

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

November 2024

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Executive summary

The Controlled Drugs (Supervision of Management and Use) Regulations¹ governing controlled drugs were strengthened in 2013, providing Healthcare Improvement Scotland (HIS) with powers to carry out external scrutiny around controlled drug (CD) governance for all designated bodies in Scotland. Designated bodies being NHS Boards, hospices, and independent hospitals. This brought Scotland in line with the scrutiny and governance arrangements with the rest of the UK.

At the time of our review, there were fifty-two designated bodies listed on the HIS register of Controlled Drug Accountable Officers (CDAOs). We contacted, via email, all the designated bodies in December 2023 to ask them to complete the self-assessment and self-declaration. Forty-seven (90%) designated bodies responded, five (11%) of these responses were only partially complete where either the self-declaration or self-assessment was not completed. We did not receive responses from five (10%) designated bodies. We have contacted these designated bodies to confirm their CDAO details. The results of the Special Health Board who completed post deadline are included in this report.

A summary of our key findings of the fifty-two designated bodies are:

Forty-one (79%) state they have reporting processes in place.

Twenty-eight (54%) stated a HO license was applicable to them and seventeen (61%) of these designated bodies stated they have a HO license in place.

Thirty-six (69%) report they have a controlled drug policy and standard operating procedures in place.

Seven out of twenty (35%) Independent Hospitals state they monitor/assess controlled drug prescribing data.

Forty-one (79%) have a process for the reporting and escalation of CD incidents.

All- NHS Board and NHS Special Board CDAOs were members of a Local Intelligence Network (LIN). Eleven (73%) hospices and eight (40%) independent hospitals state they are members of a LIN.

Key recommendations are:

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 report, at least, annually into the governance structure of their organisation to provide an assurance of their arrangements for controlled drugs.
5. There is currently no reporting template. Consider producing a reporting template for designated bodies to allow consistency of approach.

6. Designated bodies must confirm with the Home Office (HO) that they are compliant with any requirement for HO licenses.
7. All designated bodies must have a CD policy and standard operating procedures in place.
8. National Services Scotland (NSS) and Public Health Scotland (PHS) must collaborate to resolve software issues preventing reporting on privately prescribed CDs.
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.
10. CDAOs of Independent Healthcare designated bodies to make contact with NHS Board CDAOs regarding 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.
12. Access to HIS governance documents will be updated and made available through our website for online submission.
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.
14. HIS Medicines and Pharmacy team will work in partnership with our colleagues in Quality Assurance Directorate (QAD) to ensure the report recommendations are implemented and followed up during the inspection processes of IHC.

Setting the scene

Background

The purpose of HIS is to drive the highest quality care for everyone in Scotland by leading improvement in the quality and safety of health and care, using our skills and knowledge to tackle the quality challenges being faced.²

HIS has a statutory responsibility for the process of self-declaration and self-assessment for any designated body with a CDAO.¹ This allows both HIS and designated bodies to monitor their clinical governance arrangements for the safe use of controlled drugs. HIS produce quarterly controlled drugs occurrence reports from submitted CD notifications by regulated designated bodies which are shared with the NHS Board CDAO in which the regulated designated body is located.

HIS is also required to compile, maintain, and publish a register of CDAOs in Scotland, including managing the process that allows healthcare providers, who meet specific criteria, to apply for exemption of appointing a CDAO.¹

In 2014, a baseline scoping exercise of CD Governance arrangements in designated bodies was undertaken. This included a self-assessment which focused on the two main provisions within the Regulations:

- The appointment of CDAOs, and
- The sharing and using of information between organisations, regulators, and agencies through controlled drugs local intelligence networks.

The baseline review produced 5 recommendations:

- I. Designated bodies must check their entry on the HIS CDAO register at least annually and make sure that this is kept up to date.
- II. Designated bodies must have cover arrangements for CDAO absence of 3 weeks or more.
- III. Designated bodies are required to run or participate in a LIN under the 2013 Regulations.
- IV. Designated bodies and LIN must ensure key information is shared with governance and healthcare professionals including doctors, nurses, and pharmacy teams.
- V. Designated bodies must report annually into the governance structure of their organisation to provide an assurance of their arrangements for controlled drugs.

