Guidance for Controlled Drugs Accountable Officer
Notifications and Amendments

Appointment of Controlled Drugs Accountable Officer

From 1 April 2013 Healthcare Improvement Scotland became responsible for managing a national register of Controlled Drugs Accountable Officers (CDAO) in Scotland.

Role of the Controlled Drugs Accountable Officer

The Controlled Drugs Accountable Officer (CDAO) is the person responsible for ensuring and providing assurance that their organisation has effective systems in place for the safe and secure management of CDs. This is a requirement under the Health Act 2006. Regulations 11-13 set out the core duties and functions of the CDAO and can be found in Part 2 of The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (SI (2013/373)).

Who can be a Controlled Drugs Accountable Officer

The person appointed to this role must be a senior manager of their organisation and must not routinely supply or handle controlled drugs themselves as part of their duties as an employee or officer. Regulation 8 sets out who may be appointed to the role of Controlled Drugs Accountable Officer for both NHS and independent hospital designated bodies.

The CDAO of an NHS designated body must be either:

- a member of the board of directors, management or executive committee of the designated body; or,
- a member of the body that has responsible for the management of the designated body; or,
- an employee who reports to either of the above individuals.

The CDAO of an independent hospital designated body must be either:

- the registered manager and must report to the chief executive, chairperson or managing director of the organisation, or,
- an employee who reports to the registered manager.
Organisations that must appoint a Controlled Drugs Accountable Officer

All healthcare providers that are defined as being a ‘designated body’ under the Regulations must appoint a Controlled Drugs Accountable Officer. The following organisations are designated bodies in Scotland:

- All Health boards
- The following Special health boards:
  - National Waiting Times Centre
  - The State Hospitals Board for Scotland
  - Scottish Ambulance Service
- Voluntary hospices
- Independent hospitals
- Private psychiatric clinics
- The headquarters in Scotland of regular or reserved Armed Forces.

The Regulations permit designated bodies of the same type to group together and jointly nominate and appoint a CDAO. In these instances each designated body within the group, must submit a CDAO notification to Healthcare Improvement Scotland. The completed CDAO notification form must be submitted electronically to hcis.cdregister@nhs.net

Further details relating to which organisations are designated bodies can be found in Regulation 7 in Part 1 of The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (SI (2013/373)

Organisations that do not require to appoint a Controlled Drugs Accountable Officer

Under Regulation 4 organisations that have fewer than 10 staff (whether employed or voluntary) are automatically exempt from having to appoint a CDAO.

Organisations that are exempt on this basis must inform Healthcare Improvement Scotland in writing as soon as possible. On the exemption form please select the reason for exemption as being ‘fewer than 10 staff work within the organisation’ and submit this electronically to hcis.cdregister@nhs.net. You will not be required to provide any further information.

Healthcare Improvement Scotland will retain a record and publish a list of all exempted organisestions alongside the CDAO register. It is important to note that it is each organisation’s responsibility to inform Healthcare Improvement Scotland if they meet the exemption criteria. If we do not receive any such notification we will assume that the organisation has appointed a CDAO.
If an organisation no longer meets the exemption criteria they must notify Healthcare Improvement Scotland immediately and appoint a CDAO, following the process above, either in a temporary or permanent basis as soon as possible.

Organisations that are given this exemption become ‘relevant persons’ to the NHS board CDAO within which they are located. This means that their CD activity will be monitored by the NHS board CDAO through the Local Intelligence Network.

Organisations that can apply to Healthcare Improvement Scotland to be exempt from appointing an accountable officer

Regulation 4 set out the conditions under which independent healthcare providers with more than 10 staff can apply to Healthcare Improvement Scotland to be exempt from appointing a CDAO.

If you consider that, to appoint a CDAO in your organisation would find it difficult, and that these difficulties would far outweigh any benefits that may be gained from the appointment you must complete the exemption form and submit this electronically to hcis.cdregister@nhs.net. You must demonstrate on the form that your organisation meets the following criteria:

- does not generally have a high volume of CD usage or activity, and,
- would find it difficult to appoint a suitable individual to the role of CDAO due to the size of the hospital, and, because it is not possible to join with a similar type of hospital to make a joint appointment

Organisations that are given this exemption become ‘relevant persons’ to the NHS board CDAO within which they are located. This means that their CD activity will be monitored by the NHS board CDAO through the Local Intelligence Network.

How long will my exemption status last?

Healthcare Improvement Scotland will grant exemption status for a period of up to one year. To renew an existing exemption status an organisation must contact HIS within one month of the expiry date of their current exemption status. You must follow the same process as you followed previously and electronically submit an ‘application for exemption form’ to hcis.cdregister@nhs.net.

For organisations that continue to have fewer than 10 staff, this must be stated on the exemption form as before.

For those wishing to renew their exemption status based on their usual level of CD activity and the degree of difficulty in appointing a CDAO, you must demonstrate that your level of CD usage and activity continues to be low and that it is still not possible to appoint a CDAO based on the specified criteria.
What happens if Healthcare Improvement Scotland does not grant my application for exemption or rescinds my existing exemption status?

In some instances Healthcare Improvement Scotland may not grant a request for exemption. If these cases we will explain to you why we have not granted the exemption and answer any questions or queries you have.

Healthcare Improvement Scotland may, on occasion, rescind an exemption. We will give you reasonable notice before we do this and we will explain the reasons behind our decision.

Can I appeal against the decision to decline my application for exemption or to rescind my exemption status?

You can appeal the decision to refuse your application for an exemption or renewal of an exemption in writing within one month of the date of the letter informing you of the decision. You will be required to provide further information in addition to what you previously submitted using the appeal form and electronically submit this to hcis.cdregister@nhs.net.

The appeal will usually be completed within one month (31 days). When we have considered your appeal we will email you to inform you of the decision.

Removal of a Controlled Drugs Accountable Officer

Regulation 9 sets out the circumstances under which a designated body or a group of designated bodies should remove the individual currently appointed to the role of CDAO from that role. These include if the person:

- is no longer considered to be a fit and proper person, or,
- no longer meets one or more of the three conditions set out below:
  - is no longer a senior manager or director of the organisation and no longer reports to such a person
  - is no longer an employee of the organisation
  - now routinely prescribes, supplies, administers or disposes of controlled drugs as part of their duties

You must inform Healthcare Improvement Scotland if the current CDAO appointment changes. This means when you remove a CDAO, you need to inform us of the replacement appointment, whether permanent or temporary, so that the position remains filled at all times. You then need only notify us of the details of the new CDAO. You must inform Healthcare Improvement Scotland in writing as soon as an appointment is made by completing the CDAO Notification Form and submit this electronically to hcis.cdregister@nhs.net.
CHECKLIST

Does your current CDAO continue to meet the specified criteria for who can be nominated to take on the role of CDAO? □

Do you have arrangements in place to ensure that you have a CDAO in place at all times? □

Have you notified Healthcare Improvement Scotland of any changes to the details of the current CDAO for your organisation? □

If the individual carryout out the role of CDAO has changed, have you notified Healthcare Improvement Scotland of the change? □

Is your current exemption status correct? □

Has the number of staff working within your organisation changed? □

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