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National Prescribing Centre

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Handbook for controlled drugs accountable officers in England

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Contents

Section 1

About this handbook

1.1 Purpose of this handbook

The purpose of this handbook is to help Accountable Officers (AOs) to fulfil their role, particularly for those new to the post. The handbook will emphasise legal requirements as well as provide recommendations for further reading. The handbook is intended to supplement existing guidance produced by the Department of Health (DH) to underpin the regulations and will complement any additional face to face training designed to support AOs.

The AO must monitor the use of controlled drugs (CDs) within their organisation and take appropriate action where necessary. The AO will also be responsible for ensuring the safe and effective use and management of CDs within local organisations subject to their oversight.

The day to day duties of the AO may vary depending on the organisation in which the AO is employed; however, the principles of the legislation and the organisational responsibilities of the role will be the same in all environments. This handbook will reflect any specific duties according to the healthcare setting for which the AO has responsibility although all AOs should read and familiarise themselves with the opening chapters and core elements of the role.

Note:
This edition of the handbook has been written to reflect the healthcare organisational structure that presently exists. In time, there will need to be amendments to regulations to reflect changes in primary care. AOs will need to remain aware of future amendments to regulations.

1.2 How to use this handbook

This handbook has been developed to assist all AOs in their role with separate sections covering what this will mean for AOs within different settings. There are however the core responsibilities that must be undertaken by all AOs in all environments. These have been detailed in section 2 of the handbook together with the legal requirements for the role and the associated references within the regulations. Each section can be accessed separately (either online or download) or the complete handbook can be viewed or downloaded as a single document. An AO, or personnel supporting an AO, should review the section/s most relevant to their healthcare setting and utilise the aide memoire checklist, provided for each setting, as a quick reference point.

The aide-memoire checklists are not intended to replace the self-assessment scoring tools for Primary Care Trusts (PCTs) and NHS Acute Trusts provided by Care Quality Commission (CQC) but will help to set a baseline position at a single point in time, such as when a new AO is appointed, from which to move forward with the role.

1.3 Background and introduction to the role of the AO

In response to the Shipman Inquiry Fourth Report[1], the Government introduced a range of measures to strengthen the systems for managing CDs to minimise the risks to patient safety of inappropriate use. The new arrangements are underpinned by the Health Act 2006[2] and The Controlled Drugs (Supervision of Management and Use) Regulations 2006[3] made under the provision of the Act.

The governance arrangements embedded within the regulations are required to be implemented in a way that supports professionals, and encourages good practice in the use of these important medicines, when clinically required by patients. CDs are an essential part of modern clinical care and are used to treat a wide variety of clinical conditions. They are however subject to special legislative controls because there is potential for them to be abused or diverted, causing possible harm.

The requirements and responsibilities of the AO are set out in regulations 3 to 31 of the Controlled Drugs (Supervision of Management and Use) Regulations 2006. The requirements should be implemented in such a way as to work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. The requirements maximise the ability to detect poor practice by combining information gathered in the use and management of CDs with information on other aspects of clinical practice.

The regulations detail the organisational responsibilities for *designated bodies*[a] and include:

- The appointment of an Accountable Office for each healthcare organisation identified as a designated body
- Ensuring that safe systems are in place for the management and use of CDs – including:
  - ensuring adequate and up-to-date standard operating procedures are in place in relation to all activities concerning CDs
  - ensuring adequate disposal and destruction arrangements are in place
- Monitoring and auditing these systems
- Ensuring that the declarations and self-assessments for CDs are undertaken in accordance with the regulations
- Having systems in place to alert the AO of any complaints or concerns involving the use or management of CDs
- Investigating concerns and incidents related to CDs
- Being part of a Local Intelligence Network (LIN), as set up by the PCT AO, of other healthcare organisations, police forces, social service authorities and the relevant inspection and regulatory bodies to collaborate and share information about potential CD offences or actual systems failures.
- Providing the PCT AO with quarterly occurrence reports detailing any concerns about the management of CDs or confirmation that there are no concerns.

