



Controlled Drugs (Supervision of management and use) Regulations 2013

Information about the Regulations

DH INFORMATION READER BOX		
Policy	Clinical Commissioner Development Provider Development Improvement and Efficiency	Estates IM & T Finance Social Care / Partnership Working
Document Purpose	Best Practice Guidance	
Gateway Reference	18764	
Title	The Controlled Drugs (Supervision of Management and Use) Regulations 2013 Information about the Regulations	
Author	DH Medicines, Pharmacy and Industry - Pharmacy Team	
Publication Date	13 February 2013	
Target Audience	PCT Cluster CEs, NHS Trust CEs, SHA Cluster CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, Local Authority CEs, Directors of Adult SSs, PCT Cluster Chairs, NHS Trust Board Chairs, Special HA CEs, Allied Health Professionals, GPs, NHS Commissioning Board, Clinical Commissioning Groups, Controlled Drugs Accountable Officers, Independent Healthcare Advisory Service, Home Office, Ministry of Defence, Care Quality Commission and Scottish Government	
Circulation List	Association of Chief Police Officers, BMA, Drug and Misuse Services, Educational Establishments, General Pharmaceutical Council, MHRA, National Patient Safety Agency, Pharmaceutical Services Negotiating Committee and Royal Pharmaceutical Society of Great Britain	
Description	This document provides additional information about the changes made to the Regulations which come into effect on 1st April 2013 and which continue to promote good governance concerning the safe management and use of Controlled Drugs (CDs) in England and Scotland.	
Cross Ref		
Superseded Docs	www.dh.gov.uk/prod_dh/groups/dh_digitalasests/@dh/@en/documents/digitalasset/dh_064458.pdf	
Action Required	N/A	
Timing	N/A	
Contact Details	Robert Allan Strategy & Finance MPI Pharmacy Room 5W24 Quarry House Quarry Hill Leeds LS2 7UE 0113 2546312	
For Recipient's Use		

Controlled Drugs (Supervision of management and use) Regulations 2013

Information about the Regulations

Prepared by: Medicines, Pharmacy and Industry – Pharmacy Team

© Crown copyright 2013
First published February 2013

Published to DH website, in electronic PDF format only.
<http://www.dh.gov.uk/publications>

Contents

Contents.....	4
Section 1: Duties to secure the safe management and use of controlled drugs.....	5
Introduction.....	5
Background.....	6
Devolved Administrations.....	6
An overview of the 2013 Regulations.....	6
Armed Forces.....	8
External monitoring of compliance with the 2013 Regulations.....	9
Section 2: The Controlled Drugs Accountable Officer.....	10
Organisations required to appoint a CDAO.....	10
Appointment of CDAOs.....	11
Removal of a CDAO.....	13
National lists of CDAOs.....	13
Overview of the role of the CDAO and the NHSCB and HB CDAOs - duties to secure safe management and use of controlled drugs.....	13
Appropriate arrangements.....	15
Systems for recording incidents and concerns.....	15
Standard Operating Procedures.....	15
Education and training.....	16
Monitoring and auditing of the management of controlled drugs: general duties.....	17
Monitoring, assessing, investigating and taking action in relation to relevant individuals.....	17
Establishing and operating Local Intelligence Networks (LINs).....	18
Co-operation between responsible bodies.....	19
Other actions relating to shared information.....	19
Relevant premises.....	19
Supplementary matters relating to inspections.....	19
Supplementary compliance declaration.....	20
Information Management.....	20
Review.....	20
Annex A: The Controlled Drugs (Supervision of Management and Use) Regulations 2013	
Question and Answers.....	21
<i>Requirements to appoint a Controlled Drugs Accountable Officer (CDAO)</i>	21
CDAO requirements.....	23
Local Involvement Networks (LINs).....	24
Standard Operating Procedures.....	25
Sharing Information.....	26
Inspections.....	28

Section 1: Duties to secure the safe management and use of controlled drugs

Introduction

1. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (“the 2006 Regulations”) came into force on 1 January 2007 in England and 1 March 2007 in Scotland. As a consequence of the passing of the Health and Social Care Act 2012, these Regulations have been revised to reflect the new architecture for the NHS in England from April 2013. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (“the 2013 Regulations”) came into force in England and Scotland on 1 April 2013.
2. The purpose of this document is to support the changes made in legislation and continue to promote good governance concerning the safe management and use of Controlled Drugs across England and Scotland. The information set out here updates earlier guidance published by the Department of Health¹ and should continue to be used alongside other relevant information and guidance that is published by professional and regulatory organisations.

This information is intended to be of use for:

- *organisations that have a responsibility for appointing a Controlled Drugs Accountable Officer (CDAO) and ensuring that systems are in place for the safe and effective management and use of CDs and that these systems are working effectively. These include the NHS Commissioning Board (NHSCB) and Scottish Health Boards, NHS Trusts, NHS Foundation Trusts, Independent Hospitals and Regular and Reserved Armed Forces;*
- *organisations which are designated as “responsible bodies” in the 2013 Regulations, who may be members of Local Intelligence Networks (LINs) convened by the relevant lead CDAO;*
- *other organisations and individuals in the health and social care sectors who may have their use of CDs monitored and inspected;*

¹ Safer Management of Controlled Drugs: (1) Guidance on strengthened Governance Arrangements, Department of Health, January 2007

- *patients and the public to understand how the supply of CDs should be managed and how concerns about the use of CDs in the health and social care sectors is handled.*

Background

3. Controlled Drugs (CDs) are essential modern clinical care. They include drugs such as diamorphine that are used in a wide variety of clinical treatments, for example, for the relief of acute and chronic pain, end-of-life treatments or as part of the treatment of substance misuse. Other medicines such as anxiolytics, sleeping pills, steroids and growth hormones are also designated as CDs, albeit these are subject to less stringent controls under the Home Office's Misuse of Drugs legislation.
4. The 2006 Regulations were introduced as part of the then Government's response to the Shipman Inquiry's Fourth Report in 2004². The Shipman Inquiry reported on the activities of the former GP and serial killer, Harold Shipman, who used quantities of CDs to kill his patients. As a consequence of his criminal activities, the Inquiry in its Fourth Report recommended that the governance arrangements for the use and management of CDs should be strengthened.
5. The 2006 Regulations have been subject to only consequential amendments since they came into force in 2007. There has been no fundamental review of these Regulations until now.

