new template (see **Key Finding 7**).

Key Findings		Risk & Impact	Agreed Management Action
6	**Controlled Drugs Management & Assurance Plans (CDMAPs)** CDMAPS are used at Service Group level to ensure compliance and continued improvement of Controlled Drugs. However, at the Primary Care Service Group, such is not being issued /monitored on a routine basis.	Issues with CDs in the Service Groups or noncompliance against the plans are not identified without regular review.	**Agreed Action:** 1. Reiterate the expected schedule for issuing and reviewing CDMAPS within the Primary & Community Care Service Group 2. Review the purpose and structure of CDMAPS in the context of the changes being made of organisational structure.

Key Findings		Risk & Impact	Agreed Management Action
			Expected Evidence of Implementation: 1. Communication with PCCSG regarding the expected schedule for issuing and reviewing CDMAPS, and Controlled Drugs and High-Risk Medicines Group Meeting Minutes/papers evidencing compliance. 2. Confirmation of the position regarding the ongoing utilisation of CDMAPS, including training materials and reporting schedules as appropriate, based on the new organisational structure as new governance structures emerge
		Medium Priority	**Officer:** Controlled Drugs Accountable Officer **Target Implementation Date:** (1) 30 June 2026; (2) 31 March 2027
	Theme: Reporting	Control Operation	
7	**Corporate Reporting** Since October 2025, the health board has sought to implement an enhanced governance and reporting structure for Controlled Drugs, including a new quarterly reporting template for Service Groups to present at the Quality & Safety Group (QSG). This approach aims to strengthen oversight, promote best practice, and ensure Controlled Drugs management remains a priority at both Service Group and corporate levels. The Controlled Drugs Accountable Officer confirmed that biannual meetings with Service Group Leads have not been in operation. We recognise the infancy of the reporting structure, and it will take time to mature. At the October QSG meeting, only Morriston and NPT/Singleton submitted reports, with Morriston using its Controlled Drugs Management & Assurance Plan rather than the new template.	Corporate reporting process is not embedded, with incomplete and inconsistent submissions, limiting oversight and increasing the risk of undetected governance or CD compliance issues.	**Agreed Action:** 1. Report template to be adapted to include additional reporting (training compliance and audit reporting) 2. Issue formal directive that all Service Groups must submit the new CD quarterly report using the revised template by the published QSG deadlines, with guidance for completion if appropriate. 3. Track and report on the Service Groups using the correct template; and providing the required information as per the template; with escalation for non-compliance defined. 4. Review of meeting arrangements with the Control Drugs Accountable Officer once new care group arrangements and CDAO are in place **Expected Evidence of Implementation:** 1. Revised report template 2. Communication and associated guidance if appropriate 3. QSG papers and supporting reporting, with escalation to QSC as/if required. 4. Updated Management of Controlled Drugs Policy based on

Key Findings		Risk & Impact	Agreed Management Action
		Medium Priority	**Officer: (1)** Controlled Drugs Accountable Officer (2) Executive Medical Director; (3) Head of Service, Medical Director; (4) Controlled Drugs Accountable Officer **Target Implementation Date:** (1) 31 March 2026 (2) 30 April 2026; (3) 31 August 2026; (4) 31 December 2026
	Theme: Reporting	Control Operation	

Objective 7: Recommendations raised in the recent Health Inspectorate Wales review are being actioned and monitored.	**Reasonable**

In March 2025, Health Inspectorate Wales (HIW) issued its report following their unannounced inspection of the Emergency Department at Morriston Hospital (November 2024). The review identified a number of key issues, including that *controlled drugs were stored securely in locked cabinets, however, Datix incidents highlighted items of controlled medication which were unaccounted for within the department, a matter currently under investigation by the health board's pharmacy team*.

HIW made the following recommendations regarding Controlled Drugs and Medicines Management:

- Reinforce awareness of health board policy on CD management for all staff working within the Emergency Department (Clinical & Non-Clinical).
- Completing an SBAR assessment of CD management.
- Commence weekly assurance checks to confirm medication fridge checks.

Our review of the Morriston Service Group's Controlled Drugs Management and Assurance Plan confirmed these recommendations were incorporated and marked complete. A letter dated 9 June 2025 provided HIW with a three-month progress update confirming full implementation of actions relating to CDs. Further updates were presented to the Quality & Safety Committee in July and November 2025.

Substantive testing was not undertaken in ED to support these closures, however stock checks at other areas within the Service Group did not identify any issues with missing CDs. The letter issued to HIW did however note that the daily fridge temperature checks is still an issue for the department.