What we did

We built on the baseline review, carried out in 2013/14 and designed a self-assessment and self-declaration template, informed by the National Institute for Health and Care Excellence (NICE) guidelines.³

We took a risk based and proportionate approach; the self-assessment focused on the organisational governance arrangements for the safe management and use of CDs and covered the main elements of the 2013 Regulations.

At the time of our review, there were 52 designated bodies listed on the HIS register of CDAOs. We contacted, via email, all the designated bodies in December 2023 to ask them to complete the self-assessment and self-declaration.

Our findings

Forty-seven designated bodies (90%) responded, five (11%) of these responses were only partially complete where either the self-declaration or self-assessment was not completed. We did not receive responses from five (10%) designated bodies. We have contacted them to clarify their CDAO details. The results of the Special Health Board who had completed post deadline have been included in this report.

Table 1: responses to self-assessment and self-declaration

	Total	NHS Boards	Special NHS Board	Hospices	Independent hospitals
Total	52	14	3	15	20
Fully Completed	41	13	2	13	13
Not complete/ partially complete	6	1	1	2	2
Not received	5	0	0	0	5

The current register of designated bodies is available at: [Register of controlled drugs accountable officers in Scotland – Healthcare Improvement Scotland](#).

Self-declaration

Designated bodies must notify HIS in writing of any changes to their CDAO arrangements. This includes interim or temporary CDAO appointments.

The self-declaration requires designated bodies to provide details of their current CDAO and deputy CDAO cover arrangements. The self-declaration also requires the Chief Executive/Senior Officer of the designated body and the CDAO to confirm that to the best of their knowledge the information provided on the self-assessment is true and accurate at the time of submission.

The arrangements reported to support the CDAO, to ensure the CDAO role and function is always covered, were variable. Twenty-five (48%) designated bodies that had completed the self-declaration had formally appointed or nominated a deputy CDAO. This is an increase from 27%, reported in the 2014 baseline review.

The number of designated bodies with confirmed CDAO and Deputy CDAO in place is represented in Table 2 and Table 3.

Table 2: confirmation of CDAO

	Total	NHS Boards	Special NHS Board	Hospices	Independent hospitals
Total	52	14	3	15	20
Confirmed name of CDAO (Y)	45	13	2	15	15
Confirmed name of CDAO (N)	1	0	1	0	0
Unknown	6	1	0	0	5

Table 3: confirmation of deputy CDAO

	Total	NHS Boards	Special NHS Board	Hospices	Independent hospitals
Total	52	14	3	15	20
Confirmed deputy CDAO (Y)	25	8	2	5	10
Confirmed deputy CDAO (N)	21	5	1	10	5
Unknown	6	1	0	0	5

Recommendations

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.

Self-assessment

Section 1: Governance arrangements and accountability

This section details the reporting arrangements and the governance structures used to provide assurance about the safe management and use of controlled drugs.

The NICE Guidelines³ state designated bodies are required to have robust governance structures in place, including reporting structures for controlled drugs issues. The self-declaration has taken cognisance to establish similar arrangements for Scotland.

The baseline report carried out in 2014 made the recommendation: Designated bodies must report annually into the governance structure of their organisation to provide an assurance of their arrangements for controlled drugs.

Forty-one (79%) designated bodies state they have reporting processes in place. Table 4 below represents the breakdown of where reporting processes are in place across all designated bodies.

Table 4: reporting processes

	Total	NHS Boards	Special NHS Board	Hospices	Independent hospitals
Total	52	14	3	15	20
Reporting process in place (Y)	41	14	2	13	12
Reporting process in place (N)	2	0	1	0	1
Reporting process in place (unknown)	9	0	0	2	7

The process in the way designated bodies report varied. NHS Boards and Special NHS Boards report annually whereas Hospices and Independent Hospitals tended to report quarterly.

Designated bodies were asked to confirm that the appropriate Home Office (HO) licenses were in place where CDs were held as stock. Twenty-nine (56%) designated bodies stated a HO license was applicable to them, seventeen (59%) of these designated bodies stated they have a HO license in place and four (14%) stated they do not. Six (21%) designated bodies who state a HO license is applicable to them did not confirm if one was in place and two (7%) designated bodies who stated a HO license was applicable further stated there was no HO license requirements due to no storage off site of CDS. All

the designated bodies who state they require a HO license and do not have one are either awaiting advice from Scottish Government or are working towards a HO license application.

