Healthcare Improvement Scotland

# Report on self-declaration and assessment of controlled drugs governance arrangements: Scottish designated (health) bodies

November 2026

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# Executive Summary

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2013,[1] Healthcare Improvement Scotland (HIS) is responsible for providing independent external scrutiny and assurance of controlled drug (CD) governance arrangements within all designated bodies in Scotland.

At the time of reporting, fifty-three designated bodies were recorded on the Healthcare Improvement Scotland (HIS) register of Controlled Drug Accountable Officers (CDAOs). In April 2026, all designated bodies were invited to complete a self-assessment and self-declaration on their controlled drug governance arrangements. Responses were received from all fifty-three designated bodies, representing a 100% response rate.

## Key Findings

Designated bodies that hold stocks of controlled drugs (CDs) should ensure that they have considered Home Office licensing requirements and, where necessary, seek advice from the Home Office.

The proportion of designated bodies that are members of a Local Intelligence Network (LIN) has increased since our previous report, rising from 69% to 75%.

All CDAOs reported that their organisation has governance arrangements in place with clear lines of responsibility and accountability for the management and use of controlled drugs. However, HIS, in collaboration with the CDAO Working Group, will develop and publish a suggested template for annual CD reporting to support a consistent approach across designated bodies.

Training and education relating to the use of CD Standard Operating Procedures (SOPs) varied across designated bodies. As this question was not included in the previous review, no comparison can be made.

Work is ongoing to improve the reporting of privately prescribed and privately dispensed CDs, including those prescribed in a different country of the UK from where they are dispensed, to allow NHS Board CDAOs to fully undertake their monitoring responsibility.

# Introduction

Healthcare Improvement Scotland (HIS) has a statutory responsibility for overseeing the self-declaration and self-assessment process for designated bodies required to appoint a Controlled Drugs Accountable Officer (CDAO). This enables both HIS and designated bodies to monitor and assure the effectiveness of their clinical governance arrangements for the safe management and use of controlled drugs.

HIS also produces quarterly controlled drug (CD) occurrence reports based on CD notifications submitted by HIS regulated services. These reports are shared with the NHS Board CDAO for the area in which the regulated service is located.

In addition, HIS is responsible for compiling, maintaining, and publishing the Scottish register of CDAOs. This includes administering the process through which eligible healthcare providers may apply for an exemption from the requirement to appoint a CDAO, where the specified criteria are met.

HIS completed a national review of CDAO self-declarations and self-assessments, findings were published in November 2024. The review evaluated controlled drugs governance arrangements across designated healthcare bodies in Scotland and resulted in a series of recommendations aimed at strengthening governance, assurance, and oversight. Further updates and follow-up actions were undertaken during 2025 to support and assess progress against these recommendations.

# What we did

Following the review conducted in 2024/2025, HIS further developed the self-assessment and self-declaration process, to evaluate controlled drugs governance arrangements across designated bodies and provide assurance to HIS.

Using a risk-based and proportionate methodology, the review assessed organisational compliance with the principal requirements of the 2013 Regulations.[1]

At the time of review, 53 designated bodies listed on the HIS CDAO Register were invited to complete the self-assessment and self-declaration.  There were 52 designated bodies on last review with the addition of an independent hospital.

# Our Findings

## Self-Declaration

When all designated bodies had completed their self-assessment and self-declaration, amendments to the HIS CDAO register were made where required. Since the last report, HIS has developed and launched electronic application and amendment forms for CDAOs, available through the HIS website Controlled Drug Accountable Officer (CDAO) applications and amendments – Healthcare Improvement Scotland.

A dedicated email address has also been established to provide a single point of contact for CDAO queries his.cdregister@nhs.scot.

Designated bodies are required to have arrangements in place to ensure continuity of the CDAO role and function during periods of absence of the post holder lasting three weeks or more. At the time of reporting, 31 (58%) designated bodies had a named deputy in place to fulfil these responsibilities. This is an increase from 25 (48%) on the last report. 6 (11%) NHS Boards and 16 (30%) Independent Healthcare Services reported not having a named deputy in place. However, two of these designated bodies have a CD governance team and one NHS Board is awaiting the vacancy to be filled.
CDAOs must confirm they have arrangements in place to ensure the role of the CDAO is continued in a period of absence greater than three weeks when they complete their yearly HIS annual return.

