

# The Controlled Drugs (Supervision of Management and Use) Regulations 2013

NHS England

Single Operating Model



## NHS England INFORMATION READER BOX

### Directorate

Medical	<b>Operations</b>	Patients and Information
Nursing	Policy	Commissioning Development
Finance	Human Resources	

### Publications Gateway Reference:

00809

<b>Document Purpose</b>	Guidance
<b>Document Name</b>	NHS England The Controlled Drugs (Supervision of management and use) regulations 2013 Single Operating Model
<b>Author</b>	NHS England Medical and Operations Directorates
<b>Publication Date</b>	29th November 2013
<b>Target Audience</b>	CCG Clinical Leaders, CCG Chief Officers, CSO Managing Directors, Medical Directors, NHS England Regional Directors, NHS England Area Directors, GPs
<b>Additional Circulation List</b>	
<b>Description</b>	This single operating model will support Area Teams in executing their statutory responsibilities in relation to the Controlled Drugs (Supervision of management and use) Regulations 2013. Feedback will be addressed by the NHS England National Controlled drugs group
<b>Cross Reference</b>	
<b>Superseded Docs</b> (if applicable)	
<b>Action Required</b>	NHS England Area Teams Controlled Drugs Accountable Officers to implement.
<b>Timing / Deadlines</b> (if applicable)	NA
<b>Contact Details for further information</b>	Sandra McGregor Primary Care Commissioning Team 4N04 - Quarry House Leeds LS2 7UE 0113 825 0912
<b>Document Status</b>	This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet

# NHS England Controlled Drugs (Supervision of Management and Use) Single Operating Model

*Guidance for Area Teams to exercise their responsibilities in relation to The Controlled Drugs (Supervision of Management and Use) Regulations 2013*

*First published: November 2013*

*Publications Gateway Reference: 00809*

*Updated: (only if this is applicable)*

*Prepared by: Clare Howard, Deputy Chief Pharmaceutical Officer, NHS England*

**Note: This document supports implementation of the Regulations but is no substitute for them. Area Team Controlled Drugs Accountable Officers (CDAOs) should satisfy themselves as to the specific requirements, duties and powers set out in the Regulations.**

## Contents

Executive Summary.....	5
Background.....	7
The role of NHS England.....	7
NHS England as a Commissioner.....	8
The Controlled Drugs Accountable Officer.....	9
Establishing and operating the LIN.....	12
Relationship with CCGs.....	14
Destruction of CDs.....	16
Resources.....	17
Reports and Records.....	17
Transition/Legacy.....	18
Private prescriptions and requisitions.....	19
Future Issues.....	19
Useful Links.....	20
References.....	21
Annex 1: Criteria for a fit and proper person to be NHS England CDAO.....	22
Annex 2: Template Agenda for LIN.....	24
Annex 3: Suggested Terms of Reference for LIN.....	25
Annex 4: Suggested Memorandum of Understanding between ATs and CCGs .....	30
Annex 5: Occurrence Report Template.....	36
Annex 6: Authorisation of witnesses to destroy Controlled Drugs.....	39
Annex 7: Private Prescriptions.....	43
Annex 8: The Controlled Drugs Short Life Working Group.....	60

## Executive Summary

In 2007, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced as part of the Government's response to the Shipman Inquiry's Fourth report in 2004. The aim of these regulations was to strengthen the governance arrangements for the use and management of controlled drugs.

Controlled Drugs (CDs) are essential to modern clinical care. As such, it is essential that NHS England enforces robust arrangements for the management and use of CDs to minimise patient harm, misuse and criminality.

As a consequence of passing the Health and Social Care Act 2012, the 2006 regulations have been revised to reflect the new architecture in the NHS in England. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force in England on 1<sup>st</sup> April 2013.

## The role of NHS England

The regulations make clear that NHS England must ensure that systems are in place for the safe and effective management and use of CDs and that these systems are working effectively.

NHS England must **formally** determine how many Local Intelligence Networks (LINs) there are to be in England and how many lead CD Accountable Officers are required to cover them.

In January 2013, an operating model was drafted to outline Area Team responsibilities. It is the responsibility of the main employing organisation (NHS England) to ensure adequate governance arrangements for the lead Controlled Drugs Accountable Officers (CDAOs) conduct and for registering that individual with the Care Quality Commission (CQC).

In March 2013, an assurance exercise was conducted to establish an understanding of any risk or issues relating to this regulation as NHS England took over its new responsibilities. Following that exercise, a short life working group was set up to ensure consistency of approach across the NHS in England and to develop NHS England work in this area. This revised operating model reflects the work of the group and aims to support Area Teams in ensuring that NHS England has systems in place for the effective and safe management and use of Controlled Drugs and that these systems are working effectively.

## This Single Operating Model covers

- The role of NHS England
- The role of the lead Controlled Drugs Accountable Officer at Area Team level.

- The establishing, operating and constitution of the Local Intelligence Networks (LIN), including suggested membership, suggested terms of reference and template agendas
- The relationship with Clinical Commissioning Groups (CCGs)
- Destruction of Controlled Drugs
- Resources for Area Teams
- Reports and records
- Transition and legacy
- Future issues

This operating model also provides a number of templates for use within Area Teams although it is recognised that some local changes may take place.

# **Single Operating Model for NHS England Area Teams responsibilities in relation to The Controlled Drugs (Supervision of Management and Use) Regulations 2013.**

This single operating model is intended to support NHS England Area Teams in relation to their responsibilities for establishing and managing arrangements for Controlled Drugs.

It should be read in conjunction with The Controlled Drugs (Supervision of Management of Use) Regulations 2013 and the Department of Health (DH) accompanying “Information about the regulations”.

## **1. Background**

In 2007, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced as part of the Government’s response to the Shipman Inquiry’s Fourth report in 2004 <sup>(1)</sup>. The aim of these regulations was to strengthen the governance arrangements for the use and management of controlled drugs.

Controlled Drugs (CDs) are essential to modern clinical care. As such, it is essential that NHS England enforces robust arrangements for the management and use of CDs to minimise patient harm, misuse and criminality.

As a consequence of passing the Health and Social Care Act 2012, the 2006 regulations have been revised to reflect the new architecture in the NHS in England. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force in England on 1<sup>st</sup> April 2013.

## **2. The role of NHS England**

The regulations make clear that the NHS Commissioning Board (now known as NHS England) must ensure that systems are in place for the safe and effective management and use of CDs and that these systems are working effectively.

NHS England must formally determine how many Local Intelligence Networks there are to be in England and how many lead CD Accountable Officers are required to cover them.

NHS England has decided that LINs are best matched with its Area Teams. Therefore, one or more LINs should be established within all ATs and each AT must appoint a lead Controlled Drugs Accountable Officer in respect of those LINs. This CDAO is responsible for and must set up the Local Intelligence Networks (one or more) within the AT and ensure that the whole of the Area Team geography is covered by a LIN. The whole of England must be covered by these arrangements. However, an NHS England CDAO can be appointed to cover two or more LIN areas. Therefore, two or more Area Teams could share a CDAO.

It is the responsibility of NHS England to ensure adequate governance arrangements for its Area Team lead CDAOs and for notifying the CQC of the name of each Area Team CDAO.

NHS England, via the Operations Directorate will conduct an annual assurance process to monitor Area Teams progress in relation to the Controlled Drugs (Supervision of Management and Use) Regulations 2013. A report outlining the main findings will be made available to NHS England each year and will be shared with the Care Quality Commission to provide an annual review of any issues that require national resolution.

### **3. NHS England as a Commissioner**

It is important to highlight that as well as having a responsibility for the system-wide arrangements for the supervision of management and use of controlled drugs, NHS England is also a commissioner. As such must ensure that any person, or those organisations commissioned with providing relevant services on their behalf, must establish and operate appropriate arrangements for securing safe management and use of CDs and that those systems are reviewed as appropriate as described in regulation 11.

These measures must include;

- Compliance with Misuse of Drugs legislation
- Systems (or an overarching system) for recording concerns including complaints and for reporting untoward incidents
- Up to date standard operating procedures to cover all commissioned activities including, amongst other matters, best practice in the prescribing, supply and administration of CDs and clinical monitoring of patients prescribed CDs
- Appropriate arrangements for monitoring and auditing these requirements and that the AT CDAO has similar arrangements in place to monitor and audit providers' compliance.

Regulation 12 (2) sets out that a CDAO of a commissioning body or a group of commissioning bodies must:

- establish and operate appropriate arrangements for monitoring and auditing the management and use of controlled drugs and;
- ensure that any person that provides the body or group with relevant services establishes and operates appropriate arrangements for monitoring and auditing the management and use of controlled drugs.

## 4. The Controlled Drugs Accountable Officer

### 4.1 Fit and proper person

The 2013 Regulations 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 healthcare and social care professionals within the organisation and with other organisations 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.
2. The second condition is that the CDAO must be an officer or employee of the organisation concerned.

***It is therefore NOT possible for an NHS England CDAO to "contract out" their primary roles and functions to another organisation such as a Commissioning Support Unit or Service (CSU) (although it may well be the case that the CDAO will wish to draw on information and analysis available from such organisations).***

3. The third condition is that the CDAO should not “prescribe, supply, administer or dispose of controlled drugs” as part of their duties (Regulation 8(8)) or only does so exceptionally. 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.

***The Area Team must decide who is the most appropriate person to be the CDAO within the parameters outlined within this operating model. Whilst it is not automatically assumed that the AT Medical Director will be undertaking such activities as part of their duties within NHS England, NHS England will need to be satisfied that the overall CD governance arrangements are not compromised or prejudiced if such a person is also, for example, practising as a part-time GP at a practice which that NHS England CDAO (or a neighbouring NHS England CDAO) may be required to review or investigate.***

See Annex 1 for “Criteria for a fit and proper person for CDAO”.

### 4.2 Support for CDAOs

It has been agreed that NHS England will bring together all the lead CDAOs across NHS England at least once a year. We will work with the National Institute for Health and

Clinical Excellence (NICE) and the Care Quality Commission (CQC) to provide two annual training events to help lead CDAOs with their responsibilities. There is an expectation that all lead CDAOs will attend at least one event per year. In addition, NICE and NHS England will develop a network of support for lead CDAOs which again is intended for all Area Team CDAOs.

#### **4.3 The roles and responsibilities for the NHS England CDAO**

Regulation 12 (2) sets out the responsibilities of a CDAO of a commissioning body (see section 3 of Single Operating Model)

Each CDAO is responsible for establishing and leading the Local Intelligence Network (LIN) (s) for their Area Team geography. The LIN will be drawn from representatives of designated and responsible bodies. It is for the lead CDAO to determine the number and membership of LINs appropriate to their area. See section 5.1.