Devolved Administrations

6. The 2013 Regulations apply in England and Scotland only. Wales and Northern Ireland have their own equivalent, but separate, Regulations which continue unaffected by these changes.

An overview of the 2013 Regulations

7. These Regulations³ carry forward a number of measures in the 2006 Regulations to underpin the arrangements to ensure the safe management and use of CDs in England and Scotland. They replace the 2006 Regulations, which are revoked by these Regulations (**regulation 21**).

²The Shipman Inquiry Fourth Report "The Regulation of Controlled Drugs in the Community"

³The Controlled Drugs (Supervision of Management and Use) Regulations 2013 S.I. 2013/373 can be obtained directly from www.legislation.gov.uk.

8. The 2013 Regulations designate a number of health care providers that are required to appoint CDAOs (**regulation 7**) and set out who may be appointed to the CDAO role, under what circumstances they should be removed from this role and the registration requirements for all CDAOs (**regulations 8-10**). **Regulations 11-13** continue to set out the core duties and functions of CDAOs that must be established and reviewed in order to secure the systems for the safe management and use of CDs within their own organisation or at those, they contract from. These must include:

- compliance with the Misuse of Drugs legislation;
- systems for recording and reporting concerns or untoward incidents about CD use; and
- a range of up to date standard operating procedures to support those governance arrangements.

CDAOs must also ensure that relevant staff within their organisation receives, as appropriate, information, education or training about these arrangements.

9. **Regulation 13** sets out the duties of CDAOs regarding how the use of CDs by relevant staff (referred to as “relevant individuals” or RIs) must be scrutinised. CDAOs should ensure they have appropriate arrangements in place to monitor and assess an RI’s performance in respect of their management and use of CDs, to determine whether incidents or concerns require investigation and to carry out those investigations or arrange for someone else to do so on their behalf, and to take appropriate action where these concerns are well-founded. In England, Clinical Commissioning Groups (CCGs) are required to assist CDAOs appointed by the NHSCB for these purposes.

10. NHSCB CDAOs are the assigned lead CDAOs for establishing LINs in England for a particular area. In Scotland, Health Board (HB) CDAOs continue to be the assigned lead CDAO. It is for the NHSCB to determine how many LIN areas there are to be in England and the number of lead CDAOs required to cover them. However, the NHSCB must ensure that the whole of England is covered by these arrangements. Membership of LINs is determined by the NHSCB or HB CDAO from the list of responsible bodies set out in **Regulation 6**. These include:

- regulatory bodies;
- designated healthcare providers with their own CDAOs;
- CCGs in England;
- the Common Services Agency and the Care Inspectorate in Scotland;
- the Care Quality Commission (CQC);
- Healthcare Improvement Scotland (HIS);
- local authorities; and
- the police.

11. **Regulations 15 and 16** set out the requirements for responsible bodies to co-operate with other LIN members in relation to the handling of, and acting on, shared information including steps to protect the safety of patients and the general public. There are provisions regarding the action that CDAOs should take, as far as is practicable, to remove patient identification information that is confidential and not material to the matter in hand before disclosure. Where it is not practicable to remove confidential information that identifies a patient before disclosure, CDAOs should determine that disclosure is necessary and seek, if practicable to do so, the patient's consent to that disclosure.
12. **Regulations 17 and 18** govern the arrangements for lead CDAOs to carry out inspections of premises which manage and use CDs. Lead CDAOs should not carry out inspections of premises which the CQC, HIS, the Care Inspectorate in Scotland, the General Pharmaceutical Council (GPhC) or Armed Forces CDAOs already inspect or where an NHS trust or independent hospital has an appointed CDAO. The same applies to premises of the Scottish Ambulance Service Board, National Waiting Times Centre Board and the State Hospitals Board in Scotland. **Regulation 19** allows the CQC, HIS, the Care Inspectorate in Scotland or the GPhC to obtain information from the persons registered with those bodies who are engaged in relevant CD activities. This information can take the form of periodic declarations or self-assessments stating how CDs are managed and used at the relevant registered premises.
13. **Regulation 20** sets out how CDAOs should record and manage information arising from their duties and the steps CDAOs need to take to prevent inappropriate handling of that information. In general terms, access to information should be limited to persons on a need-to-know basis and who fully understand the confidential nature of the information and the purposes for which they are being given access to it. Where a CDAO, responsible body or someone acting on their behalf is permitted to share information, which includes personal data by virtue of a function of the 2013 Regulations, it is assumed that such disclosure is required by the 2013 Regulations. CDAOs should not otherwise disclose information, which is prohibited by law, would prejudice, or would be likely to prejudice, legal proceedings or compromise any responsible body's investigations or proceedings concerning service discipline in the Armed Forces. CDAOs should note that civil proceedings do not lie against them for disclosure of information where this is done in good faith and the CDAO has reasonable grounds for disclosing the information.

Armed Forces

14. The 2006 Regulations did not require the Armed Forces to establish similar arrangements for the safe management and use of CDs. Over time, the Armed Forces have devised their own equivalent internal arrangements. However, this meant that they were not able to participate in the activities of LINs or to share relevant information. To

address this, the 2013 Regulations now give the headquarters of reserved or regular Armed Forces the status of a “designated body” so that, from 1 April 2013, CDAOs must be appointed. It is for the Armed Forces to determine how they discharge this function. However, lead CDAOs can now invite such personnel to be members of LINs.