All designated bodies, including Primary Care Trusts (PCTs), NHS Trusts, NHS Foundation Trusts and English independent hospitals, have a statutory duty to nominate or appoint a specific individual to be the AO for CDs. The AO is responsible for ensuring the safe and effective use and management of all CDs prescribed, dispensed, supplied and administered in accordance with the services provided and functions of the organisation.

The regulations also set out the duty of cooperation which enables a range of organisations, including health and social care organisations, the Care Quality Commission (CQC), NHS Counter Fraud Services, the General Pharmaceutical Council (GPhC), the police and local authorities to share information and intelligence about the management and use of CDs. The regulations also contains the power of entry and inspection for certain authorised persons, including PCT AOs where applicable, to inspect CDs and associated records with respect to CDs.

As the Health Act 2006 controls the use of CDs as medicines for human use, the role and responsibilities of the AO do not include the safe use and management of CDs for veterinary use. The use and management of CDs by vets and in veterinary premises is covered within separate legislation.

[a] Designated bodies are defined in section 17 of the Health Act 2006. *http://www.legislation.gov.uk/ukpga/2006/28/section/17*

Section

2

Core role of all Accountable Officers

2.1 Purpose of the AO

The AO is responsible for a range of measures relating to the monitoring of the safe use and management of CDs in their organisation. The AO's responsibilities are set out in regulations 8 to 18 of the Controlled Drugs (Supervision of Management and Use) Regulations 2006[3].

The AO is responsible for ensuring:

- every aspect of the journey of CDs within the organisation, or by services provided for which the designated body is responsible, are set out in appropriate and up–to–date standard operating procedures
- adequate destruction and disposal arrangements are in place
- relevant individuals receive appropriate training
- monitoring and auditing the management and use of CDs
- effective routes for reporting concerns or complaints are in place
- adequate records are maintained regarding concerns or complaints
- concerns or complaints are assessed and investigated
- appropriate action is taken to protect patients and/or the public where concerns or complaints are well-founded
- the sharing of information with other responsible bodies regarding the management and use of CDs.

It is a legal requirement that designated bodies acknowledge their commitment to the legislative requirements of the role of the AO and provide sufficient funds and resources to enable the role to be undertaken. Such resources may include information systems, accommodation and support staff.[4] The AO will need to establish robust auditing and monitoring arrangements to assess the management and use of all CDs by health and social care personnel within their organisation as well as efficient reporting and investigation processes of incidents or concerns.

The AO needs to provide assurance to their Board that the CD regulations are being complied with. The way this assurance can be reported will depend on the organisation. The AO could provide reports quarterly (or other suitable time interval to be determined locally) to outline the ongoing monitoring, incidents or poor professional practice investigated and the associated outcomes.

2.2 Who can be an AO?

Regulation 5 of the *Controlled Drugs (Supervision of Management and Use) Regulations 2006* state that an AO of an **NHS designated body** must be an officer or employee of the designated body, and

(i) a member of the board of directors, or the management or executive committee of the designated body,

(ii) a member of the body (howsoever it may be called) that has responsibility for the management of the designated body; or

(iii) is answerable to a person referred to in (i) or (ii) above.

An AO of an **independent hospital** must be its registered manager or one of its officers or employees who is answerable to its registered manager. If the AO is the registered manager, s/he must be answerable to the Chief Executive, Chairman or Managing Director of the hospital.

The AO must be a "fit, proper and suitably experienced person" who does not routinely supply, administer or dispose of CDs as part of their duties. A designated body can nominate or appoint an AO who has an occasional, exceptional role in the use of CDs (for example, in emergencies). However, their use of CDs should be open to the scrutiny of another person to whom they are answerable.

They should have credibility with all healthcare and social care professionals and sufficient seniority to be able to take action regardless

of how a concern is raised. Individuals such as Medical Directors, Pharmacy Directors or Directors of Nursing, can be appointed as AOs if they meet the above criteria. The AO can be a stand-alone or additional role depending on local circumstances.

An AO can assume the role for more than one designated body of the same type in specific circumstances as set out in the regulations.