In addition, the NHS England CDAO has local responsibility to do the following:

- 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 Prescribing Analysis Reports provided by NHS Business Services Authority (NHSBSA). See Section 9;
- request periodic declarations or self-assessments from a range of healthcare providers regarding their management and use of CDs but who are not required to appoint a CDAO, for example general medical practitioners on a medical performer's 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 are not subject to inspection by other regulatory bodies such as the CQC or General Pharmaceutical Council (GPhC); \* See below;
- 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;
- promote good prescribing practice in relation to Controlled Drugs. This will include strategies to improve the safety of prescribing of controlled drugs, increase the levels of incident reporting, especially from primary care in relation to controlled drugs and reduce the harms to patients exposed to controlled drugs, working in conjunction with the NHS England patient safety team;
- manage direct reporting of incidents reported from independent contractors;

- promote and extend good clinical practice in respect of the management and use of controlled drugs within the LIN, and supporting CDAOs in other organisations to do the same;
- facilitate cooperation between responsible and designate bodies;
- oversee occurrence reporting within their area.\*\*

\* Premises used in connection with the management or use of CDs that are not subject to an inspection by the CQC include the following:

1. Providers who carry out research – i.e. pharmaceutical company run units (similar in appearance to small hospitals) where volunteers are admitted and administered medicines whilst being closely monitored.
2. There are certain instances where medical practitioners carrying out treatment in a surgery or consulting room are exempt from CQC registration. See link for information about this exemption and as such the types of places that CQC would not inspect.  
[http://www.cqc.org.uk/sites/default/files/media/documents/20130725\\_800617\\_v2\\_0\\_0\\_medical\\_practitioners\\_scope\\_of\\_registration.pdf](http://www.cqc.org.uk/sites/default/files/media/documents/20130725_800617_v2_0_0_medical_practitioners_scope_of_registration.pdf)
3. Treatment carried out in sports grounds or gymnasiums or associated premises for persons taking part in or attending the sporting activities or events. This type of provision is exempt from CQC inspection.
4. Similarly treatment carried out under temporary arrangements to those taking part or attending cultural events – **although it's unlikely that a premises would be involved in these cases**, apart from a temporary medical station or vehicle.
5. Defence medical and dental establishments.
6. Midwifery services carried out by an individual private midwife acting on their own behalf and not in pursuant of the NHS Act and only providing the services in a woman's own home - again **a premises would most likely not be involved in these cases** other than a woman's home for the duration of labour.

In summary, the main area of interest to NHS England Lead CDAOs would be point 2 and for issues related to such premises, CQC has recommended that NHS England CDAO liaise with them directly on a service specific basis.

#### 4.4 Oversight of occurrence reports

To date, occurrence reports from controlled drug (CD) designated bodies have been submitted to the lead CDAO at Area Team level but there has been no mechanism for gathering of the data to review trends either regionally or nationally.

CQC has responsibility for national oversight and external scrutiny around how the CD safer management arrangements are working within England and national data collection would provide a much clearer picture across all Area Teams.

To achieve this, it is proposed that each Controlled Drugs Designated Body<sup>1</sup> completes the second section of the quarterly occurrence reporting template in Annex 5, to provide a breakdown of the total number of occurrences within their organisation by category and submits to their Area Team CDAO.

The Area Team CDAO will then collate the data for all CDDBs in their area and submit to CQC via the mailbox: [CDOccurrenceData@cqc.org.uk](mailto:CDOccurrenceData@cqc.org.uk)

---

<sup>1</sup> NHS Foundation Trusts, NHS Trusts, independent hospitals and the headquarters of regular or reserve forces.

## 5. Establishing and operating the LIN

Who must be a member of the LIN is no longer set out in the Regulations. It is for the NHS England Lead CDAO's to determine the membership of the LIN appropriate to their local area and the frequency of meetings.

It has been agreed that Area Teams can operate more than one LIN (because one LIN for one Area Team may prove unworkable because of the large geography and large number of organisations involved). Area Teams must notify the NHS England Operations Central Support of the number and geography of their LINs and provide assurance that all parts of that Area Team geography is covered by a LIN. This information will be requested by NHS England via the annual assurance framework.

NHS England does not expect more than three LINs per Area Team. Decisions on how many LINs are required should be based on population, number of organisations, health economies and natural boundaries e.g. motorways or rivers.

NHS England expects that the Area Team CDAO is responsible for leading and operating the LIN(s) in their area and therefore will usually chair each of their constituent LINs but may, by exception, delegate responsibility for chairing the meeting.

NHS England expects that LINs will meet at least twice a year with meetings not more than 6 months apart.

### 5.1 The membership of the LIN

The CDAO in each AT is responsible for determining the membership of the LIN based on local controlled drugs activity in that area. Suggested members might include:

**CCGs**

**Police representatives**

**Acute Providers**

**Community Providers**

**Ambulance Trusts**

**Prisons - Note: It has been agreed that Offender Health representatives will attend the LIN where their premises are based and NOT the Area Team responsible for commissioning services from them.**

**Armed forces –Note: It has been agreed that Military Health representatives will attend the LIN where their premises are based and NOT the Area Team responsible for commissioning services from them.**

**Private Hospitals**

**Local Authority representation**

**Out of hours providers**

**Providers of substance misuse treatment and care**

**Care Quality Commission**

**Consideration should be given to local social enterprise organisations and community interest companies if they prescribe controlled drugs.**

**The LIN should also consider how to engage regulators including the GPhC and other regulators, and Local Medical Committees Local Pharmaceutical Committees and NHS Protect (formerly NHS Counter Fraud and now part of the NHS Business Services Authority).**

**They should also have links to the Prescription Analysis department of Business Services Authority**

Comprehensive membership of LINs is encouraged as members have a statutory obligation to cooperate with each other and a clear statutory basis to share information relevant to CDs.

See Annex 2 (template agenda for the LIN) and Annex 3 (Draft terms of Reference for the LIN)

## **6. Relationship with CCGs**

Clinical Commissioning Groups (CCGs) are not required to appoint a Controlled Drugs Accountable Officer (CDAO). However, Regulation 13(4) of the Controlled Drugs (Safe Management and Use) Regulations 2013 (SI 2013/373) states that “A CCG..... must assist the relevant CDAO of the NHSCB (now NHS England) in the carrying out of the CDAO’s functions under paragraph (1).

Paragraph (1) requires NHS England CDAOs to establish and operate appropriate arrangements for those activities listed in paragraph (2). These are:

- Monitoring and assessing a relevant individual’s performance (e.g. a health professional in a GP practice) in connection with the management and use of controlled drugs
- Determining whether incidents or concerns that relate to that individual’s performance in respect of controlled drugs require further investigation;
- Investigating such incidents or concerns; and
- Taking appropriate action with regard to such incidents or well-founded concerns.

All CCGs in England are designated as responsible bodies under Regulation 6. It is open to NHS England CDAOs to invite their CCGs to be members of the relevant Local Intelligence Networks (LINs). LIN members have certain duties and functions set out in Regulations 14 – 16. These include a duty to co-operate with other LIN members in identifying cases where action may be appropriate, what the best course of action is and then putting it into effect. The regulations expressly provide that LIN members can share information and intelligence, including personal confidential information where necessary. All responsible bodies are under a duty (Regulation 15(3) and (4)) to notify their local lead

CDAO at NHS England and any other responsible bodies they consider relevant, where they are investigating an incident, complaint or other concern about CD management or use, or where action is being taken. Responsible bodies are also required to assist each other in sharing relevant information about a serious concern. Area Team CDAOs should ensure that the LIN actively engages with all CCGs.

Since CCGs are not required to appoint CDAOs, CCGs may wish to consider nominating a relevant senior individual within the CCG as CD Lead, who will act as a focal point for liaison with NHS England CDAOs on controlled drugs matters locally, bringing in others as appropriate. NHS England considers it good practice for CCGs to assist its CDAOs in the following ways:

- To assist the NHS England CDAO in any investigation involving primary medical care services;
- Report all complaints involving controlled drugs;
- Report all incidents or other concerns involving the safe use and management of CDs to the CDAO;
- Share all standard operating procedures (SOPs) in relation to the management of CDs, or ensure organisations from whom they commission services, do so;
- Analyse the CD prescribing data available; and
- Supply, or ensure that the organisations that CCGs commission services from, which involve the regular use of CDs, supply periodic self-declaration and/or self-assessments to NHS England CDAO as requested by the NHS England CDAO.

The CQC has responsibility for making sure that health and social care providers and other regulators maintain a safe environment for the management of controlled drugs. As part of this responsibility for oversight of the arrangements for controlled drugs in England the CQC is of the view that both NHS England CDAOs and CCG CD leads must be mindful of their continuing responsibilities for good governance and safe use of CDs and that this will be critical to ensure progress. It is therefore important that there is on-going, constructive dialogue between CCGs and NHS England Area Teams to ensure the system is safe.

This dialogue should include ensuring that there are sufficient authorised witnesses across primary care to ensure that there is not a build-up of obsolete controlled drugs that could represent a threat to patient and public safety.

Many Area Teams and CCGs have already established good working arrangements underpinned by a Memorandum of Understanding.

Area Teams should develop a Memorandum of Understanding (MoU) with their constituent CCGs to agree terms of collaboration. A suggested MoU is included in Annex 4.

NHS England Area Team CDAOs will also need to develop relationships with social enterprises and community interest companies as appropriate to the area.

## 7. Destruction of CDs

NHS England lead CDAO, will be responsible for overseeing and supporting CD destruction arrangements in primary care including community pharmacies. The CDAO will need to ensure there are sufficient, fully trained witnesses to avoid build-up of expired or unwanted stock of CDs. Any person authorised to witness destruction by an NHS England lead CDAO should continue to be subject to a professional code of ethics, be subject of a satisfactory Disclosure and Barring Service (DBS) check in accordance with good established practice and have received appropriate training and be independent of day to day use or management of CDs in that premises.

***The CDAO can work with local CCGs to ensure that there are sufficient, fully trained witnesses across the geography of the Area Team. See Annex 6 for a detailed outline of NHS England's approach to authorising witnesses.***

## 8. Resources

Regulation 8 (11) states that “Each designated body that has an accountable officer must provide that person with the funds and other resources necessary for enabling that person to discharge their responsibilities as accountable officer (in the case of joint nominations or appointments, this obligation may be discharged through joint arrangements for provision of funds and other resources).

Regulation 8(12) states that “the “other” resources” may include access to and use of information systems, accommodation and staff.

Resource for CDAOs is still variable across the Area Teams. Some have a team of people experienced in managing controlled drugs and the role of CDAO, whilst others do not have this level of support. The short life working group has attempted to produce many materials centrally to reduce the burden but there is still variation in capacity and capability that needs to be addressed.

The short life working group has, over the last six months been working on a number of risks in relation to Controlled Drugs identified via a review of Area Teams’ arrangements for Controlled Drugs:

1. Capability – three out of the four NHS England regions now have access to pharmaceutical expertise to support CDAOs in their roles. NHS England and the CQC have agreed to provide at least two annual events for CDAOs to support their development and share best practice.
2. Capacity – NHS England has recently completed the annual Controlled Drugs Assurance process for all Area Teams. The results are currently being reviewed by NHS England. NHS England is looking carefully at the capacity issues identified by the review.

## 9. Reports and records

NHS England is working with the Business Services Authority (BSA) to determine what reports related to Controlled Drugs prescribing will be made available routinely to Area Teams.

It is proposed that data is provided as three tiers.