External monitoring of compliance with the 2013 Regulations

15. The UK Government is asking the CQC to continue to monitor progress on the implementation of these Regulations and overall compliance with the requirements. The CQC prepares annual reports for this purpose. Previous reports are available on the CQC’s website at: www.cqc.org.uk.

Section 2: The Controlled Drugs Accountable Officer

Organisations required to appoint a CDAO

1. Organisations providing health care services within England and Scotland who have been assigned “designated body” status (**regulation 7**) must appoint a fit, proper and suitably experienced person to be its CDAO. These organisations include:
 - the NHSCB;
 - Scottish HBs;
 - England and Scottish NHS and independent hospitals, including businesses with more than 10 staff (but see paragraph 3 below); and
 - the headquarters of regular or reserved Armed Forces.
2. Under **Regulations 3 and 4**, there are new exemptions in England and Scotland for independent private hospitals that are micro businesses or start-up businesses with fewer than 10 staff. The term “staff” includes employees, volunteers or otherwise. It does not include those working for outside contractor companies who provide services, such as maintenance, cleaning etc. Such micro-businesses are not required to support a CDAO. It is UK Government policy that such businesses should be exempt from new regulatory burdens and requirements. It may be the case that smaller businesses, for example, drug misuse service providers, hospices or care homes, may have a significant level of CD usage and that they may require a larger degree of supervision from a lead CDAO. Where these businesses provide NHS services, it is expected that their commissioners will require such organisations to demonstrate adequate arrangements for ensuring the safe management and use of CDs. It will also be open to such businesses to decide to appoint a CDAO of their own volition, but this is not a regulatory requirement. The Department of Health is asking the CQC to monitor and report, via its annual reports, the effect of this exemption within England on the adequate supervision of the management and use of CDs.
3. Larger such businesses in England and Scotland that employ more than 10 staff, but which do not generally have a high degree of CD activity or usage, will, from 1 April 2013, be able to apply directly to the CQC to be exempt from the requirement to appoint a CDAO. The CQC will use the criteria set out in **regulation 3(1)(b)** to determine whether these businesses meet the requirements for the exemption to apply. Those criteria are:
 - the number of individuals working at the business;
 - the level of CD activity on the premises; and

- whether the business would have difficulties identifying a suitable individual to act as a CDAO.

In Scotland, HIS will apply the same set criteria for determining whether a Scottish business can also be exempt under **regulation 4(1)(b)**. CQC and HIS are preparing further information concerning the operation of this exemption.

Appointment of CDAOs

Suitability

4. The 2013 Regulations continue to stipulate that a CDAO for a designated body must be a “fit, proper and suitably experienced person” (set out in **regulation 8(1)**). The CDAO must have credibility with all health care and social care professionals within the organisation and have sufficient seniority to be able to take action regardless of how a concern is raised. A CDAO must meet three conditions for appointment:
 - (1) The first condition is that the CDAO must be a senior manager of the organisation in question, or answerable to such a senior manager. Ideally, therefore, a CDAO will be a director or equivalent, or directly reporting to such a person. Armed Forces’ CDAOs must, at the minimum, be of the rank of brigadier or equivalent.
 - (2) The second condition is that the CDAO must be an officer or employee of the organisation concerned, including where designated bodies act jointly (see paragraph 6 below) or are part of the same umbrella undertaking.
 - (3) The third condition is that the CDAO should not routinely “prescribe, supply, administer or dispose of controlled drugs” as part of their duties (**regulation 8(8)**). The key word here is “routinely”. An organisation can continue to nominate and appoint a CDAO who has occasional, exceptional need to use controlled drugs (for example, in emergencies). Where this is the case, their use of controlled drugs at that organisation should be open to the scrutiny of another person to whom they are answerable.
5. For independent hospitals, it is likely the CDAO will be the registered manager of the organisation or an officer or employee reporting directly to the registered manager. Individuals such as Medical Directors, Chief Nurses or Chief Pharmacists can be appointed as CDAOs if they meet the above criteria. It is good practice for organisations to have clear policies and procedures in place as to whom any employee of an organisation should approach if they have concerns about the CD practices of the CDAO themselves.

Joint appointments or nominations

6. A CDAO can continue, as before, to be jointly nominated or appointed between groups of designated bodies which operate in England and Scotland. However, it is the responsibility of the main employing organisation to ensure adequate governance arrangements for the CDAO's conduct and for registering that individual as the CDAO with the CQC or HIS as appropriate. Where a CDAO is responsible for designated bodies, which act jointly or are part of the same umbrella undertaking (for example, a group of private hospitals), the head office (or regional head office) for the group at which the CDAO is based must be located in England or Scotland.

NHS Commissioning Board – CDAO

7. **Regulation 8(4)** places a requirement on the NHSCB to nominate or appoint a fit, proper and suitably experienced person to be its CDAO in respect of each of its LIN areas. A NHSCB CDAO can be responsible for one or more LIN areas. How the NHSCB determines those areas and the appointment of its CDAOs is a matter for the NHSCB. However, the three conditions applying to all CDAOs described above apply equally to NHSCB CDAOs. The NHSCB CDAO will take on the lead CDAO role for the LIN areas covered that was previously the responsibility of Primary Care Trust (PCT) CDAOs. It is important, therefore, for NHSCB CDAOs to liaise with existing PCT CDAOs in the period leading up to 1 April 2013.

Armed Forces CDAO

8. For the first time, from 1 April 2013, the armed forces in England and Scotland are required to appoint a CDAO. As with other CDAOs, the CDAOs representing the headquarters of regular or reserve armed forces must be fit, proper and suitably qualified persons commanding a senior position. This is set at the minimum rank of brigadier or equivalent or a superior rank. Armed Forces CDAOs must similarly register with CQC or HIS as appropriate (see paragraph 11 below).

Resources and support

9. Each designated body that appoints a CDAO, or the main organisation employing the CDAO must, as before, provide the necessary funds and other resources for the CDAO to discharge their responsibilities in accordance with the Regulations. In the case of a joint nomination or appointment, this obligation can be discharged through joint arrangements for provisions of funds and resources such as access to and use of information systems, accommodation and staff as set out in **regulation 8(11) and (12)**.