2.3 Starting point for the role

The key document that an AO must be familiar with fully to understand their role and responsibilities is the *Controlled Drugs (Supervision of Management and Use) Regulations 2006* *(http://www.legislation.gov.uk/uksi/2006/3148/contents/made)*. The Regulations came into force in England on 1st January 2007. To accompany the regulations the DH produced a comprehensive guidance document *'Safer management of Controlled Drugs: (1) guidance on strengthened governance arrangements (January 2007)'* which is available on the Department of Health website. *http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064460*

As the role of AO has been mandatory from January 2007, designated bodies, unless newly established, will have an AO who will have set up systems to manage the use of CDs. However, it would be wise to review these systems whether as an AO new to the role or for existing AOs on a regular basis to ensure they are fully compliant with current legislation. The aide memoire checklists provided in this handbook can help to give an AO a brief overview of the high level systems and processes in place within their organisation. The CQC self-assessment tools for NHS Primary Care Trusts and NHS Acute Trusts are designed for controlled drug designated bodies to assess and score the status of CD governance and suggest actions for areas of improvement. The self-assessment is not a data collection tool but a recommended exercise that should help AOs and their designated bodies assess whether they are complying with guidance and legislative requirements around CDs. *http://www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/controlleddrugs/self-assessmenttools.cfm*

An additional source of information for AOs is the NPC Accountable Officer's website *www.npci.org.uk/cd* which contains links to key relevant legislation, guidance and publications as well as providing supportive resources to enable AOs to fulfil their role effectively. The NPC website has two tiers, one being open access and contains e-learning resources and guidance documents; the second tier is password protected and provides a secure forum for discussions and sharing locally developed documents and resources between all AOs in England and up to three additional nominated support personnel for each organisation.

AOs are not directly notified of any changes to the legislation therefore they must actively check regularly for any amendments or significant changes.

2.4 Notifying the Care Quality Commission

Legal Requirement **– Controlled Drugs (Supervision of Management and Use) Regulations 2006** ***Regulation 4***

A designated body must nominate or appoint a fit, proper and suitably experienced person as its Accountable Officer.

Regulation 4 of the Controlled Drugs (Supervision of Management and Use) Regulations 2006 requires the Designated Body organisations to notify CQC of the appointment of their Accountable Officer.

Notifications can only be accepted by CQC using the on-line web form on their website. *http://www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/controlleddrugs/accountableofficers/accountableofficernotificationform.cfm*
The notification form is password protected. A password can be obtained on request by e-mailing, enquiries@cqc.org.uk, from your NHS or Independent Healthcare e-mail address,

quoting your name, role and organisation.

The regulations also require any changes of the Accountable Officer appointment to be notified to CQC. This is done using the same on-line notification form. The register of Accountable officers is published on the CQC website, which is updated on a regular basis.

It is recommended that new AOs contact the chair of the LIN to inform them of their appointment. The LIN chair can often provide additional support for those new to the position. Details of all AOs can be found on the register maintained on the CQC website.
www.cqc.org.uk/publications.cfm?de_id=15975
The CQC website CDs pages provide detailed information and self-assessment tools for AOs.
www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/controlleddrugs.cfm

2.5 Establishing and delegating the tasks required

Legal Requirement **– Controlled Drugs (Supervision of Management and Use) Regulations 2006** ***Regulation 11***
AOs need to develop and implement systems for routinely monitoring the use of CDs, through pro-active analysis and identifying triggers for concern, then taking action if required.

The extent of the tasks required for effective discharge of the AO role can be significant due to the scope of responsibilities of the designated body. In particular PCT AOs will be responsible for ensuring arrangements are established for the safe management and use of CDs by healthcare providers not covered by other AOs within the PCT geographical area – for example prisons, private practitioners. Further information regarding the responsibilities of the PCT AO are detailed in section 3.1 of this handbook.

It is recommended that AOs work with others in their organisation to implement fully the requirements of the role. The additional staff required will depend on the designated body and the size of the organisation. In some cases there is no power to delegate the AO's authority, such as appointing CD destruction witnesses; however it may not be necessary for the AO personally to undertake all the operational tasks associated with the role requirements. Where tasks are undertaken by members of staff assigned delegated duties they must be adequately trained. **Whilst the AO may delegate some aspects of the role, the *responsibility* cannot be delegated and there needs to be clarity of accountability.** The AO can be supported by a named senior pharmacist such as the Head of Medicines Management in a PCT, Chief Pharmacist of an acute Trust or Pharmacy Manager of an Independent hospital. For many hospices, the AO will be supported by the Chief Nursing Officer.