### **Tier 1**

The short life working group have recommended that there is a need for central prescribing data to be provided to each Area Team. It has been agreed that:

- The reports should be sent to Area Teams on a quarterly basis;
- They should be easy to understand;
- They should identify outliers;

- They should take a risk based approach ;
- There should be a mechanism for Area Teams to feedback to the BSA to provide local intelligence (e.g. clinical reason for a GP practice to appear as an outlier);
- CDAOs and the BSA will wish to refer to the latest CQC Controlled Drugs annual report to consider which priority drugs should be scrutinised.

Therefore on a quarterly basis all Area Teams will be provided with a prescribing report outlining CCG level prescribing across their area. These reports will cover a core data set including growth, schedule 2 CDs, injectable CDs and a review of the variance between practices. A rolling programme of focus topics could be developed so for example one quarter there is a focus report on e.g. methylphenidate and then the next quarter; the report covers a different topic.

Further work is required to develop criteria for outliers both clinical and statistical.

### **Tier 2**

In addition to these regular, standardised reports, there is a need to agree how Area Teams respond to issues raised by the reports. The BSA are exploring a dashboard giving high-level view (Tier 1) that could then be used to drill down by CCG, practice, prescriber, dispenser, drug, quantity etc.

### **Tier 3**

This level is only for investigations into practice in relation to Controlled Drugs. In the longer term, the BSA is exploring a service whereby the prescription could be viewed on screen remotely and appropriate detailed information is made available to facilitate investigations to be conducted.

In the shorter term existing systems will be utilised with support from NHSBSA.

Currently, Area Teams can access a “log-in” to epact.net but they can’t access individual prescriber level data. Data is available to CCG level only.

The “ePACT Monitor” system will remain available to all Area Teams. This has prescriber level data and private prescription analysis.

CD Requisition Report will be accessible using AT log in to the Prescribing Reports, accessed via <http://www.nhsbsa.nhs.uk/PrescriptionServices/3166.aspx>

The BSA will support a WebEx for CDAOs to demonstrate how to work through the ePACT monitor system.

## **10. Transition/Legacy**

Area Teams should have already discussed with former PCTs how Controlled Drugs information could be transferred. If this has not happened it should be agreed as soon as

possible. It is not possible to centrally mandate how this transfer should take place because of the large variation in what was held at PCT level. But Area Teams should as a minimum address the following:

- i. What is available and where is it held
- ii. What needs to be transferred to the Area Team and what should be archived?
- iii. How will the transfer take place?

## 11. Private Prescriptions and Requisitions

### **Private Prescribers of Schedule 2 and 3 Controlled Drugs**

Private prescribers of Schedule 2, and 3 Controlled Drugs will order their prescription forms through their designated Area Team or the contractor providing this service for them. The Area Team or their contractor will be responsible for the onward secure delivery or collection of the forms.

Prescription form theft and misuse is an area of concern as these forms can be used to obtain drugs illegally, often for misuse. Anyone involved in the handling, storage or distribution of prescription forms should ensure they have read and follow the guidance provided by NHS Protect;

[http://www.nhsbsa.nhs.uk/Documents/SecurityManagement/Security\\_of\\_prescription\\_forms\\_guidance\\_Updated\\_August\\_2013.pdf](http://www.nhsbsa.nhs.uk/Documents/SecurityManagement/Security_of_prescription_forms_guidance_Updated_August_2013.pdf)

NHS England Area Teams will need to agree local arrangements for the authorising and ordering of such forms but Annex 7 contains a suite of template documents that can be used locally.

## 12. Future issues

As part of the work of the short life working group, there was a process to identify how we could, once we had ensured that our statutory responsibilities were met, develop systems to further enhance our capabilities around the safer use and management of controlled drugs. Such issues include:

- A national information sharing agreement;
- NHS Protect forthcoming work looking at Controlled Drugs;
- NICE Good Practice Guidance for Controlled Drugs (The safe use and management of controlled drugs)- expected in 2015;
- Closed community for the Area Team CDAOs to share good practice, support each other in the role and develop single solutions;
- A private prescription and requisitions request database;
- Central data base for reporting and incidents and occurrence reports.

CDAOs will be updated on developments as they happen.

## Useful links

<http://www.dh.gov.uk/health/2012/09/controlled-drugs/>

[http://www.npc.nhs.uk/controlled\\_drugs/](http://www.npc.nhs.uk/controlled_drugs/) (Note this is a legacy site. In future, support will be provided by the Medicines and Prescribing Centre at NICE)

<http://www.nice.org.uk/mpc/index.jsp>

<http://www.legislation.gov.uk/all?title=controlled%20drugs>

<http://www.cqc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs>

## References

1. *The Shipman Inquiry Fourth Report “ The regulation of Controlled Drugs in the Community”*
2. *The Controlled Drugs (Safer management and Use) regulations 2013*  
<http://www.legislation.gov.uk/uksi/2013/373/made>

*Thanks to DH Controlled Drugs policy team, CQC, BSA, HSCIC and all members of the short life working group and various NHS England Area Teams for their hard work and support with the development of this operating model.*

## Annex 1: Criteria for a fit and proper person to be NHS England CDAO

Regulation 8(4) places a requirement on NHS England to nominate or appoint a fit, proper and suitably experienced person to be its CDAO in respect of each of its LIN areas. An NHS CB (NHS England) CDAO can be responsible for one or more LIN areas.

NHS England has a responsibility to inform the CQC of the name of the CDAO in each Area Team and to keep this list up to date. See Regulation 10(1)(a)

Notifications to the CQC can be made at

<http://www.cqc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs/controlled-drug>

NHS England CDAOs are responsible for establishing and leading LINs drawn from the representatives of designated and responsible bodies.

Below, NHS England sets out the statutory and best practice requirements it expects of its CDAOs

### Statutory

The CDAO must have credibility with healthcare 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 Area Team 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.
2. The second condition is that the CDAO must be an officer or employee of the Area Team concerned.
3. The third condition is that the CDAO does not “prescribe, supply, administer or dispose of controlled drugs” as part of their duties (Regulation 8(8)) or does so only exceptionally. 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.

## **Best Practice**

To meet the term fit and proper person, NHS England considers that in addition to the statutory requirements outlined in section 4, the CDAO should be:

- A senior healthcare professional, with at least 5 years' experience post registration.
- A senior health care professional who, if not the Medical Director or Chief Nurse has direct reporting responsibilities to them.
- A person with an understanding of the prescribing and dispensing of controlled drugs and the law relating to these activities.
- A person who has a good awareness of the Information Service provided by NHSBSA and demonstrable understanding of accessing and interpreting CD prescribing data (training and support to be provided by NHSBSA).
- A person who at least annually has attended the CDAO training/ support event provided by NICE and/or NHS England.
- A person fit to conduct an investigation concerning issues related to controlled drugs.
- A person able to establish and retain credibility with a range of NHS and external members in order to establish and maintain a fully functioning LIN, carry out investigation and convene and chair an incident panel where required.

## **Removal of Controlled Drugs Accountable Officers**

Regulation 9 outlines the circumstances under which designated bodies should remove a CDAO from Office.

The circumstances are if the CDAO is no longer considered to be a fit and proper person to be a CDAO or no longer satisfies any one or more of the three conditions set out in regulations 8(6) to 8 (Described at 1 to 3 under statutory responsibilities above.)

The Area Team is responsible for notifying the CQC of the removal of the CDAO and for updating the CQC list with the newly appointed CDAO. Interim arrangements must be made to ensure that the Area Team is not left without a CDAO role once the CDAO has been relieved of his or her duties. Any interim appointments must also be notified to the CQC.

<http://www.cqc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs/controlled-drug>

## Annex 2: Template agenda for LIN

Name of Area Team:

Agenda No	Item description	Objectives/ Desired outcomes	Process	Item presenter	Time
1.	Welcome and Apologies				
2.	Minutes of Previous meeting Action Points Matters arising not on the agenda				
3.	Controlled Drugs Prescribing Update		BSA-provided report		
4.	CD related Serious Untoward Incidents Requiring Investigation (SIRIs)				
6.	Accountable Officer Reports Each designated body to update				
7.	Reports from CQC				
8.	Reports from local Police Force				
9.	Rule 43 letters		See below*		
10.	AOB to include Request for private prescription report Review of record of CD destruction Sharing of learning/ best practice Other incidents considered to be relevant				

Rule 43 letters – Issued by HM Coroners, these are reported 6 monthly and those related to CDs could be highlighted. <http://www.justice.gov.uk/publications/policy/moj/summary-of-reports-and-responses-under-rule-43-of-the-coroners-rules2>  
Now referred to as ‘reports on action to prevent other deaths’

## Annex 3: Suggested Terms of reference for LIN

### 1. Purpose

The establishment of the **Name of AT** Controlled Drugs Local Intelligence Network satisfies the requirements stipulated in regulation 14 (2) of The Controlled Drugs (Supervision of Management and Use) Regulations 2013.

1. **Name** Controlled Drugs Local Intelligence Network is established and managed by **Name** Area Team.
2. **Name** of AT CDAO responsible for convening and chairing the LIN
3. It has responsibility for sharing information regarding the use and management of controlled drugs across the **Name** Health Community.
4. **Insert the geographic area covered by this LIN**
5. The **Name** Health Community through the **Name** Controlled Drugs Local Intelligence Network will take all reasonable steps to ensure that arrangements to provide services that involve, or may involve, the management or use of controlled drugs by relevant individuals or designated bodies comply with The Controlled Drugs (Supervision of Management and Use) Regulations 2013.
6. The priority of the **Name** Controlled Drugs Local Intelligence Network will be to share intelligence and ensure all reasonable steps are taken to improve patient and public safety with regards to the safe and secure handling, management and use of controlled drugs.
7. The network will act in a way that ensures that the availability of controlled drugs is not compromised in patients for whom there is an appropriate clinical need.
8. Under Regulations 15 and 16, members representing responsible bodies are required to co-operate with each other. In doing so, members may disclose to other members information which that member reasonably believes it should disclose so that the LIN can properly consider the matter before it. Sharing information is therefore a vitally important part of the LIN's work. Where that information contains confidential details that relate to and can identify a patient, and those confidential details are not needed either for the LIN to consider what action to take, or to take such action, then the member concerned should remove the personal confidential information about the patient, unless it is not practicable to do so. Where a member discloses confidential information which relates to and identifies a patient, the disclosure is justified provided that member, prior to disclosure, determines that it is necessary to do so and, where practicable, has obtained the consent of the patient, or someone acting on the patient's behalf, to such disclosure (Regulation 15(7)). The same considerations apply where further personal information is sought from other LIN members about a concern (Regulation 15(6)). Where these procedures are followed, the member disclosing the information should have assurance that relevant information governance requirements have been met.

9. In the interests of the efficient conduct of meetings, attendees may be asked to provide occurrence reports in writing to the NHS England, **Name** Accountable Officer in advance of the meeting. These reports will be treated as if they had been disclosed in the relevant part of the meeting and will be subject to the relevant rules of confidentiality.
10. The **Name** Controlled Drugs Local Intelligence Network fulfils part of the duty of collaboration between organisations and members should ensure that mechanisms are also in place across the Name Healthcare Communities for the rapid dissemination of information relating to concerns about the management or use of controlled drugs by relevant individuals in between network meetings.
11. Responsible Bodies should ensure consistent representation at meetings. The meeting will be divided into two sections:

## Part A

All Trusts and other organisations or bodies who use or manage controlled drugs are invited to send a representative to Part A of the **Name** Local Intelligence Network for Controlled Drugs meetings. This will be known as the **wider network**. Part A of the meeting will address general issues and may include an expert speaker, consider procedural issues, share best practice and encourage the sharing of intelligence on an anonymised basis (Quarterly Occurrence Reports). The minutes of this part of the meeting may be released under the Freedom of Information Act 2000.