Removal of a CDAO

10. **Regulation 9** continues the circumstances under which designated bodies or groups of designated bodies that have nominated or appointed a CDAO should remove that CDAO from office. The circumstances are:
 - if a CDAO is no longer considered to be a fit and proper person to be a CDAO; or
 - a CDAO no longer satisfies any one or more of the three conditions set out in **regulation 8(6) to (8)** and described in paragraph 4 above.

National lists of CDAOs

11. As before, CQC and HIS will compile, maintain and publish lists of registered CDAOs via their websites.
12. **Regulation 10** places a requirement on each designated body in England or Scotland as soon as practically possible, to notify the CQC or HIS as appropriate in writing of new appointments of CDAOs. This also applies when a CDAO is removed from post, whatever the circumstances. Where a joint nomination or appointment of a CDAO or their removal from office is made by a group of designated bodies, it is the responsibility of the umbrella organisations employing the CDAO to inform the CQC or HIS on behalf of the group. It is desirable that, when doing so, the organisation lists all the premises for which the CDAO is responsible.

Overview of the role of the CDAO and the NHSCB and HB CDAOs - duties to secure safe management and use of controlled drugs

13. The 2013 Regulations give CDAOs more flexibility and discretion as to how they should discharge their duties and functions than under the previous regime. It is, however, important that CDAOs in provider or commissioning bodies familiarise themselves with what they must do under the Regulations – in particular, the registration requirements in Regulation 10, their specific duties in Regulation 11 and the monitoring and audit requirements in Regulations 12 and 13.
14. A CDAO of a provider body must establish and operate appropriate arrangements for securing the safe management and use of CDs and to review them as appropriate. In general, the CDAO has a variety of duties and functions such as to:
 - ensure the safe and effective use and management of CDs within their own organisations and by anybody or person providing services to their organisation;
 - ensure monitoring and auditing of the management and use of CDs;
 - maintain a record of concerns regarding relevant individuals;
 - assess and investigate concerns;

- take appropriate action if there are well-founded concerns;
 - establish arrangements for sharing information;
 - produce quarterly reports of CD occurrences for the lead NHSCB or HB CDAO;
 - ensure adequate and up to date standard operating procedures (SOPs) are in place in relation to the management and use of CDs;
 - ensure relevant individuals receive appropriate information, education or training; and
 - ensure adequate destruction and disposal arrangements for CDs.
15. A CDAO who is appointed for a group of provider bodies must also ensure that all those bodies in their charge have in place appropriate arrangements for securing the safe management and use of CDs and to review them as appropriate, as outlined in **regulation 11**.
16. NHSCB and HB lead CDAOs are responsible for establishing and leading LINs drawn from representatives of designated and responsible bodies. It is for the lead CDAO to determine the membership of LINs appropriate to their area. Who must be a member of a LIN is no longer set out in the Regulations. In addition, lead CDAOs should:
- convene incident panels. The LIN must have a transparent process for establishing an incident panel if serious concerns are raised. The process should outline the responsibilities of key individuals and how the panel should be called together;
 - analyse NHS and private prescribing of CDs using electronic Prescribing Analysis and Cost (ePACT) in England and Prescribing Information Systems for Scotland (PRISMs) in Scotland;
 - request periodic declarations or self-assessments from a range of healthcare providers regarding their management and use of CD but who are not required to appoint a CDAO. This includes general medical practitioners on a medical performers' list, or providers of dental, nursing or midwifery services;
 - ensure their organisation operates arrangements for periodic inspections of premises used in connection with the management or use of CDs which is not subject to inspection by other regulatory bodies such as the CQC, HIS, the Care Inspectorate or GPhC; and
 - ensure adequate steps are taken to protect patients and the public if there are concerns about inappropriate or unsafe use of CDs by a person who is not providing services for any designated body, but who provides services in the LIN area.
17. A CDAO of a commissioning body, or for a group of commissioning bodies, must also ensure that any person, or those organisations commissioned with providing relevant services on their behalf, establish and operate appropriate arrangements for securing the safe management and use of CDs and that those systems are reviewed as appropriate, as described in **regulation 11(2)**.

Appropriate arrangements

18. CDs are primarily governed by the Misuse of Drugs Act 1971 as well as medicines legislation. The legitimate clinical use of CDs derives from the Misuse of Drugs Regulations 2001. Therefore, appropriate arrangements to secure the safe management and use of CDs must fully comply with that legislation, irrespective of whether an organisation is required to appoint a CDAO or not.

Systems for recording incidents and concerns

19. As before, under **regulation 11(3)(b)(i) and (ii)**, all incidents or concerns involving the safe use and management of CDs must be reported to the organisation's CDAO. Concerns include complaints. The details of the incident or concern should be recorded and investigated, where appropriate, using locally agreed procedures. The information must continue to be recorded such as on an internal secure database with restricted access. It may be that incidents in isolation may not require further investigation but these should still be recorded and stored for future review and to establish whether trends develop.
20. Incidents that are considered to be serious enough should be reported as an organisational Serious Incident (SI). The CDAO should continue to have an established risk assessment process for determining the seriousness of an incident or concern. The process adopted should be capable of assessing any risk to patient or public safety and the likelihood of that risk becoming real. There are a number of assessment tools in use throughout the health and social care sectors, although the CDAO may wish to seek advice from the organisation's clinical governance or patient safety lead on which tools it would be appropriate to adopt.

Standard Operating Procedures

21. **Regulation 11(3)(c)** continues to require a CDAO of either commissioner or provider organisations to have in place up to date SOPs in relation to the management and use of CDs. To reduce regulatory burdens, the 2013 Regulations do not stipulate a minimum list of SOPs that each and every organisation with a CDAO must have in place. Instead, the development and dissemination of SOPs are left, as with other aspects of CD management, to local determination and the discretion of CDAOs. However, CDAOs should satisfy themselves that these adequately fulfil the requirement in the 2013 Regulations that organisations must have in place sufficient and up to date SOPs covering the prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed CDs.