### Requirements

1. Designated bodies must complete periodic self-declaration and self-assessment when requested by HIS as per The Controlled Drugs (Supervision of Management and Use) Regulations 2013.

2. Designated bodies must inform HIS of any changes to their CDAO role, temporary or permanent via the online reporting function.

3. Designated bodies must have arrangements in place to ensure the role and function of the CDAO are continued in periods of absence (3 or more weeks) of the post holder.

## Self-Assessment

Previously all designated bodies reported they were compliant, or working towards being compliant, with Home Office license requirements where 17 designated bodies reported having a Home Office licence in place, where one was required. This has increased to 39 (74%) designated bodies reporting having a Home Office license.

### Recommendations

1. CDAOs must confirm with the Home Office if a Controlled Drug License is required for their service.

Local Intelligence Networks (LINs) provide a mechanism for organisations, regulators, and agencies to raise concerns and share intelligence with designated bodies or individuals in relation to the safe management and use of controlled drugs. This facilitates the early sharing of concerns with relevant agencies, supporting timely action and the identification of additional information where required.

At the time of reporting, of the 53 designated bodies, 40 (75%) CDAOs stated they are a member of and participate in a LIN and 45 (85%) CDAOs stated they are a member of the Accountable Officers Network for Controlled Drugs (Scotland).

There were 13 (25%) CDAOs who were not members of a LIN and 8 (15%) CDAOS who were not members of the Accountable Officers Network for Controlled Drugs (Scotland). There was one hospice CDAO was not a member of either a LIN or the Accountable Officers Network for Controlled Drugs (Scotland), the post holder had only recently taken up the role and was unable to locate the membership details. The relevant details have since been provided

directly to the hospice CDAO. HIS Inspectors for the four independent hospitals that are also not members of a Local Intelligence Network (LIN), or the Accountable Officers Network for Controlled Drugs (Scotland) have been provided with the appropriate contact details and will engage with the services at their next individual monthly meeting. One NHS Board stated they are not a member of a LIN due to changes in the current structure where a new LIN is being established.

In line with NICE Guideline NG46 (Controlled Drugs: Safe Use and Management)[2], organisations are expected to maintain robust governance frameworks, including defined reporting arrangements for controlled drug matters. The self-declaration has been developed with due regard to these principles and aims to support the establishment of comparable governance arrangements across Scotland. All CDAOs report their organisation to have governance arrangements in place with clear lines of responsibility and accountability for controlled drugs.

Designated bodies must report annually into the appropriate governance structure of their organisation to provide an assurance of their arrangements for controlled drugs. Responses indicate variation in reporting arrangements. However, 51(96%) designated bodies confirmed that at least an annual reporting process was in place. Two designated bodies from the independent healthcare sector stated that controlled drug-related issues are not reported through a formal report to the appropriate senior management governance committee.

### Requirements

4. Designated bodies must provide, at least annually, a CD governance report to the appropriate safety committee of the organisation.

Most designated bodies (51, 96%) reported having adequate resources in place to discharge their CDAO responsibilities, an increase from 62% previously reported. 2 (4%) NHS organisations reported that resources were not currently adequate. Reasons provided included the absence of an appointed deputy and an ongoing review of resource allocation.

### Recommendations

2. Designated bodies to report insufficient resource through their governance structures to ensure recorded as a risk within their organisation.

Designated bodies must put in place standard operating procedures (SOPs) for processes relating to prescribing, supplying and administering controlled drugs, including clinical monitoring for people who have been prescribed controlled drugs, in line with Regulation 11 of the Controlled Drugs (Supervision of Management and Use) Regulations 2013. A designated body reported not having SOPs in place however has a CD policy. 2 (4%) designated bodies, both are NHS Boards reported their SOPs have not been reviewed at regular intervals. An NHS organisation reported no regular CD audits are undertaken to assess adherence to their CD policy and SOPs. 2 (4%) NHS organisations that complete regular audits state they do not develop action plans based on any identified gaps

We asked if staff receive relevant training and undergo competency assessment and the organisation hold a register of trained personnel. Overall, 42 (79%) of designated bodies have this in place. Refer to table 1 for breakdown of designated bodies.