## Part B

The second part of the meeting will be restricted to the Accountable Officers and representatives of responsible bodies which will form the **core network**. The **core network** is responsible for ensuring appropriate functioning of the whole network. Part B will include discussion and review of intelligence received (where sharing is agreed and appropriate) including named details in the quarterly occurrence reports from Accountable Officers, major concerns raised, analysis of prescribing data and concerns identified by responsible inspecting bodies. Concerns regarding named individuals will be shared in a confidential manner. For any concern raised, the **core network** may consider:

- What action is to be taken;
- Who will be take this action and nominated lead person;
- Timescales for the action to be undertaken/completed;
- Ensuring that all organisations have agreed and signed up to this action;
- Ensuring that all information shared regarding the named individual is confidential to those attending the meeting unless otherwise agreed;
- Ensuring that any learning arising from an incident is disseminated in an appropriate manner.

There is a duty to share information including, if necessary, sharing concerns about named organisation, health professionals. Sharing of data is addressed by Regulations 15 and 16 of the Regulations.

Information discussed during Part B of the meeting may be exempt from disclosure under the Freedom of Information Act 2000. Consideration should be given to the fact that disclosure may impede an existing or future investigation.

As an information forum, the **Name** Controlled Drugs Local Intelligence Network, in itself, is not responsible for legal compliance. As a result, each organisation represented is fully responsible for its own activities and for setting up its own detailed governance arrangements over the conduct of their Accountable Officers and supporting staff. The proceedings of **Name** Controlled Drugs Local Intelligence Network meetings may be used by members in conjunction with other relevant data as contributing evidence to the discharge of their own statutory responsibilities.

## 2. Reporting Arrangements

The **Name** Controlled Drugs Local Intelligence Network is bound by the Data Protection Act and codes of practice on confidentiality in particular the Caldicott principles. Any sharing of information both within the group and within the wider network and reporting mechanisms must adhere to these principles. Separate minutes will be provided for part A and part B of the meeting.

## 3. Membership

The **Name** Controlled Drugs Local Intelligence Network comprises Accountable Officers and other professionals who are responsible within their own organisations for the safe use and management of Schedule 2, 3, 4 and 5 controlled drugs in compliance with the legislation.

The attendees for part B will be restricted to the **core network** comprising Accountable Officers and representatives of responsible bodies. Part A attendance will comprise the **core network** and **wider network**.

It is for the lead NHS England Area Team CDAO to determine the membership of the LIN that they are responsible for. Membership may vary according to the particular characteristics and circumstances for CD use in each LIN area. Under regulation 14(2)(a) membership of LIN may include those organisations listed in Regulation 6 as responsible bodies.

All core members are obliged to attend, deputies may be sent in exceptional circumstances. CQC will be informed of persistent failure to attend **Name** Controlled Drugs Local Intelligence Network by a CDAO.

## 4. Meetings

There will be **Insert number** annual meetings of the, **Name** Controlled Drugs Local Intelligence Network in each year.

**Insert local arrangements for frequency of meeting and how they will be managed.**

LINs must meet not less than six monthly.

**Part A minutes** will be circulated to all members of the **core** and **wider network**. Note: All documentation produced by or for the **Name** Controlled Drugs Local Intelligence Network Part A Meetings may be released under Freedom of Information Act 2000 unless otherwise indicated.

**Part B minutes** should be considered confidential and information is disclosed to members of the **core network** for the purposes of fulfilling responsibilities of The Controlled Drugs (Supervision of management and Use) Regulations 2013.

## 5. Sharing of Intelligence

- The main aim of **Name** Controlled Drugs Local Intelligence Network is to provide a structured framework for reporting and sharing information or concerns on the use of Schedule 2, 3, 4 and 5 Controlled Drugs within the **name** Heath Community in accordance with statutory requirements (Health Act 2006).
- The **Name** Area Team CDAO will act as the hub of the **Name** Local Intelligence Network.
- The Area team CDAO will be responsible for sharing intelligence with other Area Team CDAOs where necessary.

## **Annex 4: Suggested MoU for Area Teams to agree with their constituent CCGs**

### **Memorandum of Understanding between NHS England and Clinical Commissioning Groups on the Safe Use of Controlled Drugs**

#### **Background**

As a consequence of the passing of the Health and Social Care Act 2012 the regulations concerning the safe use of controlled drugs were revised to reflect the new architecture of the NHS in England.

The Controlled Drugs (Supervision of Management and Use) Regulations 2013<sup>2</sup> were laid before Parliament on 25<sup>th</sup> February 2013 transferring many responsibilities for the safe use of controlled drugs from Primary Care Trusts to the NHS Commissioning Board (subsequently referred to as NHS England) and outlining the responsibilities of Clinical Commissioning Groups. Supporting Information about the Regulations was also published by the Department of Health in February 2013<sup>3</sup>.

#### **Purpose**

It is vitally important for NHS England and the wider health community to continue to learn the lessons from the Shipman Inquiry especially with its many parallels to the Francis Inquiry in terms of patient safety and ensuring local intelligence is used effectively to safeguard patients and the public.

This document outlines the respective responsibilities of NHS England Area Teams and Clinical Commissioning Groups to ensure there is clarity about where responsibility lies and how organisations will work together to ensure effective implementation of this legislation across the new architecture.

#### **Scope**

There are many designated and responsible bodies defined in the legislation and others have important responsibilities such as police forces and Local Authorities – particularly for Drug and Alcohol Services. This document deals only with the arrangements for working together of Clinical Commissioning Groups and NHS England Area Teams in the Name and not with the wider relationships. It provides guidance only and should be read in conjunction with the legislation and guidance<sup>1,2</sup>.

---

<sup>2</sup>The Controlled Drugs (Supervision and Management of Use) Regulations 2013, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/141407/15-02-2013-controlled-drugs-regulation-information.pdf.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/141407/15-02-2013-controlled-drugs-regulation-information.pdf.pdf)

<sup>3</sup><https://www.gov.uk/government/publications/information-about-controlled-drugs-regulations>

## **Responsibilities of Respective Organisations**

NHS England has responsibilities under the Regulations as the lead CDAO for a Local Intelligence Network area and also as a commissioner of services. Clinical Commissioning Groups will have responsibilities both as commissioners of services and also with respect to their responsibilities for quality and governance in constituent practices and their duty of collaboration with NHS England and others. All organisations have a duty to patients to ensure the safe, effective and lawful management and use of controlled drugs.

## **Responsibilities of NHS England**

NHS England is defined as both a responsible body and a designated body in the Regulations. As a designated body it must appoint a fit and proper and suitably experienced person to be its Controlled Drug Accountable Officer (as set out in regulation 8(1)) for each of its Local Intelligence Networks (LINs). It is up to NHS England to formally determine the geography of Local Intelligence Networks and to notify the Care Quality Commission of the Controlled Drug Accountable Officer (CDAO) appointments. The NHS England CDAO is required to take on the lead CDAO role for the Local Intelligence Network area. (This responsibility previously sat with the Primary Care Trust CDAO). NHS England is required to provide the necessary funds and other resources for the CDAO to discharge their responsibilities in accordance with the Regulations. NHS England will also have responsibilities as a commissioner of services parallel to those of CCGs and other commissioners.

## **Responsibilities of Clinical Commissioning Groups**

Clinical Commissioning Groups (CCGs) are defined in the legislation as responsible bodies. There is no requirement for a CCG to appoint a CDAO. The CCG has a duty to co-operate with the relevant NHS England CDAO for example in investigating concerns or analysing data. It is good practice for the CCG to nominate a relevant individual within the CCG as CD Lead who acts as a focal point for liaison with the NHS England CDAO. The CCG has a duty to co-operate with other responsible bodies to identify cases where action may be taken in relation to the safe management and use of controlled drugs and to share intelligence where appropriate to ensure the safe use of controlled drugs. The CCG must also seek to ensure compliance with all medicines legislation by its constituent practices and by providers of commissioned services.

## **Respective responsibilities for the safe use and management of controlled drugs**

Table 1 sets out the understanding of NHS England with regard to the respective responsibilities of NHS England Area Teams and CCGs for effective implementation of these Regulations.

**Table 1: Responsibilities for safe use of controlled drugs for NHS England Area Teams and Clinical Commissioning Groups**

<b>NHS England/Area Team As lead Controlled Drug Accountable Officer (CDAO)</b>	<b>Clinical Commissioning Group</b>
Appoint a suitably experienced and qualified person to act as the lead CD AO	Name an individual as CD Lead to act as a focal point for liaison with the NHS England lead CDAO in relation to the safe use and management of controlled drugs.
Notify the CQC of the CD AO name and contact details so this can be readily accessed on the CQC website.	Ensure the Clinical Commissioning Group, its governing body and member practices are aware of who represents them on the Local Intelligence Network and how and when to raise concerns.
Formally define Local Intelligence Network (LIN) geography (and sub geography where appropriate).	
Set up and run the Local Intelligence Network determining membership and agreeing terms of reference.	Play an active part in the Local Intelligence Network, sharing intelligence as appropriate and taking action to improve the safe use of controlled drugs.
Provide guidance for appropriate intelligence sharing and recording.	Follow guidance regarding intelligence sharing and recording with respect to well- founded concerns reported to any officer of the Clinical Commissioning Group including sharing with a responsible body.
Provide guidance as to when a controlled drug incident should be reported as an organisational Serious Incident.	Report Serious Incidents in line with guidance and Serious Incident policy.
Set out requirements for sending quarterly occurrence reports from designated bodies to the lead CD AO.	
Convene incident panels. (The Local Intelligence Network must have a transparent process for establishing an incident panel if serious concerns are raised. The process should	Take part in incident panels where appropriate as agreed with the Area Team Lead CDAO.

outline the responsibilities of key individuals and how the panel should be called together).	
Ensure a system is in place for learning from controlled drug incidents and near misses and sharing of this learning.	Participate in a system for learning from controlled drugs incidents and sharing this learning.
Analyse NHS and private prescribing of CDs using electronic Prescribing Analysis and Cost (ePACT) and examine prescribing issues arising from the analysis.	Practice and prescriber level analysis of controlled drug prescribing trends and investigation of outliers in line with assuring appropriate, safe and effective prescribing within the CCG. Report concerns to the Area Team CDAO as appropriate.
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. Following up any concerns raised by returns.	Bring concerns about the safe use of controlled drugs by other healthcare providers to the attention of the Local Intelligence Network or Area team CDAO in line with intelligence sharing agreement.
Operate arrangements for periodic inspections of premises used in connection with the management or use of CDs which are not subject to inspection by other regulatory bodies such as the CQC, or GPhC .	Alert Area Team CDAO of intelligence received regarding premises used in connection with the management or use of CDs which is not subject to inspection by other regulatory bodies.
Ensure adequate steps are taken to protect patients and the public if there are concerns about inappropriate or unsafe use of controlled drugs by a person who is not providing services for any designated body, but who provides services in the LIN area.	Support Area Team CD AO in ensuring adequate steps are taken to protect patients and the public if there are concerns about inappropriate or unsafe use of controlled drugs by a person who is not providing services for any designated body, but who provides services in the Local Intelligence Network area.
Authorise sufficient fully trained witnesses for destruction of controlled drugs who are subject to a professional	

code of ethics, have received appropriate training and are independent of the day-to-day use or management of controlled drugs.	
Make arrangements for the safe and lawful destruction of controlled drugs in community pharmacies and practices.	
Ensure complaints, safety and professional performance issues are effectively linked to the NHS England Area Team CDAO.	
Form effective partnerships with the regulators such as CQC, General Medical Council (GMC), Nurse and Midwifery Council (NMC) and GPhC to share intelligence as appropriate.	