Destruction of controlled drugs

22. The 2006 Regulations specified that CDAOs must have procedures in place concerning the destruction of controlled drugs. This is no longer a separate mandatory requirement. It is, however, expected that organisations whose use of CDs involves their disposal will wish to ensure they have in place adequate procedures covering this activity and that relevant staff receive the appropriate information and training.

Witnesses for destruction of CDs

23. Where CDs are destroyed, it is important that this act is witnessed as required under regulation 27 of the Misuse of Drugs Regulations 2001, it will be the responsibility of the CDAO to ensure witnesses are available to oversee destruction. CDAOs will also need to take into account other legislation in relation to the destruction and disposal of CDs such as the Environment Agency's Waste Management Licensing Regulations 1994 and the Hazardous Waste Regulations 2005.
24. The NHSCB's lead CDAO, who will be responsible for overseeing CD arrangements in community pharmacies and dispensing practices, will need to ensure there are sufficient fully trained witnesses to avoid build-up of expired or unwanted stocks of CDs. Any person authorised to witness destruction by a lead CDAO should continue to be subject to a professional code of ethics, have received appropriate training and be independent of day-to-day use or management of CDs.

Education and training

25. A CDAO of a provider body or acting on behalf of a group of bodies must ensure that any person who is a "relevant individual" receives information, education or training in relation to SOPs.

Meaning of relevant persons

26. Under **regulation 5** of the 2013 Regulations, the meaning of relevant persons for the purposes of these Regulations refers to both "relevant person" and "relevant individual":

Relevant person (regulation 5(1)(a))	= the NHSCB's lead CDAO (England)
Relevant person (regulation 5(1)(b))	= the HB's CDAO (Scotland)
Relevant individuals (regulation 5(2)(a)-(c))	= healthcare professionals who provide healthcare services (including medical, dental, pharmaceutical, nursing or midwifery services) including those who provide private services

27. CDAOs should therefore ensure that all individuals working with CDs, either as employees of the designated body or as a commissioned or contracted service provider, have received appropriate training to enable them to carry out their responsibilities in accordance with the appropriate legislation. A training requirement should be included within all service level agreements or commissioning/contracting agreements. This can include anyone prescribing, supplying, administering, transporting or disposing of CDs. Induction training should include the necessary aspects required to ensure the safe use and management of CDs, supported by regular updates as and when appropriate. The CDAO must ensure appropriate organisational processes are established and are effective in communicating information about CDs on the premises to all relevant individuals. The CDAO may wish to hold regular briefing sessions with relevant individuals. These sessions may include examples of good practice, issues or concerns to be aware of, any changes to SOPs and where to find additional educational resources.

Monitoring and auditing of the management of controlled drugs: general duties

28. Under **regulation 12**, a CDAO of a provider body or a group of provider bodies must continue to establish and operate, or ensure that the provider body, or each member of the group of provider bodies, establishes and operates appropriate arrangements for monitoring and auditing the management and use of CDs. As before, these arrangements must include arrangements for assessing and investigating concerns that have been recorded and responding to those incidents that have been reported under those systems, including actions that have arisen as a consequence of following or not, the requirements set out in an SOP.

Monitoring, assessing, investigating and taking action in relation to relevant individuals

29. Under **regulation 13**, a CDAO of a provider body, a group of provider bodies, commissioning body or groups or commissioning bodies, must establish and operate, or ensure that each member of the group establishes and operates, systems for monitoring and assessing a relevant individual, such as a healthcare professional's performance in connection with the management and use of CDs. A CDAO must continue to determine whether incidents or concerns arise as a result of that individual's performance in relation to the safe management and use of CDs and whether these require further investigation. Should the concern demand further action, the CDAO will be responsible for undertaking those investigations and for taking appropriate action with regards to well-founded concerns.
30. Where data in respect of a relevant individual who prescribes CDs are available to the CDAO's designated body, the arrangements must continue to include monitoring and assessing the relevant individual's performance using that data and those tools, which

are available. The data sources continue to be provided by the NHS Business Services Authority (ePACT) while, in Scotland, PRISMs is held by the Common Services Agency.

31. Organisations, such as CCGs, are not required to appoint a CDAO but are required to assist the relevant NHSCB's lead CDAO, for example, in investigating concerns or analysing data. It is good practice for the CCG to nominate a relevant individual within the CCG who will act as focal point for liaison with the NHSCB lead CDAO, bringing in others as appropriate.
32. When a reported incident requires investigation, either the CDAO will need to carry out the investigation themselves, or it will be conducted by another officer or employee of the organisation or group of organisations for which the CDAO is accountable (**regulation 13(5)**). That person's investigations will need to include deciding what information relating to the incident or incidents relate to the relevant individual's performance in connection with the management of CDs and record those decisions.
33. Following an investigation, if it appears to the CDAO that there are well-founded concerns that relate to the relevant individual's performance of the management and use of CDs, the CDAO can, as before, request additional advice, support, mentoring or training for the relevant individual from people such as prescribing advisors or clinical governance leads. However, should those concerns be of a more serious nature (such as a serious incident) the CDAO can refer their concerns to a regulatory body, the police force, or NHS Protect, as appropriate. In Scotland, the CDAO can relay those concerns to Scottish Counter Fraud Services to officials at the Scottish Health Board.

Establishing and operating Local Intelligence Networks (LINs)

34. LINs continue under the new arrangements with the responsibility for their establishment and management in England assigned to the lead NHS CB CDAO. The NHS CB is responsible for determining the number of LIN areas in England and their geographical coverage. It is for the lead NHS CB CDAO to determine the membership of the LIN or LINs for which they are responsible. Membership may therefore vary according to the particular characteristics and circumstances for CD use in each LIN area. However, under Regulation 14(2)(a), membership of LINs should be drawn from those organisation listed in Regulation 6 as responsible bodies. In Scotland, the responsibility for establishing LINs continues with the lead HB CDAO.
35. The main aims of a LIN continues to be the facilitation and co-operation of responsible bodies in the identification and consideration of concerns and incidents where action may need to be taken in respect of the safe management and use of CDs by relevant persons, and to agree to the actions to be taken in respect of such matters.