### Requirements

5. Designated bodies must have appropriate SOPs in place as per the Controlled Drugs (Supervision of Management and Use) Regulations 2013.
6. SOPS must be subject to regular review and where gaps are identified corrective action is put in place.
7. Designated bodies must ensure that any person who requires education and training in relation to SOPs, receives the relevant training, as appropriate.

CDAOs must have regard for managing the risks associated with the clinical use of controlled drugs. The CDAO is empowered through regulations to direct services to protect the safety of patients, where the use of controlled drugs is considered unsafe for patients. While all organisations reported having systems for reporting, investigating and learning from controlled drug incidents, gaps remain in prescribing surveillance. Two NHS Boards and two independent hospitals do not routinely monitor controlled drug prescribing. Furthermore, these organisations and a further five independent services reported having no formal process for identifying and following up outlier prescribing.

### Recommendations

3. CDAOs of designated bodies to ensure that they are members of a LIN and actively participate in meetings.
4. HIS to produce a reporting template for designated bodies to allow consistency of approach.
5. CDAOs of designated bodies to ensure that:
    - An appropriate organisational governance structure regularly reviews (minimum of every 6 months) CD incidents and issues identified.
    - That corrective actions identified from reviews are fully implemented
    - An annual statement of assurance can be given that their organisation is compliant with CD governance requirements.
6. Designated bodies to establish a process for monitoring controlled drug prescribing and identifying outliers.

## NHS Board CDAO Specific Self-Assessment

NHS Board CDAOs completed a self-assessment specific to their role. Of the 14 territorial NHS Boards that should receive data relating to private prescribing of Schedule 2 and 3 controlled drugs on PPCD(1) pads issued by them, four (29%) did not. In addition, one NHS Board reported that they do not monitor or analyse the data provided.

12(86%) Territorial NHS Board CDAO/controlled drug teams are involved with the application process for awarding private prescriber codes and respective pads. The two NHS Territorial Boards not involved in this process may not have Independent Healthcare Services requiring CDs.

One of the functions of HIS is to collate CD notifications submitted by independent healthcare services into quarterly reports, which are shared with the relevant NHS Board CDAO. This information can support local intelligence networks by highlighting themes, trends or concerns that may extend across organisational boundaries and require a coordinated response. However, two NHS Boards reported that they do not receive quarterly occurrence reports. Due to there being no independent healthcare provision using CDs in their geographical area.

### Recommendations

7. NHS Public Services Delivery (PSD) Scotland, Scottish Government, NHS England and CQC must resolve issues preventing reporting on privately prescribed CDs.
8. NHS Board CDAOs to monitor and analyse privately prescribed CD data provided by NHS PSD Scotland using the same criteria as applied to NHS Board prescribing.
9. HIS Medicines and Pharmacy team will work in partnership with our colleagues in Quality Assurance & Regulation Directorate (QARD) to ensure the report recommendations are implemented and followed up during the inspection processes of IHC.

## Summary

Review of the self-assessment and self-declaration submissions did not identify any serious patient safety issues requiring immediate intervention or escalation. However, several areas were identified where assurance arrangements could be strengthened. These included vulnerabilities in Controlled Drugs Accountable Officer (CDAO) leadership resilience, which could be mitigated by ensuring that robust continuity arrangements are in place to maintain oversight of controlled drug (CD) governance during periods of absence.

Patient safety could be further enhanced through greater engagement with local intelligence networks, targeted horizon scanning of CD-related issues within Board areas, improved assurance regarding training compliance, and strengthened prescribing surveillance. To support consistency in CD assurance processes across organisations, Healthcare Improvement Scotland (HIS), in collaboration with the CDAO Working Group, will develop and publish a template outlining the minimum reporting requirements for annual organisational-level CD governance reports.