Appendix A: Status of Prior Year Recommendations

Ref	Summary of key finding and recommendation	Agreed Management Response	2025/26 Status	2025/26 outcome
1	**CD order and register compliance** A number of key control exceptions were identified with CD orders where we examined order and register documents for compliance with requirements. Further, testing identified instances where the ward signatures in the register dispensing entries were illegible. We recommended that the exceptions identified were addressed and that rules requiring double signatories for all CD register movements are applied without exception (signatures should always be accompanied by printed names in order that they may clearly identify the individual signing). Additionally, we recommend that the health board consider introducing the requirement to provide a second (witness) signature on CD order stationery to strengthen further the existing controls.	The Controlled Drug Accountable Officer will work with Service Group Controlled Drug Leads to review the controlled drug policy in respect of witness signatures for the receiving of CDs and for existing controls in place. This will include as a minimum: • Making all staff involved in the management of controlled drugs aware of the above findings in order to help staff reflect on current practice. • Drawing staff attention to the Health Board's controlled drug policy and in particular the relevant sections relating to the above recommendation with the aim of improving adherence to policy requirements. • Ensuring performance relating to the above recommendation is re-audited by the Service Group within 6 weeks to provide the Service Group, the Executive team and the Controlled Drug Accountable Officer with the necessary assurance that mitigating action has been successful and that practice is fully compliant with policy. • Ensuring that the above findings and recommendation are discussed at the relevant Service Group controlled drug governance and quality & safety forums together with the outcome of mitigating actions.	As detailed at objective 2, continued issues have been noted in the ordering and administration of CDs, including illegible signatures (15 compared to the 11 identified at the 2022/23 review)	Recommendation superseded. See Key Findings 1 & 2.

Ref	Summary of key finding and recommendation	Agreed Management Response	2025/26 Status	2025/26 outcome
2	**Ward/theatre CD balance checks by Pharmacy** Testing confirmed pharmacy teams conduct CD audits, but gaps exist: balance checks were often not recorded in registers, and some audit documentation was missing. We recommended recording checks on individual drug pages and in the Pharmacy CD dashboard, enabling formal management review and sharing results with stakeholders.	Pharmacy Leads will work with Service Group Controlled Drug Leads to ensure as a minimum: • All staff involved in the joint controlled drug checks are made aware of the above findings in order to help staff reflect on current practice. • Staff are made aware of the requirements around undertaking the joint controlled drug checks, including appropriate recording of such checks. • The results of such audits are being captured and acted upon accordingly to improve controlled drug governance. • Ensuring performance relating to the above recommendation is re-audited by pharmacy leads and the Service Group following the next scheduled joint CD checks, to provide the Chief Pharmacist, the Service Group, the Executive team and the Controlled Drug Accountable Officer with the necessary assurance that mitigating action has been successful. • Ensuring that the above findings and recommendations are discussed at the relevant Pharmacy and Service Group controlled drug governance and quality & safety forums together with the outcome of mitigating actions.	As detailed at objective 3, all registers met prescribed standards, with accurate entries, signatures and balance updates. SOP compliance was strong, with daily checks documented, except minor gaps at Morriston AMAU. Pharmacy teams conducted periodic audits, and independent checks confirmed no discrepancies between registers and physical stock, ensuring overall compliance and control.	We recommend closing of this recommendation within the audit tracker.
3	**Service Group's CDMAP updates** The review found CDMAPs across Service Groups were outdated, lacked routine review, and were not aligned with	The Service Group Controlled Drug Lead will direct the Service Group's response to the recommendation. This will include as a minimum:	As detailed at objective 6, updated CDMAPS were received with the exception of Primary Care; others show regular updates with RAG	Recommendation superseded. See Key Findings 6 & 7.

Ref	Summary of key finding and recommendation	Agreed Management Response	2025/26 Status	2025/26 outcome
	legislation. Documents had unclear actions, missing dates, and incomplete items. Mental Health, Singleton/NPT, and Morriston showed significant gaps, including expired target dates and insufficient monitoring frameworks, despite previous advisory recommendations.	• Ensuring that the Service Group reviews their Controlled Drug Management & Assurance Plan (CDMAP) in line with the above recommendations. • Discussing the Service Group's updated CDMAP, or latest draft if ongoing, at the Service Group Controlled Drug Lead/Controlled Drug Accountable Officer biannual meeting in late November/early December 2022, to provide the Controlled Drug Accountable Officer with the necessary assurance that mitigating action has been successful. • Ensuring that the above findings and recommendations are discussed at the relevant Service Group controlled drug governance and quality & safety forums, together with the outcome of mitigating actions	ratings. New reporting was introduced in October 2025 for CD governance, but compliance was poor and outdated templates were still being used.	

Appendix B: Assurance Opinion & Prioritisation of Findings

Assurance Opinion

	**Substantial**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
	**Reasonable**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
	**Limited**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
	**Unsatisfactory**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
	**Advisory**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Findings

Priority	Explanation
High	Significant risk to achievement of a system objective OR evidence present of material loss, error, or misstatement. Poor system design OR widespread non-compliance.
Medium	Some risk to achievement of a system objective. Minor weakness in system design OR limited non-compliance.

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Audit work undertaken by NHS Wales Audit and Assurance Services conforms with the International Standards for the Professional Practice of Internal Auditing and associated Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Chartered Institute of Public Finance & Accountancy in April 2023.

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