36. The lead NHS CB or HB CDAO will remain responsible for that LIN and as before, be able to request a periodic self-declaration and self-assessment from a provider of medical, dental, nursing or midwifery services in that LIN area whether the provider uses CDs at any premises that the provider provides healthcare services.

Co-operation between responsible bodies

37. As described in **Regulation 15**, each responsible body set out in **Regulation 6** that is a member of a LIN must continue to co-operate with other members of that LIN in identifying cases where action may be taken in relation to safe management and use of CDs by relevant persons. The responsible body may continue to disclose to any other LIN member where they consider it appropriate confidential information that relates to or identifies a relevant person but not so far as to identify a patient. If a responsible body has information relating to the management or use of CDs that it considers is of a serious nature, the responsible body can, as before, request additional information from other responsible bodies. Those other bodies need not be members of the same LIN.

Other actions relating to shared information

38. **Regulation 16** carries forward the provisions for a CDAO of a responsible body to share information with a CDAO of a designated body that may then make recommendations as to what actions are to be taken to protect the safety of patients and the general public. As before, the lead NHS CB or HB CDAO will be responsible for taking reasonable steps to protect the safety of patients or the public, including referring the matter as appropriate to the individual's regulatory body or the police.

Relevant premises

39. **Regulation 17** maintains the "powers of entry and inspection" provisions to secure the safe management and use of CDs on premises registered as providing healthcare services, which are not subject to inspections by professional, regulatory bodies or by the CDAO for the headquarters of regular or reserved forces. **Regulation 17(2)** prescribes what those relevant premises are. The requirements specified here apply equally to organisations in both England and Scotland.

Supplementary matters relating to inspections

40. **Regulation 18** continues the provisions that the lead NHS CB or HB CDAO or a person authorised in writing by that lead CDAO when carrying out an inspection of relevant premises need not give the owner of the relevant premises notice of the inspection. However, these provisions do not apply to officials from English or Scottish regulatory or professional bodies.

Private dwellings

41. The Regulations permit the lead CDAOs to inspect private dwellings provided these are registered as providing healthcare services and are not part of a professional or regulatory body inspection. CDAOs can only enter these private dwellings at a reasonable hour and must be accompanied by a police constable. CDAOs should only ever enter such premises (for example a medical practice) where there are legitimate concerns regarding poor CD practice and governance and not for routine visits.

Supplementary compliance declaration

42. In addition to the lead CDAO, **regulation 19** continues the provision that allows the CQC, HIS, the Care Inspectorate in Scotland and the GPhC to request periodic declarations and self-assessments concerning the safe management and use of CDs on premises that they inspect.

Information Management

43. Records maintained by a designated body in respect of inspections, complaints, untoward incidents and other concerns, including the response to those concerns must be accessible to the CDAO or a person authorised by the CDAO. The CDAO or authorised person can share this information with other responsible bodies in so far as to identify cases in which action may need to be taken. However, steps must continue to be taken in respect of preventing unauthorised processing of the information. These measures include limiting access on the need to know basis. Those who are accessing the information must be made fully aware of the confidential nature of the information being provided.
44. **Regulation 20(4)** continues the provision that allows a CDAO or authorised person to share information, which may include personal data under the Data Protection Act 1998. This means that civil proceedings do not lie against a person in respect of loss, damage or injury of any kind suffered by another person as a result of disclosure of information, under these regulations, provided it is done in good faith and there were reasonable grounds for sharing that information.

Review

45. This information will be reviewed and updated in the light of experience reported in implementing the 2013 Regulations.

Annex A: The Controlled Drugs (Supervision of Management and Use) Regulations 2013 Question and Answers

Requirements to appoint a Controlled Drugs Accountable Officer (CDAO)

I have more than 10 staff. How do I apply for an exemption to appoint a CDAO?

Businesses in England and Scotland that employ more than 10 staff, but which do not generally have a high degree of CD activity, will be able to apply directly to the Care Quality Commission (CQC) or Health Improvement Scotland (HIS) to be exempt from the requirement to appoint a CDAO.

*The CQC and HIS will use the criteria set out **Regulation 3(1)(b)** to determine whether these businesses meet the requirements for exemption.*

The CQC and HIS are producing further information as to how to apply.

I am the owner of a small healthcare facility previously exempt from appointing a CDAO. Activity has expanded and now involves more use of CDs. I also have more than 10 staff. What should I do?

You should notify the CQC or HIS. You can also consider applying to the CQC or HIS to continue to be exempt from the requirements to appoint a CDAO.

How will the CQC and HIS monitor changes in CD activity at a facility which is exempt from appointing a CDAO?

It is open to the CQC and HIS to request regular updates on CD activity from those organisations that are not required to appoint a CDAO.

Such organisations should also ensure that they bring any major changes in CD activity to the attention of CQC or HIS as appropriate at the earliest opportunity.

My business is exempt from appointing a CDAO - is there other legislation concerning controlled drugs with which I must comply?

Yes. All organisations concerned with the prescribing, supply, administration or disposal of controlled drugs must meet the requirements of relevant Misuse of Drugs legislation.

More information about the various Regulations is available on the Home Office website at www.homeoffice.gov.uk

Are community hospitals covered by the CDAO requirements?

Community hospitals will likely vary in size, how they are styled, and the scope and range of healthcare services provided at the facility.

*If they come within the definition of a "hospital" as set out in **Regulation 2**, then they should consider appointing a CDAO.*

If a community hospital is a private healthcare facility, and fewer than 10 staff work there, then a CDAO does not need to be appointed. If more than 10 staff work there, but the level of CD activity is considered low, then a community hospital can apply to the CQC or HIS to be exempt from the requirement to appoint a CDAO.