# Table 1 Responses to Self-Declaration and Self-Assessment

| | Yes / No | Total | NHS Boards | National NHS Boards | Hospices | Independent Hospitals |
|---|---|---|---|---|---|---|
| | | 53 | 14 | 3 | 16 | 20 |
| Name of Deputy CDAO provided | Yes<br>No | | 8<br>6 | 3<br>0 | 10<br>6 | 10<br>10 |
| Does the organisation hold the appropriate Home Office License on all sites to hold Controlled Drugs stock? | Yes<br>No | | 11<br>3 | 2<br>1 | 8<br>8 | 18<br>2 |
| Is the CDAO a member of the Accountable Officers Network for Controlled Drugs (Scotland)? | Yes<br>No | | 13<br>1 | 3<br>0 | 15<br>1 | 14<br>6 |
| Is the CDAO a member of and participate in a Local Intelligence Network (LIN)? | Yes<br>No | | 13<br>1 | 3<br>0 | 13<br>3 | 11<br>9 |
| Does the organisation have governance arrangements in place with clear lines of responsibility and accountability for CDs? | Yes<br>No | | 14<br>0 | 3<br>0 | 16<br>0 | 20<br>0 |
| Are there adequate resources in place to fulfil the duties of the role of the CDAO? | Yes<br>No | | 12<br>2 | 3<br>0 | 16<br>0 | 20<br>0 |

| | Yes / No | Total | NHS Boards | National NHS Boards | Hospices | Independent Hospitals |
|---|---|---|---|---|---|---|
| | | 53 | 14 | 3 | 16 | 20 |
| Does the organisation have a CD policy? | Yes<br>No | | 13<br>1 | 3<br>0 | 16<br>0 | 20<br>0 |
| Does the organisation have standard operating procedures (SOPs) for; ordering, receiving, prescribing, supply, administration, storing, transporting, destroying and disposing of CDs? | Yes<br>No | | 13<br>1 | 3<br>0 | 16<br>0 | 20<br>0 |
| Are the SOPs/policies reviewed regularly? | Yes<br>No | | 12<br>2 | 3<br>0 | 16<br>0 | 20<br>0 |
| Do staff receive relevant training and undergo competency assessment and the organisation hold a register of trained personnel? | Yes<br>No | | 5<br>9 | 2<br>1 | 16<br>0 | 19<br>1 |
| Are regular CD audits undertaken to assess adherence to policies and SOPs? | Yes<br>No | | 13<br>1 | 3<br>0 | 16<br>0 | 20<br>0 |
| Are action plans developed and followed through where there are gaps identified? | Yes<br>No | | 12<br>2 | 3<br>0 | 16<br>0 | 20<br>0 |

| | Yes / No | Total | NHS Boards | National NHS Boards | Hospices | Independent Hospitals |
|---|---|---|---|---|---|---|
| | | 53 | 14 | 3 | 16 | 20 |
| Does the organisation have a process/mechanism for reporting, investigating and learning related to the management and use of CDs? | Yes<br>No | | 14<br>0 | 3<br>0 | 16<br>0 | 20<br>0 |
| Does the organisation have a system to routinely monitor prescribing of CDs? | Yes<br>No | | 13<br>1 | 2<br>1 | 16<br>0 | 18<br>2 |
| Does the organisation have a system in place to follow up on outlier prescribing? | Yes<br>No | | 13<br>1 | 2<br>1 | 14<br>2 | 15<br>5 |

## Table 2 Responses to NHS Board CDAO Self-Assessment

| Self-Assessment Question | Yes | No |
|---|---|---|
| Does the NHS Board CDAO receive information on private prescribing for schedule 2 & 3 CDs from national prescribing data sources | 10 | 4 |
| Does the NHS CDAO analyse and report on this private prescribing for schedule 2 & 3 CDs? | 9 | 5 |
| Is the NHS Board CDAO/CD Team involved with the application process for awarding private prescriber CD codes and respective pads? | 12 | 2 |
| Does the CDAO receive quarterly occurrence reports from HIS which includes collated reports of all CD incidents from all independent healthcare services10 | 12 | 2 |