**Table 2 outlines the responsibilities of commissioners of services and these apply to both NHS England Area teams and to Clinical Commissioning Groups as commissioners of services.**

Table 2: Responsibilities of commissioners for the safe use of controlled drugs

<p>Work in partnership with responsible bodies to share intelligence and identify areas of concern.</p> <p>Ensure intelligence from complaints, monitoring, incidents and other concerns are effectively collated and acted upon.</p> <p>Ensure providers of commissioned services have in place arrangements for the safe management and use of controlled drugs including:</p> <ul style="list-style-type: none"> <li>• compliance with the Misuse of Drugs Act 1971 and other medicines legislation;</li> <li>• standard operating procedures being in place for the safe management, use, transportation and disposal of controlled drugs including the prescribing, supply and administration of controlled drugs and the clinical monitoring of patients who have been prescribed controlled drugs;</li> <li>• education and training in relation to these standard operating procedures, good practice and the law in relation to the safe management and use of controlled</li> </ul>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

drugs;

- a system for recording concerns, incidents, intelligence and complaints in respect to controlled drugs and for raising concerns with others as appropriate;
- a system for monitoring, assessing, investigating and taking action in relation to relevant individuals with regard to well-founded concerns;
- a system for assessing and investigating concerns, incidents, intelligence and complaints;
- a system for monitoring and assessing individual health professionals performance in relation to the safe management of controlled drugs;
- a system for reviewing the effectiveness of the above arrangements.

## Annex 5: Occurrence report templates

### NHS England Occurrence Report – Controlled Drugs Concerns

This template form may be adapted for use by Accountable Officers for quarterly reports of any concerns that their designated body has regarding management and use of controlled drugs (Clause 29).

Name of designated body				
Name of Accountable Officer				
Report for three-month period				
Name of local intelligence network (LIN)				
Name of Area Team CD Accountable Officer				
I confirm that my designated body has <b>no/the following</b> (delete as appropriate) concerns regarding its management or use of controlled drugs during this period				
Accountable officer signature				
Date signed				
Date aware of incident <sup>1</sup>	Organisations/agencies involved <sup>2</sup>	Summary of concern <sup>3</sup>	Brief details of action taken <sup>4</sup>	Case open/closed and learning to date <sup>5</sup>
<b>Categories<sup>6</sup></b>			<b>No of occurrences</b>	
Losses: <ul style="list-style-type: none"> <li>➤ known theft</li> <li>➤ known fraud</li> <li>➤ unaccounted for losses</li> </ul>			<i>Insert the number of occurrences for each category reported.</i>	
Patient related incidents			<i>Insert the number of occurrences for each category reported.</i>	
Governance issues			<i>Insert the number of occurrences for each category reported.</i>	
Individuals of concern			<i>Insert the number of occurrences for each category reported.</i>	

Other	<i>Insert the number of occurrences for each category reported.</i>
-------	---------------------------------------------------------------------

1. Date on which the Accountable Officer (AO) was made aware of the incident
2. Details of all organisations involved in the incident
3. The date and brief details of the incident which occurred
4. What action was taken by the AO following the incident?
5. Has the case been closed or is it on-going? What learning has been identified, how has this been disseminated and to whom. Does the learning need to be shared across Health Community (or wider) and how has/will this be done eg. CD Newsletter.

**If case is open an update must be provided in all subsequent quarterly reports until closed**

6. Provide a breakdown of occurrences in each category.

## Null report

(Complete a null report if you have not provided information in Section above or update on previous concern

There have not been any reportable concerns or trends in this organisation during this period	Date from:	Date to:

## Declaration

I declare that by submitting this report I agree that, to the best of my knowledge and understanding, the contents of this report are true and accurate.

Print Name

Date

Designation

## Controlled Drugs Quarterly Occurrence Report Form From Area Team to CQC

This form should be used by Area team CDAOs to collate their occurrence reports and send to CQC at the email address below.

Area Team:	Date reported:
Contact name:	Contact telephone number:
Contact address:	
Quarter period:	Total number of occurrences reported:
Number of NHS trusts:	Number of non-NHS organisations:
<b>Categories</b>	<b>No of occurrences</b>
Losses: <ul style="list-style-type: none"> <li>➤ known theft</li> <li>➤ known fraud</li> <li>➤ unaccounted for losses</li> </ul>	<i>Insert the number of occurrences for each category reported.</i>
Patient related incidents	<i>Insert the number of occurrences for each category reported.</i>
Governance issues	<i>Insert the number of occurrences for each category reported.</i>
Individuals of concern	<i>Insert the number of occurrences for each category reported.</i>
Other	<i>Insert the number of occurrences for each category reported.</i>
Please use this area to list those organisations that have not submitted an occurrence report for two or more consecutive quarters:	
Area Team Lead CDAO Name:	Area Team Lead CDAO Signature:

Send to the CQC at: [CDOccurrencedata@cqc.org.uk](mailto:CDOccurrencedata@cqc.org.uk)

## Annex 6: Authorisation of witnesses to destroy Controlled Drugs

The Misuse of Drugs Regulations 2001, as amended, require that CDs that are held as stock by healthcare professionals and/or organisations **must** only be destroyed in the presence of an Authorised Witness. The Act designates certain classes of person as Authorised Witnesses. This includes *any* Police Constable and Inspectors of the General Pharmaceutical Council.

Additionally a Controlled Drugs Accountable Officer (CDAO) of NHS England may authorise further persons or class of persons as Authorised Witnesses

Within the NHS in England CDs may be legitimately be stocked at a number of organisations including community pharmacies, doctors surgeries, dental surgeries and out of hours services. Should CD stock expire or otherwise become obsolete an Authorised Witness **must** be present to witness its destruction.

1. NHS England must ensure that there are adequate Authorised Witnesses within the system to allow the timely destruction of CDs when the need arises.
2. Patient held CDs returned to community pharmacies **do not** require an Authorised Witness to be present for them to be destroyed.

The management of CDs in the health system, including their destruction, is a shared responsibility between NHS England, service providers, regulators and the Police as the prompt and lawful destruction of obsolete CD stock is a matter of patient safety and public protection. It is the aspiration of NHS England that when a healthcare premises where obsolete CD stock requires destruction is visited by an organisation with a duty to ensure patient safety and/or public protection that the destruction should take place.

While witnessing the destruction of CDs does not form the core business of any organisation it should be incidental to the core business of any organisation that has a responsibility to ensure patient safety and/or public protection. Suitably trained employees of such organisations should be empowered, as Authorised Witnesses, to assist service providers in managing their obsolete CD stock.

NHS England will empower Clinical Commissioning Groups (CCG) to assist their members and contractors to manage their obsolete CD stock by designating suitably trained members of CCG employees and/or their agents as Authorised Witnesses.

NHS England may designate further suitably trained individuals and/or classes of person as Authorised Witnesses, including its own employees to facilitate the timely destruction of obsolete CDs.

## **Authorised Witnesses**

- Any Police Constable and Inspectors of the General Pharmaceutical Council are, by virtue of their office, Authorised Witnesses.
- Additionally any NHS England CDAO may designate an individual and/or class of persons as an Authorised Witness.
- Where an individual and/or class of persons have been designated an Authorised Witness by any NHS England CDAO that authorisation shall be recognised as valid by all NHS England CDAOs.
- All authorisations granted by an NHS England CDAO **must** be in writing, name the individual and/or class of persons authorised, have an expiry date (two years from the date of issue) and be signed by the Area Team CDAO.
- NHS England expects any Authorised Witness to facilitate the destruction of obsolete CDs at any premises they visit where they consider there is a risk to patient safety if the CDs are not destroyed.
- It is a requirement that an Authorised Witness report any concerns that they may have about the management and safe use of CDs by an individual or at any premises of which they become aware while witnessing the destruction of CDs to the NHS England Area team CDAO. This is a non-delegable duty.

## **The destruction of date expired and obsolete controlled drugs**

### ***NHS Medical Practices***

All NHS Medical Practices are required to be members of a CCG. NHS England expects CCGs to assist its member practices in the management of obsolete CDs by providing an Authorised Witness. NHS England will designate suitably qualified employees and/or agents of the CCG as Authorised Witnesses to facilitate this.

### ***Services commissioned by CCGs***

NHS England expects that where a service is directly commissioned by a CCG such as an out of hours service or a palliative medicine service that CCGs will provide an Authorised Witness to facilitate the destruction of obsolete CDs associated with the commissioned service. NHS England will designate suitably qualified employees and/or agents of the CCG as Authorised Witnesses to facilitate this.

### ***NHS Dental Practices***

Where an NHS Dental Practice requests an Authorised Witness to witness the destruction of obsolete CDs NHS England will ensure that one is made available.

The Authorised Witness may be an employee or agent of NHS England or any other Authorised Witness which may include independent contractors.

### ***Independent healthcare providers***

- Where independent healthcare providers such as private GPs or dentists request an Authorised Witness to witness the destruction of obsolete CDs NHS England will ensure that one is made available.
- The Authorised Witness may be an employee or agent of NHS England or any other Authorised Witness which may include independent contractors.
- The provision of Authorised Witnesses to the independent healthcare sector should be cost neutral to the NHS and NHS England may therefore charge for the provision of an Authorised Witness. Independent contractors acting as Authorised Witnesses will enter into their own contractual arrangements, including the cost, with the independent provider.
- Where any part of the business of an independent provider consists of services provided on behalf of or commissioned by NHS England no charge will be made for the provision of an Authorised Witness.

### ***Community Pharmacies – multiples***

- NHS England anticipates that body corporate operating in excess of 5 or more pharmacy premises will seek to have suitably trained employees designated as Authorised Witnesses by the appropriate NHS England CDAO.
- A body corporate operating 5 or more pharmacies may apply to the appropriate NHS England CDAO to designate suitably trained individual employees and/or class of employees as Authorised Witnesses.
- The appropriate NHS England CDAO is the one for the Local Area Team where the body corporate's registered office is located.
- The appropriate NHS England CDAO may designate suitably trained individual employees and/or class of employees in a body corporate as Authorised Witnesses where the individuals described are not routinely involved in the management and use of CDs in the premises in which they are acting as an Authorised Witness.
- The Superintendent Pharmacist of the body corporate is accountable to the appropriate NHS England CDAO for the governance arrangements around the witnessed destruction of CDs in their premises.