Designated bodies were asked to confirm they had adequate resources in place to fulfill the duties of the CDAO in terms of time allocated, support staff etc.

Eleven (79%) of NHS Boards, two (67%) Special Health Boards, eight (53%) Hospices and eleven (55%) of Independent Hospitals answered that they have adequate resources in place, one NHS Board answered no, highlighting their CDAO resource is insufficient to fulfil the duties of the role of CDAO in terms of proactive risk management. One designated body further explained its CD team comprises of CD Inspection Officer, Principal Pharmacist Governance and Specialist Pharmacist in Substance use Management. Four designated bodies receive support from other NHS Boards to allow them to have adequate resources in place.

These responses highlight the variety of arrangements in place across designated bodies to meet the requirements of the CDAO role.

Recommendations

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.
5. A standardised reporting template may be of value. If so the CDAOE may wish to commission work to produce a reporting template for designated bodies to allow consistency of approach.
6. Designated bodies must confirm with the Home Office (HO) that they are compliant with any requirement for HO licenses.

Section 2: Policies, processes, and procedures

Designated bodies are required to have up to date standard operating procedures in place in relation to the management and use of CDs, which cover best practice relating to prescribing, supply and administration of CDs, and clinical monitoring of patients who have been prescribed CDs.¹

Eleven (79%) NHS Boards, two (67%) Special Health Boards, ten (67%) Hospices and thirteen (65%) Independent Hospitals report they have a controlled drug policy and standard operating procedures in place. The frequency of auditing against these policies varied. Some were on a rolling program, and some took on a risk-based approach. Some hospices have links with their NHS Board for support with audits and one Independent Hospital has CD audits performed monthly through their pharmacy service contract.

Recommendation

7. All designated bodies must have a CD policy and standard operating procedures in place.

Section 3: Policies and process for prescribing

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.

Fourteen (100%) NHS Boards, three (100%) Special NHS Boards, thirteen (87%) Hospices and seven (35%) Independent Hospitals state they monitor controlled drug prescribing data.

From a review of the submitted self-assessments, primary care prescribing was reported as being the most frequently monitored data set within NHS Boards. There is variation in the monitoring and analyses of privately prescribed CD data across NHS Boards. At the time of the report this was exacerbated by data access issues which were actively being resolved.

Hospice monitoring differed from NHS Boards and Independent Hospitals, where they use evidence based prescribing guidance to regularly audit drug charts against, and expenditure reports.

Recommendations

8. National Services Scotland (NSS) and Public Health Scotland (PHS) must collaborate to resolve software issues preventing reporting on privately prescribed CDs.
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.
10. CDAOs of Independent Healthcare designated bodies to make contact with NHS Board CDAOs regarding 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.

Section 4: Process for reporting controlled drug related incidents

Thirteen (93%) NHS Boards, three (100%) Special Health Boards, thirteen (87%) Hospices and twelve (60%) Independent Hospitals stated they have a process for the reporting and escalation of CD incidents. One NHS Board acknowledged there could be improvements with the sharing and learning after an incident has taken place and that work is being carried out at a regional level including Datix reporting to facilitate this.

CD notifications submitted to HIS by registered designated bodies are reviewed by the service inspector and a pharmacist within a given timescale, as per HIS procedures. These may require further investigation by HIS and communication with the NHS Board. HIS compiles a quarterly report of these CD notifications which are sent to the relevant NHS Board CDAO.

Section 5: Governance and safety in the use of controlled drugs

This section of the self-assessment covers information sharing through controlled drugs local intelligence network (LIN).

LINs provide a forum for organisations, regulators, and agencies to raise concerns and share intelligence about designated bodies or individuals in relation to the safe management and use of controlled drugs. This means that concerns can be shared at the earliest stage with other agencies that may be affected or that may hold additional information.

At the time of writing, all NHS Board and NHS Special Board CDAOs were members of a LIN. Eleven (73%) hospices state they are members of a LIN. One hospice had subsequently joined through being made aware via the self-assessment process.

Eight (40%) Independent Hospitals state they are members of a LIN. Two independent hospitals who do not currently attend a LIN have stated they will join; one was not aware of being able to join a LIN. Details have been provided to the CDAO as a result.