# Appendix 1 Table of Designated Bodies

| NHS Health Boards | | | |
|---|---|---|---|
| NHS Ayrshire and Arran | NHS Borders | NHS Dumfries & Galloway | NHS Fife |
| NHS Forth Valley | NHS Grampian | NHS Greater Glasgow & Clyde | NHS Highland |
| NHS Lanarkshire | NHS Lothian | NHS Orkney | NHS Shetland |
| NHS Tayside | NHS Western Isles | | |
| National Boards | | | |
| Scottish Ambulance Service | State Hospital's Board for Scotland | NHS Golden Jubilee (The National Waiting Times Centre) | |
| Hospices | | | |
| Accord Hospice | Children's Hospice Association Scotland (CHAS) – Rachel House | Marie Curie Hospice (Glasgow) | St Margaret of Scotland Hospice |
| Ardgowan Hospice | Children's Hospice Association (CHAS) – Robin House | Marie Curie Hospice (Edinburgh) | St Vincent's Hospice |
| Ayrshire Hospice | Highland Hospice | St Andrew's Hospice | Strathcarron Hospice |
| Bethesda Hospice | Kilbryde Hospice | St Columba's Hospice | The Prince and Princess of Wales Hospice |
| Independent Hospitals | | | |
| Alpha Clinic at Aberdeen Independent Hospital | Circle Health – Ross Hall Hospital | Murdostoun Brain Injury and Neurological Care Centre (Active Care Group) | Spire Murrayfield Hospital |
| BrainKind – Graham Anderson House | Cosmedicare UK Ltd | Nuffield Health Edinburgh Hospital | Spire Shawfair Park Hospital |
| Castle Craig Hospital | Cygnet Health Care | Nuffield Health Glasgow Hospital | Surehaven Low Secure Hospital |
| Circle Health – Albyn Hospital | Elanic Clinic | Priory Ayr Clinic | Waterfront Private Hospital |
| Circle Health – Kings Park Hospital | Electiva Hospital | Priory Hospital Glasgow | William Quarrier Scottish Epilepsy Centre |

# Appendix 2 Table of Recommendations for Designated Bodies

| | |
|---|---|
| **Requirement Number** | **Requirement** |
| 1 | Designated bodies must complete periodic declarations and self-assessment when requested by HIS as per The Controlled Drugs (Supervision of Management and Use) Regulations 2013, 19 (4). |
| 2 | Designated bodies must inform HIS of any changes to their CDAO role, temporary or permanent via the online reporting function. |
| 3 | Designated bodies must have arrangements in place to ensure the role and function of the CDAO are continued in periods of absence (3 or more weeks) of the post holder. |
| 4 | Designated bodies must provide, at least annually, a CD governance report to the appropriate safety committee of the organisation. |
| 5 | Designated bodies must have appropriate SOPs in place as per the Controlled Drugs (Supervision of Management and Use) Regulations 2013. |
| 6 | SOPS must be subject to regular review and where gaps are identified corrective action is put in place. |
| 7 | Designated bodies must ensure that any person who requires education and training in relation to SOPs, receives the relevant training, as appropriate. |
| | |
| **Recommendation Number** | **Recommendation** |
| 1 | CDAOs must confirm with the Home Office if a Controlled Drug License is applicable to their service. |
| 2 | Designated bodies to report insufficient resource through their governance structures to ensure recorded as a risk within their organisation. |
| 3 | CDAOs of designated bodies to ensure that they are members of a LIN and actively participate in meetings. |
| 4 | HIS to produce a reporting template for designated bodies to allow consistency of approach |
| 5 | CDAOs of designated bodies to ensure that:<br>• An appropriate organisational governance structure regularly reviews (minimum of every 6 months) CD incidents and issues identified.<br>• That corrective actions identified from reviews are fully implemented |

| | |
|---|---|
| | • An annual statement of assurance can be given that their organisation is compliant with CD governance requirements. |
| 6 | Designated bodies to establish a process for monitoring controlled drug prescribing and identifying outliers. |
| 7 | NHS Public Services Delivery (PSD) Scotland, Scottish Government, NHS England and CQC must resolve software issues preventing reporting on privately prescribed CDs. |
| 8 | NHS Board CDAOs to monitor and analyse privately prescribed CD data provided by NHS PSD Scotland using the same criteria as applied to NHS Board prescribing. |
| 9 | HIS Medicines and Pharmacy team will work in partnership with our colleagues in Quality Assurance & Regulation Directorate (QARD) to ensure the report recommendations are implemented and followed up during the inspection processes of IHC. |

# References


1. The Controlled Drugs (Supervision of Management and Use) Regulations 2013, SI 2013/373.
2. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE), 2006. *Controlled drugs: safe use and management NICE guideline NG46 Methods, evidence, and recommendations.* London: NICE

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**Healthcare Improvement Scotland**

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Glasgow Office
Delta House

50 West Nile Street
Glasgow
G1 2NP

0141 225 6999

**www.healthcareimprovementscotland.scot**