If a community hospital is an NHS Trust or Foundation Trust, then a CDAO must be appointed for that Trust. If a community hospital is part of a NHS Trust, then the remit of the CDAO for the Trust will already extend to cover the CD governance arrangements at the community hospital

Do hospices or SEOs need to appoint a CDAO?

*Hospices and Social Enterprise Organisations, which fall within a definition of a hospital, as interpreted under **Regulation 2**, will need to appoint a CDAO.*

Organisations that fall outside that definition will not be required to appoint a CDAO. However, even if an organisation is not required to appoint a CDAO under these Regulations, it is open to them to nominate a relevant individual who will act as a focal point for liaison on CD matters with the lead CDAO and others.

How will Social Enterprise Organisations and Community Interest Companies be integrated into CD governance arrangements?

*Whilst Social Enterprise Organisations (SEOs) and Community Interest Companies (CICs) may not be required to appoint a CDAO if their activities do not come within the definition of a "hospital" as defined in **Regulation 2**, we expect commissioners will wish to ensure adequate CD governance arrangements are in place in SEOs and CICs through their contracting mechanisms.*

It is open to SEOs and CICs to consider appointing a designated senior officer for this purpose. It is not, however, a regulatory requirement.

Where SEOs and CICs are subject to registration with the CQC or HIS, then the CQC or HIS can request periodic declarations and self-assessments from these organisations as to how CD governance requirements are being met.

Why aren't Clinical Commissioning Groups (CCGs) and Local Authorities (LAs) required to appoint a CDAO?

*CCGs and LAs are not required to appoint a CDAO primarily because they are commissioners rather than providers of services. The NHS Commissioning Board (NHS CB) will have the overall responsibility for supporting CCGs and ensuring the overall governance framework for the NHS system. However, by inclusion as a responsible body under **Regulation 6**, CCGs and LAs will be obliged to co-operate with the lead NHS CB CDAO.*

What is the definition of a hospital for the purposes of appointing a CDAO?

*The definition of a hospital, as set out in **Regulation 2**, is*

- *an institution for the reception and treatment of persons suffering from illness whether physical or mental health;*
- *a maternity home; or*
- *an institution for the reception and treatment of persons during convalescences or rehabilitation.*

In Scotland, this definition also includes institutions providing dental treatment in connection with a dental school.

The term "hospital" includes clinics, dispensaries and out-patient departments connected with such a home or facility.

Maternity homes must appoint a CDAO. What is a maternity home in this context?

Under the Registration of Maternity Homes Act 1934, the expression "maternity home" means any premises which are, either wholly or partly, used or intended to be used for the reception of pregnant women or of women immediately after child-birth.

If a maternity home is a privately run facility with more than 11 staff, it may apply to the CQC or HIS to be exempt from the requirement to appoint a CDAO if it meets the criteria. If fewer than 10 staff are employed there, it does not need to appoint a CDAO.

CDAO requirements

I am a CDAO but do not have a professional healthcare background. What should I do?

You will need to ensure you have access to relevant clinical healthcare advice within your organisation and/or elsewhere, as you consider necessary, to fulfil the requirements of your role as set out in the Regulations. You will also need to ensure that you can access relevant data concerning the prescribing and supply of CDs.

Can a Medical Director be a CDAO?

*Yes, provided they are not routinely involved in the provision of CDs at the facility for which they are the Medical Director and meet all the requirements for a CDAO set out in **Regulation 8(6) - (8)**.*

If a Medical Director also works outside the facility in a capacity that involves the routine prescribing or supply of controlled drugs (e.g. as a part-time GP) then the senior management will need to be satisfied this does not affect or compromise their ability to be the CDAO at that facility.

Budget constraints in my organisation are affecting my ability to meet CD training requirements for staff.

Each designated body that appoints a CDAO must continue to provide the necessary funds and other resources for that CDAO to discharge their responsibilities in accordance with the Regulations.

In the case of a joint appointment, this obligation can be discharged through joint arrangements for the provision of funds and resources.

Given the constraints on organisations budgets and limited resources, it is acceptable for organisations to pool resources together to provide training and further information on relevant CD activities and requirements.

Local Involvement Networks (LINs)

What is a suitable size for a LIN?

*This is a matter for the NHS Commissioning Board under **Regulation 14**.*

What does the duty of co-operation with a lead CDAO mean in practice for CCGs and LAs?

Lead CDAOs are responsible for the establishment, management and membership of Local Involvement Networks (LINs).

LINs bring together a range of local organisations to consider matters of mutual interest or concern involving the use of CDs.

CCGs and LAs – along with other LIN members as appropriate – will be required to assist the relevant lead CDAO in investigating such concerns. CCGs must also assist the lead NHS CB CDAO where, for example, data that monitor an individual's activity in respect of controlled drugs are available.

CCGs and LAs are not required to appoint a CDAO. It is open to these organisations, however, to nominate a relevant employee who will act as a focal point for liaison with the lead CDAO.

I am a lead CDAO. Is there a recommended list of members for my LIN?

*LIN membership is for the relevant lead CDAO to determine. Membership should be drawn from the list of responsible bodies in **Regulation 6**.*

I am a lead CDAO. Can I invite SEOs or CICs to be members of my LIN? If not, can they attend meetings of the LIN if I want them to?

*SEOs or CICs can be invited to be members of a LIN if they fall within the definition of a responsible body as set out in **Regulation 6**.*

Depending on the nature of a matter under discussion at a LIN, lead CDAOs may invite other organisations that are not eligible to be LIN members to meetings to discuss areas of mutual interest or concern. In doing so, their participation at the meeting should be restricted to those items that are of direct relevance to the organisation(s) invited.

Lead CDAOs should ensure that such organisations understand the basis on which they are being invited to attend, the requirements for confidentiality and the basis on which they may have access to information at the meeting which they would not otherwise receive.