- Where an NHS England CDAO designates Authorised Witnesses for a body corporate then the responsibility for the provision of Authorised Witnesses to witness the destruction of obsolete CDs within their premises rest with the body corporate.
- A body corporate may contract with an independent Authorised Witness to facilitate the witnessed destruction of obsolete CDs.

### ***Community Pharmacies - independents***

- Bodies corporate, partnerships and/or individuals operating fewer than 5 community pharmacies may **not** have suitably trained individuals designated as Authorised Witnesses.
- To facilitate the timely destruction of obsolete CDs NHS England will designate sufficient, suitably trained, individuals and/or class of person as Authorised Witnesses. This may include NHS England employees and/or agents, representatives of the appropriate Local Pharmaceutical Committee and/or persons nominated as appropriate to undertake the role by a recognised trade association such as the National Pharmacy Association or Independent Pharmacy Federation.
- An independent community pharmacy may contract with an independent Authorised Witness to facilitate the witnessed destruction of obsolete CDs.
- Where an independent community pharmacy requests an Authorised Witness to witness the destruction of obsolete CDs from NHS England, NHS England will ensure that one is made available.

### **Summary**

The Regulations place a duty of the NHS England CDAOs to authorise sufficient Authorised Witnesses to secure the timely disposal of obsolete CDs held as stock in the healthcare system.

This is a shared responsibility and the approach proposed by NHS England endeavours to recognise this. The ambition is that by devolving the responsibility appropriately service providers and commissioners will be empowered to manage the timely disposal of obsolete CDs and therefore assure patient safety and public protection.

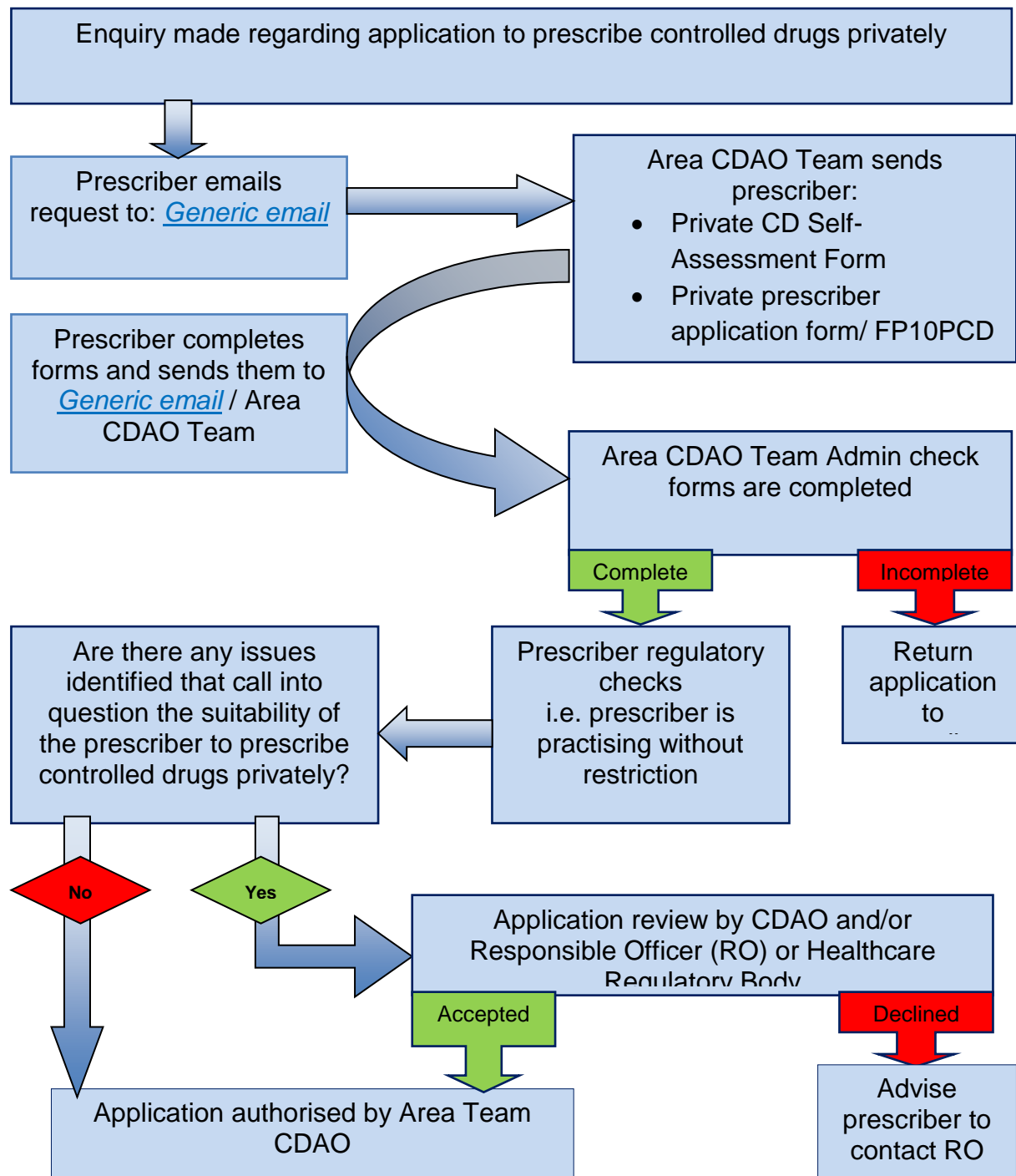
The appropriate NHS England Area Team CDAO will remain accountable for assuring the Board that there are sufficient Authorised Witnesses in their area and that there is a reliable system in place to manage the timely disposal of obsolete CDs and therefore assure patient safety and public protection.

## **Annex 7: Templates for Area Team arrangements for private prescriptions**

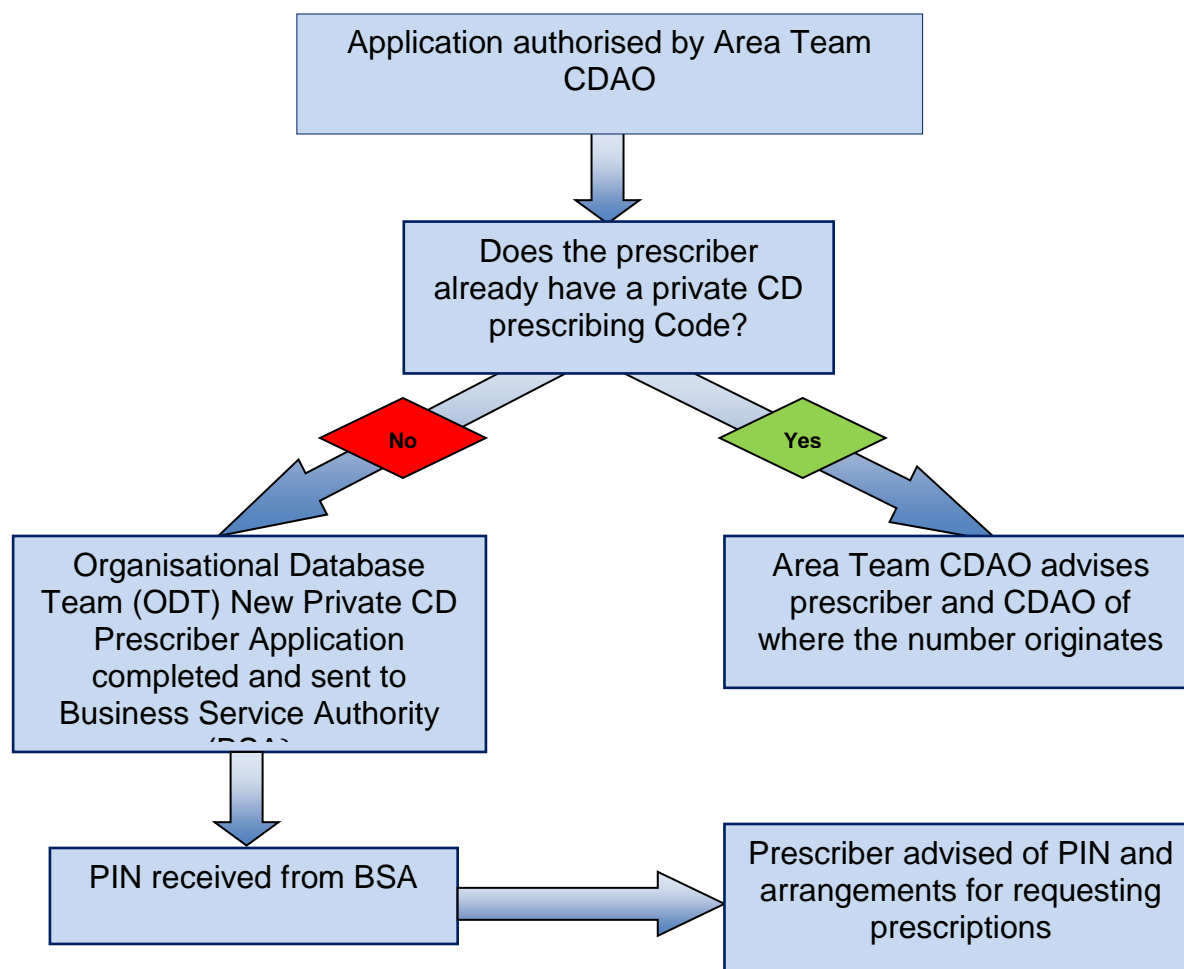
### **7.1 Flow chart for Private CD prescribing authorisation and Prescription order**

# Suggested Private CD Prescribing Authorisation & Prescription Order Process

## 1. Application

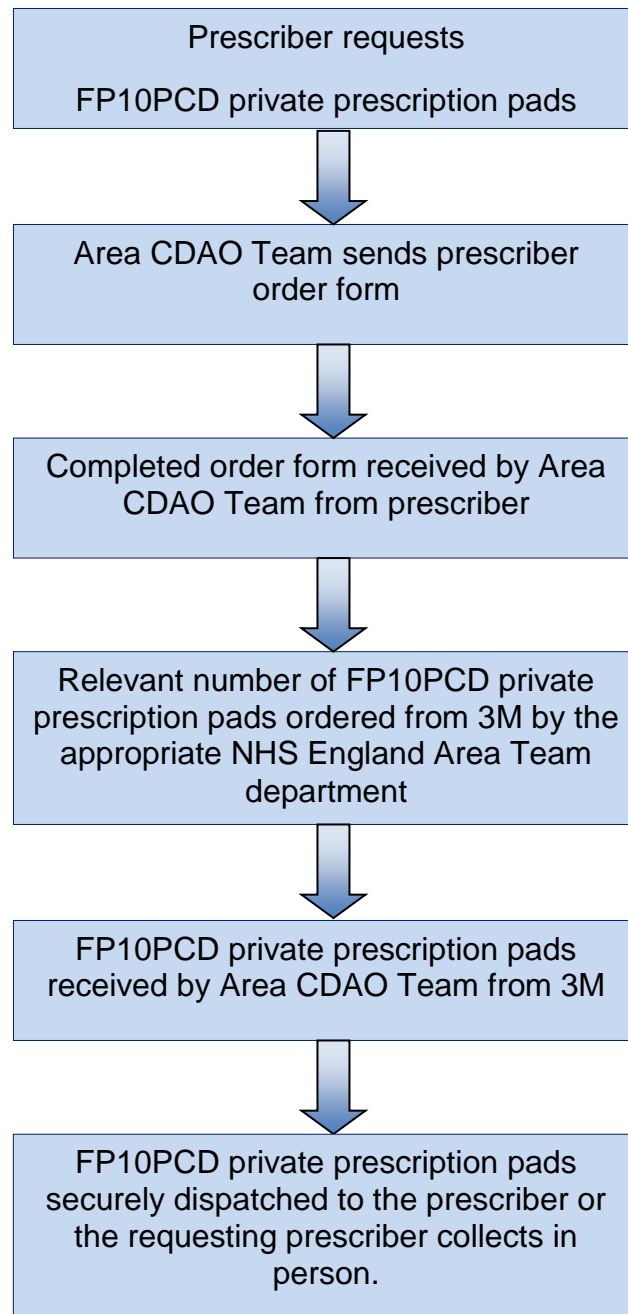


## 2. Prescriber Identification Number (PIN)



**Note:** Dental prescribers have been issued private prescriber codes on a geographical basis not an individual basis, therefore not all of the steps in section 1 and 2 will apply.