2.6 Safe operational systems and practices

Legal requirement **– The Controlled Drugs (Supervision of Management and Use) Regulations 2006** ***Regulation 9***
The regulations require AOs to ensure that his or her organisation, or a body or person acting on behalf of, or providing services under contract with his or her organisation, has adequate and up-to-date Standard Operating Procedures in relation to the use of controlled drugs.

The regulations require each healthcare organisation to have standard operating procedures (SOPs) for the use and management of CDs, having regard to best practice. The regulations also require AOs to ensure these SOPs are adequate, up-to-date and effectively communicated throughout the organisation in relation to **all** activities relating to CDs.

The SOP should be *'an unambiguous document describing the responsibilities and the procedures, including audit, necessary to safely and accountably manage any set of processes, in this case around the total management of CDs'.*[5] It must remain a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of

CDs within a specific organisation or environment.

In addition the SOP should:

1. Improve governance of CDs within the organisation
2. Provide clarity and consistency for all staff handling CDs
3. Define accountability and responsibilities and clarify where responsibility can be delegated
4. Ensure practice is in line with the regulatory frameworks
5. Be used as a training tool for new and existing staff.

Detailed guidance on standard operating procedures for CDs can be found on the DH website. *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064828.pdf*

The standard operating procedures must, in particular, cover the following matters:

(a) who has access to the CDs
(b) where the CDs are stored
(c) security in relation to the storage and transportation of CDs as required by misuse of drugs legislation
(d) disposal and destruction of CDs
(e) who is to be alerted if complications arise
(f) record keeping, including:
  (i) maintaining relevant CD registers under misuse of drugs legislation, and
  (ii) maintaining a record of the CDs specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (specified CDs to which certain provisions of the regulations apply) that have been returned by patients.

SOPs must be established and operational for all identified activities where risks to patients, staff or public safety from inappropriate management and use of all CDs is evident. A detailed process mapping exercise should be undertaken to determine the areas of high priority based on a risk assessment. The map should include all areas of activity and personnel that have contact or are involved with CDs irrespective of how little their involvement may be. It is easy to overlook activities that may seem harmless or minimal, but in reality may demonstrate a weakness in the systems for ensuring the safe management, security and use of CDs.

A risk assessment is an important step in protecting patients, staff and public, as well as complying with the law. The process helps to focus on and prioritise the risks that have the potential to cause real harm. A variety of risk assessment tools are in use within healthcare organisations and the AO should consult an appropriate expert for advice if in doubt on how to undertake a risk assessment or what documentation to use. (Section 2.11 of the handbook provides greater detail of tools used for risk assessment for the determination of severity of an incident or concern).

The SOPs should be reviewed on a regular basis, using appropriate methods such as audit, survey or observed practice. Determination of frequency of review interval must in the first instance be based on ensuring patient safety; however some consideration should also be given to organisational factors. A well established and effective procedure may need to be reviewed annually or possibly biannually, although some environments would require more frequent review. It is not necessary for the AO to be involved in the detailed operational aspects of the review but must be satisfied that the SOPs are fit for purpose and up to date. For some high risk activities, as prioritised through the risk assessment process, the AO should take an active role in the SOP review.

2.7 Appointment of approved witness for the destruction of Schedules 1-2 controlled drugs

Legal Requirement **– The Controlled Drugs (Supervision of Management and Use) Regulations 2006** ***Regulation 10***

An AO must ensure that their designated body establishes and operates appropriate arrangements for securing the safe destruction and disposal of CDs.

Healthcare environments and individual healthcare practitioners required to maintain a register for CDs may have stock that is no longer usable such as obsolete, expired and unwanted CDs that must be destroyed. The destruction must be carried out in the presence of an authorised witness.

It is important to differentiate between CDs that require a witnessed destruction, and CDs returned to a pharmacy by a patient that should be destroyed as soon as possible in order to avoid storage problems and an increased security risk. Patient-returned CDs can be destroyed without the need for an authorised witness to be present though it is advisable to record the destruction and to ensure another member of staff witnesses the destruction.