Table 5: CDAO membership to local intelligence network

	<u>Total</u>	<u>NHS Boards</u>	<u>Special NHS Board</u>	<u>Hospices</u>	<u>Independent hospitals</u>
Total	52	14	3	15	20
Member of LIN (Y)	36	14	3	11	8
Member of LIN (N)	5	0	0	2	3
Unknown	11	0	0	2	9

We included a section specific to NHS Board CDAOs to ask if the CDAO established a LIN, independently or jointly with another NHS Board. One NHS Board had not established a LIN, but there are measures in place for local escalation of issues and being part of a regional LIN.

Recommendations for HIS

12. Access to HIS governance documents will be updated and made available through our website for online submission.
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.
14. HIS Medicines and Pharmacy team will work in partnership with our colleagues in Quality Assurance Directorate (QAD) to ensure the report recommendations are implemented and followed up during the inspection processes of IHC.

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		
Special NHS Boards			
Scottish Ambulance Service	State Hospital's Board for Scotland	NHS Golden Jubilee (The National Waiting Times Centre)	
Hospices			
Accord Hospice	Ardgowan Hospice	Ayrshire Hospice	Bethesda Hospice
(CHAS) - Rachel House	Highland Hospice	Kilbryde Hospice	Marie Curie Cancer Care (Glasgow)
Marie Curie Hospice (Edinburgh)	St Andrew's Hospice	St Columba's Hospice	St Margaret of Scotland Hospice
St. Vincent's Hospice	Strathcarron Hospice	The Prince and Princess of Wales Hospice	
Independent Hospitals			
Alpha Clinic at Aberdeen Independent Hospital	BrainKind - Graham Anderson House	Castle Craig Hospital	Circle Health - Albyn Hospital
Circle Health Kings Park Hospital	Circle Health - Ross Hall Hospital	Cosmedicare UK Ltd	Cygnnet Health Care
Elanic Clinic, Bath Street, Glasgow	La Belle Forme, The Glasgow Day Surgery Centre	Murdostoun Brain Injury Rehabilitation	Nova Recovery Largs
Nuffield Health Edinburgh Hospital	Nuffield Health Glasgow Hospital	Priory Ayr Clinic	William Quarrier Scottish Epilepsy Centre
Spire Murrayfield Hospital	Spire Shawfair Park Hospital	Surehaven Low Secure Hospital	The Priory Hospital Glasgow

Appendix 2: Table of recommendations for designated bodies

CDAO executive	
Recommendation Number	Recommendation
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 report, at least, annually into the governance structure of their organisation to provide an assurance of their arrangements for controlled drugs.
5	A standardised reporting template may be of value. If so the CDAOE may wish to commission work to produce a reporting template for designated bodies to allow consistency of approach.
6	Designated bodies must confirm with the Home Office (HO) that they are compliant with any requirement for HO licenses.
7	All designated bodies must have a CD policy and standard operating procedures in place.
CDAO working group	
Recommendation Number	Recommendation
5	A standardised reporting template may be of value. If so the CDAOE may wish to commission work to produce a reporting template for designated bodies to allow consistency of approach.
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.
10	CDAOs of Independent Healthcare designated bodies to make contact with NHS Board CDAOs regarding LIN membership.

Healthcare Improvement Scotland (HIS)	
Recommendation Number	Recommendation
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
12	Access to HIS governance documents will be updated and made available through our website for online submission
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
14	HIS Medicines and Pharmacy team will work in partnership with our colleagues in Quality Assurance Directorate (QAD) to ensure the report recommendations are implemented and followed up during the inspection processes of IHC.
Public Health Scotland (PHS)	
Recommendation Number	Recommendation
8	National Services Scotland (NSS) and Public Health Scotland (PHS) must collaborate to resolve software issues preventing reporting on privately prescribed CDs.
National Service Scotland (NSS)	
Recommendation Number	Recommendation
8	National Services Scotland (NSS) and Public Health Scotland (PHS) must collaborate to resolve software issues preventing reporting on privately prescribed CDs.
Scottish Government	
Recommendation Number	Recommendation
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.

References

1. The Controlled Drugs (Supervision of Management and Use) Regulations 2013, SI 2013/373.
2. HEALTHCARE IMPROVEMENT SCOTLAND., 2023. *Leading quality health and care for Scotland: Our Strategy 2023–28*. Edinburgh: Healthcare Improvement Scotland.
3. 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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