# Healthcare Improvement Scotland logo

# Controlled Drug Accountable Officer Self Declaration, Self Assessment Update Report

June 2025

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# Introduction

Healthcare Improvement Scotland (HIS) has a statutory requirement to maintain and publish a register of Controlled Drug Accountable Officers for all designated bodies in Scotland. HIS also undertakes a periodic self-declaration and self-assessment of controlled drug governance arrangements. Self-declaration and self-assessment data was requested from all designated bodies in December 2023. The results of this were published in November 2024 and contained 14 recommendations to strengthen governance arrangements.

The report identified key findings which highlighted that requested data had been omitted by a number of designated bodies in relation to specific areas of governance. The table below details the current standing of these recommendations and provides the data that has been omitted in the original responses received.

# Key recommendations - update

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| 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. |
| *Update: Complete*  All outstanding self-declaration and self-assessment data received May 2025. |
| 2. Designated bodies must inform HIS of any changes to their CDAO role, temporary or permanent via the online reporting function. |
| *Update: Complete*  CDAO application and amendment e-forms are available on the HIS website.  [Controlled Drug Accountable Officer (CDAO) applications and amendments – Healthcare Improvement Scotland](https://www.healthcareimprovementscotland.scot/inspections-reviews-and-regulation/safe-management-of-controlled-drugs/controlled-drug-accountable-officer-applications-and-amendments/)  In addition, there is a dedicated email address for CDAO queries: [his.cdregister@nhs.scot](mailto:his.cdregister@nhs.scot) |
| 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. |
| *Update: Complete*  CDAOs must confirm they have arrangements in place to ensure the role of the CDAO is continued in a period of absence >3weeks when they complete the annual return. This information is also available on the HIS website. |
| 4. Designated bodies must report, at least annually, into the governance structure of their organisation to provide an assurance of their arrangements for controlled drugs. |
| *Update: Complete*  All designated bodies confirmed they report at least annually into their governance structure. |
| 5. There is currently no reporting template. Consider producing a reporting template for designated bodies to allow consistency of approach. |
| *Update: Ongoing*  In discussion with CDAO working group. |
| 6. Designated bodies must confirm with the Home Office (HO) that they are compliant with any requirement for HO licenses. |
| *Update: Complete*  All designated bodies reported they are compliant, or working towards being compliant, with Home Office requirements. |
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| 7. All designated bodies must have a CD policy and standard operating procedures in place. |
| *Update: Complete*  All designated bodies confirmed they have a CD policy and CD standard operation procedure in place. |
| 8. National Services Scotland (NSS) and Public Health Scotland (PHS) must collaborate to resolve software issues preventing reporting on privately prescribed CDs. |
| *Update: ongoing*  Data on private controlled drug prescription dispensed in NHS contracted pharmacies is now available via Public Health Scotland to NHS Boards. This is provided by prescriber location to allow prescribing trends to be identified.  Ongoing work required for reporting of private controlled drug prescription dispensed in private pharmacies. This requires further collaboration between NSS, PHS and cross border cooperation with NHS England. |
| 9. Agreement to be reached with Scottish Government (SG) and other stakeholders on requirements for the monitoring and analysis of privately prescribed CDs by NHS Board CDAOs. |
| *Update: ongoing*  See update for recommendation 8. |
| 10. CDAOs of Independent Healthcare designated bodies to make contact with NHS Board CDAOs regarding LIN membership. |
| *Update: Complete*  All IHC CDAOs report making contact with NHS Boards and LIN membership. |
| 11. Scottish Government to work with CDAO Executive and Healthcare Improvement Scotland to update previously issued Health Department Letters (HDL) and Chief Executive Letters (CEL) relevant to governance arrangements for Controlled Drugs. |
| *Update: ongoing*  Post implementation review feedback provided to Scottish Government regarding Controlled Drugs (Supervision of Management and Use) Regulations 2013 by HIS. No HDL or CEL required post review. |
| 12. Access to HIS governance documents will be updated and made available through our website for online submission. |
| *Update: complete*  All CD governance documents, CDAO applications and support can be found on the HIS website.  [Safe management of controlled drugs – Healthcare Improvement Scotland](https://www.healthcareimprovementscotland.scot/inspections-reviews-and-regulation/safe-management-of-controlled-drugs/) |
| 13. Publications from National CDAO Working Group relating to the safe and secure management of controlled drugs will be made available through the HIS website or via a link through the KHub. |
| *Update: complete*  All information is available via the KHub. A link to the KHub with instructions on how to sign up are available via the HIS website below.  [Controlled Drugs Accountable Officers Network (Scotland) – Healthcare Improvement Scotland](https://www.healthcareimprovementscotland.scot/inspections-reviews-and-regulation/safe-management-of-controlled-drugs/controlled-drugs-accountable-officers-network-scotland/) |
| 14. 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. |
| *Update: complete*  Report circulated to all IHC inspectors in Quality Assurance & Regulation Directorate (QARD) via the regulation operation meeting. Pharmacist input available to support inspectors for all IHC providers who use controlled drugs. |

# Key findings – update

Following further engagement with designated bodies the omitted data was successfully collected. Key findings are updated to reflect this additional data and presented below.

In June 2025 there are 53 designated bodies (17 NHS Boards, 16 hospices, 20 private hospitals).

All designated bodies report they have a CDAO in place.

All designated bodies report they have governance arrangements in place with clear lines of responsibility and accountability for controlled drugs with established links with the organisation's clinical governance/risk management support team.

All CDAOs report to the appropriate senior management governance committee on controlled drug issues at least annually.

All designated bodies report they have a process in place for reporting, investigating and sharing incidents, learning and concerns for controlled drugs.

All designated bodies report they have a controlled drug policy and standard operating procedures in place.

All NHS Boards, hospices, and 17 of the 20 (85%) independent hospitals report they monitor/assess controlled drug prescribing data.

All NHS Board and NHS Special Board CDAOs were members of a Local Intelligence Network (LIN). All IHC CDAOs report either being members of their LIN or making contact with NHS Boards regarding LIN membership.

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