### 3. Private Prescription Ordering



## 7.2 Forms for notification of a new private Controlled Drugs Prescriber

For all BSA forms please see <http://www.nhsbsa.nhs.uk/PrescriptionServices/3993.aspx>

### **Private Controlled Drug (CD) Prescribers**

An authorised signatory at the Area Team (or an agency on their behalf) must advise NHS Prescription Services of any additions/deletions or changes (e.g. change of name) to Private CD Prescribers by using one of the relevant proformas listed below.

#### **New Private CD Prescriber -**

[Form for notification of new Private CD Prescriber](#)

Only one Private CD prescriber code will be issued to a prescriber regardless of where the prescribing activity occurs. The Area Team that is responsible for the Private CD Prescriber will order FP10PCD prescriptions on the prescriber's behalf and also monitor the prescriber information on ePACT

For further information on the Safer Management of Controlled Drugs – [click here](#)

#### **Private CD Dentists –**

A generic Private CD Dentist code will be issued to the Area Team to be used by all dentist private prescribing within their area. Contact 0191 2035112 or [nhsbsa.prescriptioninformation@nhs.net](mailto:nhsbsa.prescriptioninformation@nhs.net) if you require a generic Private CD prescribing code for your dentist prescribers

#### **Change of Private CD Prescriber details -**

[Form for notification of change of details for Private CD Prescriber](#)

#### **Private CD Prescriber leaving an organisation -**

[Form for notification of Private CD Prescriber leaving an organisation](#)

Completed proforma(s) should then be emailed to [nhsbsa.prescriptioninformation@nhs.net](mailto:nhsbsa.prescriptioninformation@nhs.net)

Notifications will be actioned within 3 working days unless a query arises as a result of the information submitted to NHS Prescription Services. Queries will be sent by email to the original sender of the notification. No changes can be made to NHS Prescription Services systems until we receive a satisfactory response to the query. More complex queries can be discussed by telephone, but must always be followed up with written confirmation of the action agreed. Once actioned, the new or updated information will be sent to 3MSPSL and any replacement pads will bear the new or updated information (where applicable).

Where a new Private CD Prescriber code has been requested, the authorised signatory will be notified of the new code by email.

Following confirmation of the new code(s), the Area Team will be able to order personalised prescription pads from 3MSPSL in respect of the new Private CD Prescriber code details using the [3MSPSL ordering procedure](#).

For further information please contact 0191 2035112 or [nhsbsa.prescriptioninformation@nhs.net](mailto:nhsbsa.prescriptioninformation@nhs.net)

### 7.3 Mandate for Private Controlled Drug Prescription forms (FP10PCDs) for the supply of schedule 2 and 3 Controlled Drugs.

#### **SECTION 1 - TO BE COMPLETED BY THE REQUESTING PRESCRIBER**

<b>Name of Private CD Prescriber:</b>	<b>Title:</b>	<b>Initials:</b>
	<b>Surname:</b>	
	<b>NHS Prescriber Code</b> (if on a performers list):	
	<b>CD Prescriber Code</b> (if already issued):	

<b>Address &amp; telephone Number</b>  <i>(As would appear on prescription form)</i>		
		<b>Postcode:</b>
	<b>Telephone Number: (Office and Mobile numbers)</b>	

<b>Professional registration Number</b> ( <i>E.g. GMC/GDC</i> )	
-----------------------------------------------------------------	--

<b>Proposed reason/purpose for requiring FP10PCD forms</b> ( <i>&amp; name of service if applicable</i> ):		
<b>Expected prescription usage rate:</b>	<10 Rx's per year <input type="checkbox"/>	..... pads of 10 forms per year

<b>About the prescriber:</b>	<b>Yes/No?</b>	<b>Details</b>	<b>Checked by</b> ( <i>&amp; Date</i> )
------------------------------	----------------	----------------	--------------------------------------------

<b>Registered with a professional body?</b>		<i>If "Yes" state body (e.g. GMC, GDC) &amp; registration number:</i>	
<b>NHS prescribers:</b>  Are you on a Performer's List?		<i>State which performers list:</i>	
<b>Hospital doctors:</b>		<i>Name of employing Hospital:</i>	
<b>Is the Service registered with the Care Quality Commission?</b>			
<b>Other information:</b>  <i>(To support the right of the prescriber to privately prescribe controlled drugs. E.g. relevant training qualifications etc with dates received),</i>			

All applicants:	Yes/No	Details:	Checked by: ( & Date)
Have you completed a Private Controlled Drugs Prescribing/Transfer Self-Assessment?		<i>If "No", one must be completed prior to submission of this form</i>	
Have any details changed since you submitted a Private Controlled Drugs Prescribing/Transfer Self-Assessment?		<i>If "Yes" please supply details of minor changes or complete a new self-assessment form for major change:</i>	
Are you currently undergoing or have you ever been the subject of an investigation relating to controlled drugs, where the investigation had an adverse outcome?		<i>If yes, please provide details (continue on a separate sheet if necessary):</i>	
Have you completed a CD Self Assessment Audit			

**NHS England will monitor all private prescribing of Controlled Drugs dispensed by Community Pharmacies.**

**Please sign and date the declaration below:**

**Declaration:**

**All information provided in this document is correct to the best of my knowledge.**

**I confirm that the Controlled Drugs will not be used to treat myself or anyone with whom I have a close relationship in line with GMC /GDC Guidance.**

**I acknowledge that there may be charged for FP10PCD forms and agree to pay as invoiced by the Area Team.**

**Signed:** ..... (Requesting prescriber) **Date:**.....

**For Area team Use:**

**Mandate reviewed by: Signature: ..... Date: .....**

**Name: ..... Designation: .....**

**SECTION 2 - TO BE COMPLETED BY THE NHS ENGLAND AREA TEAM  
CONTROLLED DRUGS ACCOUNTABLE OFFICER:**

As the Accountable Officer for \_\_\_\_\_ Area Team, I approve the request for:

- \*a private PPD prescriber number to be obtained **and**;
- \*One pack of 10 (ten) FP10PCD forms to be issued **or**;
- \*Up to a maximum of ..... pads of 10 (ten) FP10PCD forms to be issued over the 12 month period from the date below (further supplies require a new approved mandate)

To the following practitioner:

**Name:.....**

**Professional registration number:.....**

**Approved by**

**Signed: .....**

**Date:.....**

Name\_\_\_\_\_

*(Area Team Accountable Officer)*

\*delete as applicable

## 7.4 Private Controlled Drugs Prescribing Self-Assessment

**This self-assessment must be completed prior to issue of:  
- FP10PCD Private Controlled Drug Prescription forms**

Please complete ALL relevant parts of this self-assessment continuing your answers on a separate sheet if necessary.

It relates to activities undertaken by you within the last 12 months and/or activities to be undertaken by you in the next 12 months involving controlled drugs (CDs) Schedule 2 & 3 only (see Appendix 1).

Name of Prescriber:		Type of organisation/Service
Address:		GP
		Dentist
		Pharmacy
		Other (please give details)

1. Controlled Drugs (to be completed by all!)	Yes / No
<p>Do you <b>prescribe, handle, store, supply, administer or destroy</b> Schedule 2 or 3 Controlled Drugs on any premises relating to your <u>private</u> practice?</p> <p style="text-align: right;"><i>If "Yes" go to question 2 (If "No" go to declaration on page 8)</i></p>	

2. General Information	Yes / No	Details
a) Do you have appropriate standard operating procedures for the initial training and updating of all staff involved in the prescribing, handling, supply, administration and destruction of CDs?		
b) Are there any special factors that influence the prescribing or use of CDs by you? For example, involved in palliative care, substance misuse (prescribing under LES for DAAT or DES for alcohol), supervised ingestion on site, sporting facility. <i>If yes, please give details.</i>		
<p><b>c) State full name of Responsible Officer (RO)</b> (Medical practitioners only)</p> <p>Name _____</p>		<b>Date of last appraisal</b> (Medical practitioners only)

3. Prescribing Controlled Drugs	Yes / No
<p>Are you involved in the <b>prescribing</b> of Schedule 2 or 3 Controlled Drugs?</p> <p style="text-align: right;"><i>If "Yes" go to question 4 (If "No" go to question 5)</i></p>	

4. Prescribing	Yes / No	If yes, please give details
a) Do you have written standard operating procedures or policies covering prescribing of CDs, appropriate to the activities you carry out?		
b) Are there any restrictions on your CD prescribing?		
c) By what means do you forward prescriptions for CDs to pharmacies for dispensing (e.g. collection by pharmacy, patient collection, post)?		
d) Have there been any patient or carer complaints involving the prescribing of CDs? <i>(This includes complaints about failing to prescribe appropriate doses and/or appropriate medicines).</i>		
e) Have there been any concerns expressed by colleagues, police, drugs misuse services, medicines management team members or others about unusual, excessive or inappropriate prescribing of CDs?		
f) Have there been any significant events involving the prescribing of CDs? <i>(Significant events include any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong)</i>		

5. Supply of Controlled Drugs	Yes / No
Are you involved in the <b>supply</b> of Schedule 2 or 3 Controlled Drugs?	
<i>If "Yes" go to question 6 (If "No" go to question 7)</i>	

6. Supply	Yes / No	Details (where applicable)
a) Do you have written standard operating procedures or policies covering supply of CDs, appropriate to the activities you carry out?		
b) Do you supply CDs for substance misuse?		
c) Do you supply CDs against private prescriptions:		<i>If yes, please give details:</i>
(i) from substance misuse services?		
(ii) other?		
d) Do you supply controlled drugs:		<i>If yes, please give details:</i>
(i) to doctors?		
(ii) to other prescribers?		
(iii) to others (e.g. care homes, pain clinics)?		
e) Where do you obtain your stocks of CDs?		
f) Do you routinely request ID from person(s)		<i>If yes, please give details:</i>

collecting CDs? Please give details.		
g) Do you provide advice to patients or carers on the safekeeping and disposal of unwanted CDs?		
h) Have there been any patient or carer complaints involving the supply of CDs? <i>(This includes complaints about failing to supply appropriate doses and/or appropriate medicines).</i>		
i) Have there been any concerns expressed by colleagues, police, drugs misuse services, medicines management team members or others about the supply of CDs from you?		
j) Have there been any significant events involving the supply of CDs? <i>(Significant events include any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong)</i>		

7. Obtaining Controlled Drugs	Yes / No
Are you involved in <b>obtaining</b> Schedule 2 or 3 Controlled Drugs?  <i>If "Yes" go to question 8 (If "No" go to question 9)</i>	

8. Obtaining	Yes / No	Details (where applicable)
a) Do you have written standard operating procedures or policies covering requisitioning of CDs, appropriate to the activities you carry out?		
b) Do you have a supply of requisitions forms (FP10CDF) for the purpose of obtaining stock of CDs?		