From August 2007 an amendment to the Misuse of Drugs Regulations 2001 gave AOs the power to authorise people to witness the destruction of stock CDs. In most NHS Trusts, Foundation Trusts and independent hospitals including hospices, the AO will authorise senior members of staff that are not involved in the day to day management or use of CDs. In primary care the AO will need to authorise appropriate people or groups of people who can witness destruction of CDs. In some organisations the Controlled Drugs Liaison Officers (CDLOs) have been authorised by the AO to carry out this function. Those who are also police officers still retain the power to carry out this function but civilian CDLOs do not and therefore would require written authorisation to enable them to witness the destruction of drugs during inspection of premises.

Any individual authorised to witness destruction should receive appropriate training including recording requirements and safe disposal procedures. The individual should also be subject to a professional code of ethics and/or have been the subject of standard Criminal Record Bureau (CRB) checks. The AO must be assured that robust SOPs for the safe storage of CDs to be destroyed are adopted by the designated body and effective SOPs are used at all times by authorised witnesses.

The DH have produced detailed guidance on destruction of CDs for AOs at: *http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078034*

2.8 Education and training

Legal Requirement **– The Controlled Drugs (Supervision of Management and Use) Regulations 2006 *Regulation 13***

The AO is required to ensure there is adequate training in place for individuals working with CDs.

The AO must be assured that all individuals working with CDs either as employees of the designated body or as commissioned or contracted service providers, have received appropriate training to carry out their responsibilities. A training requirement should be included within service level agreements or commissioning/contracting agreements. This will include anyone prescribing, supplying, administering, transporting or disposing of CDs. Induction training should include the necessary aspects required for safe use and management of CDs followed by regular updates as and when appropriate. The AO must ensure organisational processes are established and are effective to communicate information to all relevant individuals.

Regular briefings should include examples of good practice, issues or concerns to be aware of, any changes to SOPs, signposting to educational resources such as the on-line training available on the NPC website, and the availability of training workshops or one-to-one support.

Examples of newsletters from AOs and LINs around the country can be found by logging into the Shared Resources section of the NPC Accountable Officer's website. *www.npci.org.uk/cd/ao/ao_shared_resources.php (password required)*

2.9 Audit and monitoring of activity

Legal requirement* – The Controlled Drugs (Supervision of Management and Use) Regulations 2006 *Regulation 14
AOs must monitor and audit the management and use of controlled drugs by relevant individuals, and monitor and assess their performance.

As a result of the mapping process and review of SOPs the AO should have a clear picture of which CD related activities within the system require audit and monitoring.

Carefully controlled and well developed audits should be undertaken within each environment handling, administering, prescribing or dispensing CDs. The purpose of the audits must be to assess the activities being carried out in that environment in order to determine the effectiveness of those activities to minimise and control the risks associated with CDs. Poorly constructed audits may achieve data collection but provide no meaningful measure of the standards of activities or risks and issues relating to the safe management and use of CDs within that environment. AOs should seek advice from clinical and operational audit experts, or if this is not possible, the shared practice and lessons learnt from other AOs, before initiating audit plans.

Examples of audits undertaken by AOs have been uploaded to the Shared Resources section of the NPC Accountable Officer's website. *www.npci.org.uk/cd/ao/ao_shared_resources.php (password required)*

When using an audit developed by a different organisation, care should be taken to ensure it meets the specification of the audit task for the targeted activity.

All prescribing and requisitioning activity of CDs must be monitored at regular timely intervals, to identify unusual supplies and/or trends of inappropriate prescribing patterns. The AO should establish ongoing monitoring arrangements in order to be able to report quarterly to the LIN.

The systems and processes used for this task will be specific to each organisation, for example the electronic data collection and analysis provided by the NHS Business Services Authority (NHSBSA) Information System, will be used by all PCT AOs. The system has three parts, *ePACT*[b]*.net, PCT prescribing reports and Prescribing Toolkit*. ePACT is able to provide the AO with electronic information about the NHS and private CD prescriptions dispensed or supplied, and the PCT prescribing reports provides the information regarding requisitions for schedule 2 and 3 CDs that have been dispensed or supplied in the community. The information provided by the system is based on the forms returned to the NHSBSA Prescription Services by pharmacies and GP practices on a monthly basis. The use and limitations of *ePACT.net and the PCT prescribing reports* are covered in greater detail in section 3.1 of this handbook.