***Regulation 16(4)** requires the lead CDAO to take all reasonable steps to protect the safety of patients and the general public in sharing information in such circumstances.*

What exactly is the requirement for CCGs and local authorities around co-operation with the LIN?

*CCGs will be members of LINs. How they contribute to this work will be a matter for local determination within the LIN. However, CCGs are required to assist the NHS CB CDAO to carry out specific monitoring activities under **Regulation 13(4)**. Local authorities are already members of LINs and their role and functions continue unchanged.*

Who is the best person to attend the LIN on behalf of the responsible bodies?

That is a matter for local determination by the responsible body concerned.

Standard Operating Procedures

I am the CDAO for a private hospital as defined in the Regulations. What sort of Standard Operating Procedures (SOPs) should our organisation have?

In recognition of different activities being provided by healthcare providers, the development of SOPs relating to an organisation's CD activities is left to the judgment of that organisation's CDAO (or other appropriate person if no CDAO is required or appointed).

SOPs should cover all relevant activities connected with those CD activities.

Regulation 11(3)(c) sets out the minimum SOPs an organisation must have in place such as SOPs relating to the prescribing, supply and administration of CDs including clinical monitoring of those patients who have been prescribed CDs.

A CDAO or relevant individual of a provider or group of provider bodies should ensure there is appropriate information and training associated with those SOPs.

If a CDAO is in doubt in relation to which SOPs they should have in place they can liaise with their lead NHS CB CDAO, regulatory bodies or other CDAOs.

Are specimen versions of Standard Operating Procedures (SOPs) available?

Yes. There are a number of examples of SOPs in the public domain.

The Department also published guidance on SOPs which is available on its website at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824

Sharing Information

I am a lead CDAO. How should I go about sharing information about an individual who is causing concern with an employer or potential employer?

The lead CDAO will be responsible for taking reasonable steps to protect the safety of patients or the public whether this includes sharing personal information with an individual's regulatory body, the police, their employer or potential employer.

How this information is shared will be for local determination. The lead CDAO is authorised, **under Regulation 20(4)**, to share personal information under the Data Protection Act 1998.

However, access to that information should be on a "need to know" basis and individuals who are accessing the information should be made aware of its confidential nature.

On what basis can "soft" intelligence be shared with other organisations?

The revised 2013 Regulations make explicit, for the first time, three clear limitations on the handling of information provided or received where there are concerns about an individual's practice or use of CDs.

First, the recipient of the information must be receiving it on a 'need-to-know' basis.

Second, the recipient must be someone who fully understands the confidential nature of the information supplied.

Third, the recipient must fully understand the purposes for which they are being permitted access to the information that is being supplied.

These are important safeguards which CDAOs and others will wish to bear in mind in cases where the subject of a shared concern might otherwise object, on privacy grounds, to information being shared. CDAOs should satisfy themselves when sharing such information that, at a minimum, these three limitations are fully and explicitly met.

I am a CDAO for a hospital. What form should my regular reports to the lead CDAO take?

A CDAO of a hospital should continue using established methods for sharing relevant information with the lead CDAO as part of the usual LIN processes. Should a CDAO of a hospital have doubts in relation to the format of those reports, he or she should contact the lead CDAO.

Lead CDAOs will continue to be able to request periodic self-declaration and self-assessments from medical practices and, for the first time, also from dental, nursing or midwifery services.

As a CDAO should I report incidents involving the use of controlled drugs and to whom?

This is not only good practice but also a regulatory requirement under Regulation 11(3). CDAOs must ensure they have systems to record concerns and incident reporting systems for untoward incidents which involve the safe management and use of controlled drugs.

Depending on the nature of the incident, CDAOs will need to determine to which other organisations concerns and incidents are reported.

For example, if there is a clinical incident where patients have been harmed, it is likely to be appropriate to report this to the National Reporting and Learning System (a division of the NHS Commissioning Board) and specify what corrective action has been taken to minimise the risk of similar further incidents.

To whom should individual practitioners report concerns?

Depending on the circumstances of the concern and the organisation for which a practitioner works, individual practitioners should consider reporting concerns to their organisation's CDAO in the first instance. They may also want to consider reporting concerns to their lead commissioner who will be a member of the relevant LIN or to the NHS CB's lead CDAO. The CQC or HIS can provide details of local CDAOs.

Who do GP practices and community pharmacies report controlled drugs incidents to?

For GP practices, the NHS CB CDAO in the first instance. For community pharmacies this can be the NHS CB CDAO or the General Pharmaceutical Council who can request periodic declarations and self-assessments from community pharmacies as to how controlled drugs are managed on registered premises under Regulation 19(4).

Inspections

I am a lead CDAO. Do I need to inspect GP premises?

As a lead CDAO you are authorised to inspect premises registered as providing healthcare services that are not subject to part of a professional or regulatory body inspection. GPs providing private treatment already fall within the remit of the CQC. From April 2013, GPs providing NHS services will also come under the remit of the CQC and will be part of their routine inspections and you will not be required to inspect NHS GP premises.

However, should you have concerns as to a GPs activities in relation to CD use or governance you should liaise with the CQC inspector on the LIN.

What organisations should lead CDAOs actually inspect?

*Lead CDAOs can inspect those organisations that are prescribed as “relevant premises” under **Regulation 17** and which do not come under the responsibility of a professional or regulatory body’s routine inspections.*

Lead CDAOs can inspect premises belonging to NHS Trusts and Foundation Trusts including any premises of organisations who are providing services on their behalf.

Are private dwellings subject to inspections?

*The lead CDAO can continue, as set out under **Regulation 18**, to inspect private dwellings provided these are registered as providing healthcare services and are not part of professional or regulatory body inspections. Where there are legitimate concerns regarding poor CD practices, entry to such premises must be done at a reasonable hour and the CDAO must be accompanied by a police constable.*

Department of Health
Medicines Pharmacy and Industry Branch

February 2013