9. Administration of Controlled Drugs	Yes / No
Are you involved in the <b>administration</b> of Schedule 2 or 3 Controlled Drugs? <i>(Excluding supervision of CDs consumed by substance abusers)</i>  <i>If "Yes" go to question 10 (If "No" go to question 11)</i>	

10. Administration	Yes / No	Details (where applicable)
b) Do you have written standard operating procedures or policies covering administration of CDs, appropriate to the activities you carry out?		
c) Are the CDs used for administration: (i) stock CDs?		
(ii) patient's own CDs?		
d) Do you maintain records of administration? <i>If yes, please provide details? (E.g. CD register, MAR chart, Syringe driver and nurse administration record (pink card), written record in patients care home records etc)</i>		
e) Is administration of CDs witnessed?		

<i>If "Yes" please give details. If "No", what risk management policies are in place to cover administration?</i>		
f) Have there been any patient or carer complaints involving the administration of CDs? <i>(This includes complaints about failing to administer appropriate doses and/or appropriate medicines).</i>		
g) Have there been any concerns expressed by colleagues, police, drugs misuse services, medicines management team member or others about the administration of CDs?		
h) Have there been any significant events involving the administration of CDs? <i>(Significant events include any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong).</i>		

11. Storage of Controlled Drugs	Yes / No
Do you <b>store</b> any Schedule 2 or 3 Controlled Drugs on any of your premises or any other area relating to your practice?	
<i>If "Yes" go to question 12 (If "No" go to question 14)</i>	

12. Security and Safe Custody in Premises	Yes / No	Details (where applicable)
a) Do you have written standard operating procedures or policies covering security and safe custody of CDs, appropriate to the activities you carry out?		
b) Do you store CDs in:		<i>If yes, please give details:</i>
(i) a central store?		
(ii) doctors' bags?		
(iii) other places?		
c) Are there any special circumstances about your practice, which might influence the use and storage of controlled drugs?		
d) Are all CDs kept under lock and key (including patient returned CDs or unwanted/out of date CDs)?		
e) Is access to CDs controlled?		<i>If yes, please give details:</i>
f) Do you utilise CD storage facilities for storage of anything other than CDs?		<i>If yes, please give details:</i>
g) How often does date checking of CD stock take place? <i>(Give details of date checking procedures or attach copy of procedure)</i>		
h) How often does date checking of CD stock in doctors' bags take place? <i>(where applicable)</i>		<i>Please give details:</i>
i) Are all stock CDs kept in the original container until required for use?		
j) Are dispensed patients' CDs appropriately		

labelled?		
k) Are different strengths of the same medicine segregated in any way?		
l) Do you have unwanted or out of date stock CDs currently stored?		
m) Are unwanted/out of date/patient returned CDs segregated from other CDs?		
n) Are patient returned medicines ever reused?		
o) Have there been any patient or carer complaints involving the storage of CDs on any of your premises?		
p) Have there been any concerns expressed by colleagues, police, drugs misuse services, medicines management team member or others about the storage of CDs on any of your premises?		
q) Have there been any significant events involving the storage of CDs on any of your premises? (Significant events include any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong.)		

<b>13. Registers</b> (applicable when answer to question 12 is YES)	<b>Yes / No</b>	<b>Details (where applicable)</b>
a) Do you keep an up to date CD register?		
If yes:		
(i) Is it a bound or an electronic register?		
(ii) If electronic is it fully auditable?		
a) Is there a register for each area where CDs are stored e.g. stock cupboard, doctor's bag, treatment room?		
b) Do you keep running balances of stock CDs held? If yes:		
(i) Do you check your running totals against stock held?		State how often and date of last check:
(ii) Who checks the running totals?		
c) Have you identified any discrepancies between running totals and actual CDs held in the last 12 months? If yes:		
(ii) What was the explanation for the discrepancy?		
(ii) What action was taken?		
d) Do you maintain records of all receipts and supplies of CDs?		If yes, for how long do you keep records?
e) Have there been any patient or carer complaints involving the record keeping of CDs?		
f) Have there been any concerns expressed by		

colleagues, police, drugs misuse services, medicines management team members or others about the record keeping of CDs?		
g) Have there been any significant events involving the record keeping of CDs? <i>(Significant events include any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong)</i>		

14. Transport of Controlled Drugs	Yes / No
Are you involved in or responsible for the transport of CDs <i>(this includes sending CDs using third party carriers such as delivery drivers and postal system)</i> ?  <i>If "Yes" go to question 15 (If "No" go to question 16)</i>	

15. Security and Safe Custody in Transport	Yes / No	Details (where applicable)
a) Do you have written standard operating procedures or written policies covering security and safe custody of CDs in transport, appropriate to the activities you carry out?		
b) Are CDs routinely kept under lock and key during transport?		<i>If "No", then please provide details.</i>
c) What records are maintained of CDs in transport?	<i>Provide copy of delivery sheet if appropriate</i>	
d) Have there been any patient or carer complaints involving the security and safe custody of CDs in transport?		
e) Have there been any concerns expressed by colleagues, police, drugs misuse services, medicines management team member or others about the security and safe custody of CDs in transport?		
f) Have there been any significant events involving the security and safe custody of CDs in transport? <i>(Significant events include any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong)</i>		

16. Destruction or Disposal of CDs	Yes / No	Details (where applicable)
<b>16.1 Patients' CDs</b>		
a) Do you have written standard operating procedures or policies covering the receipt, destruction and disposal of patients' CDs, appropriate to the activities you carry out?		
b) What records do you keep of patients' CDs for disposal?		
c) Do you routinely destroy patients' unwanted or out of date CDs?		
d) What systems do you have in place to dispose of patients' unwanted or out of date CDs?		

e) Is the destruction of patients' unwanted or out of date CDs witnessed? If yes, by whom?		
f) Do you keep records of the destruction of patients' unwanted or out of date CDs?		
<b>16.2 Stock CDs (if applicable)</b>		
a) Do you have written standard operating procedures or written covering the destruction and disposal of stock CDs, appropriate to the activities you carry out?		
b) How often do you aim to destroy unwanted or out of date CDs?		
c) Who usually witnesses your stock destruction?		
d) When was the last-witnessed CD stock destruction?		
e) Are records of stock destruction kept in the CD register?		
f) Do you have any unwanted or out of date stock CDS awaiting destruction at this present time?		
g) Have there been any patient or carer complaints involving the destruction or disposal of CDs?		
h) Have there been any concerns expressed by colleagues, police, drugs misuse services, medicines management team members or others about the destruction or disposal of CDs?		
i) Have there been any significant events involving the destruction or disposal of CDs? (Significant events include any incident where a patient is harmed or nearly harmed and include 'near misses', when things almost go wrong.)		

<b>17. Miscellaneous</b>	<b>Yes / No</b>	<b>If yes, please give details</b>
a) Are there any roles where you may be called upon to carry CDs? E.g. forensic medical advisor, sports doctor, out of hours work		
b) Have you any special training relevant to controlled drugs? E.g. substance misuse training, palliative care training.		
c) Have there been any other significant events relating to controlled drugs? E.g. death of a patient involving CDs, theft of CDs from premises.		
d) Do you keep controlled drugs in your possession? E.g. in doctors bag		
e) Do you keep controlled drugs in any other settings, e.g. in mountaineering club?		
f) Have you been convicted of an offence under the Misuse of Drugs Act 1971?		
g) Are there any activities carried out by you in handling, use and management of CDs that you would be unable to audit?		

Please ensure that **ALL** relevant parts of this self-assessment are completed **before** signing the declaration below:

**Declaration: (Please delete sections not applicable)**

I declare to the best of my knowledge and belief that the information I have provided relating to the Misuse of Drugs Act 1971 and the associated Regulations, in its prescribing, handling, supply, administration and destruction of Schedule 2 & 3 Controlled Drugs is correct. I agree to notify the Accountable Officer within 2 working days of any major changes to the information supplied.

Signature	
Name (and registration number, if healthcare professional)	
Position within the organisation (if applicable)	
Date of signing	

**Please return completed form to:**

**Quality and Patient Safety Team**

Name \_\_\_\_\_ Area Team

NHS England

Address

**(Completed forms in pdf format may be sent to \_\_\_\_\_)**

**IMPORTANT – NOTIFICATION OF CHANGES:**

- **Minor changes:** notify the Accountable Officer within 14 days of the change by email to \_\_\_\_\_
- **MAJOR CHANGES:** Notify the Accountable Officer by email immediately then complete a new Self-assessment form and submit it within 14 days.

## Annex 8: The NHS England Controlled Drugs Short Life Working Group

### **NHS England Controlled Drugs Short Life working group**

NHS England is enormously grateful to the members of the short life working group for their hard work over such a short period support this work.

In addition, we are grateful for contributions from NHS London, NHS South of England, South Yorkshire and Bassetlaw Area Team, Devon, Cornwall and Isles of Scilly Area Team.

Clare Howard (Chair)	Deputy Chief Pharmaceutical Officer NHS England
Dr David Geddes (Co Chair)	Head of Primary Care NHS England
Sandra McGregor	Secretariat
Dr John Hussey	Partner at the Elms Medical Centre & Medical Director, NHS England (Merseyside)
Johanna Hulme	Associate Director – Medicines Advice (Medicines and Prescribing Centre) - NICE
Robert Allan	Medicines Pharmacy and Industry – Controlled Drugs - DH
Peter Dunlevy	Community Pharmacy Policy Manager - DH
Graham Mitchell	BSA
Paul Brown	HSCIS
Margaret Dockey	BSA
Dr Damian Riley	Medical Director, West Yorkshire Area Team
Margaret Kitching	Director of Nursing & Quality
Carole Pantelli	CDAO Lancashire Area Team
Samantha Travis	Clinical Leadership Adviser NHS England Derbyshire/Nottinghamshire Area Team
Dr James Gossow	Assistant Medical Director – Durham, Darlington & Tees
Bill Rial	CDAO, NHS England – London Region
Sarah Dennison	Controlled Drugs National Manager CQC
Brian Brown	National Pharmacy manager CQC
Dr Stuart Ward	CDAO, Wessex Area Team
Bridget Sampson	Director of Commissioning and CDAO Devon, Cornwall and Isles of Scilly Area Team
Heather Moulder	Director of Nursing and Quality and CDAO Hertfordshire and the South Midlands Area Team
Susanna Taylor	Specialised Commissioning Pharmacist, CDAO NHS England (Leicestershire & Lincolnshire Area)