The NHSBSA also provides a *Hospital ePACT.net* system for NHS hospital trusts to access the electronic information for hospital prescriptions dispensed in the community. This information may include some CD prescriptions written by hospital clinicians. In some locations this may be quite significant if all the hospital out-patient clinics prescribe using hospital NHS prescription pads for dispensing in the community.

Almost all CD prescribing within an NHS hospital environment will be through internal supply arrangements with the hospital pharmacy. The electronic dispensing systems in the pharmacy will provide detailed reports for analysis of CD prescribing and dispensing activity of all clinicians working within the hospital.

Independent and voluntary sector organisations may also have electronic data capture systems for recording the prescribing, requisitions and supplying of CDs, although many may also operate with manual recording systems. Whatever recording system operates the AO must ensure that the systems are effective for monitoring activity and highlighting any unusual trends or inappropriate prescribing. It may be necessary to audit the established systems and processes to confirm that assurance.

[b]ePACT — *electronic Prescribing Analysis and CosT*. Part of the NHS Business Services Authority Prescription Services information system
http://www.nhsbsa.nhs.uk/PrescriptionServices/3166.aspx

Electronic data capture systems have the capability of providing AOs and their support teams with considerable amounts of information and reports. AOs may need to rely on their support personnel to provide the expertise to refine the requirements of a report or to interpret the data. Without these skills the AO will not achieve the essential task required within the regulations for the effective monitoring of prescribing, dispensing and movements of CDs.

The requirements for monitoring and audit cover all CD related activities and AOs must ensure that sufficient attention is given to monitoring the other activities covered by SOPs such as ordering, administration, storage, record keeping, transportation and disposal of CDs. Where the practice of individuals is raised as a concern, either through monitoring activities or from a complaint, the AO must take steps to record the concern, investigate further and take appropriate actions to safeguard patients and public.

2.10 Sharing information

Legal Requirement **– The Controlled Drugs (Supervision of Management and Use) Regulations 2006 *Regulation 18***

The regulations require that the AO must establish and operate appropriate arrangements for ensuring the effective sharing of information regarding the management and use of CDs.

The regulations place a statutory duty for each designated body to share information and concerns regarding the management and use of CDs with other designated and responsible bodies such as police forces, local authorities, and the relevant inspection and regulatory bodies to share suspected or confirmed poor practice and potential or actual systems failure. The information sharing will include sharing concerns relating to the CD activities of healthcare and social care staff and professionals that have come to the AO's or responsible body's attention.

Part 4 of the regulations set out the duty to share concerns about CD handling. This may include sharing names of individual professionals. The principles that underpin the regulations are akin to the sharing of information relating to child protection matters. There is a need to consider the potential harm for not sharing and to balance the concerns about naming individuals in a secure manner.

When sharing information, organisations must comply with the Data Protection Act 1998 and The NHS Codes of Confidentiality[6]. However, the 2006 regulations include a general provision for a responsible body to share personal information with any other responsible body about an employee of the organisation, or any person contracted or commissioned to provide services for the organisation, where patient safety is at risk. This requirement takes precedence over the Data Protection Act.

Further details can be found in the DH guidance on the Safer Management of Controlled Drugs (Safer management of controlled drugs: Guidance on strengthened governance arrangements) Department of Health 2007. *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064458.pdf*

An AO or a LIN has no remit for the misuse of CDs by patients or members of the public. If patient identifiable information is included within the details of the incident or concern relating to staff or professionals, then the following Caldicott Principles apply to the information about the patient:

- must be able to justify the reason for information sharing
- patient identifiable information should not be used unless it is absolutely necessary and then use the minimum necessary patient identifiable information
- access to patient identifiable information should be on a strict need to know basis.

Further information regarding the use of patient identifiable information can be found in Regulations 25 and 26 of *The Controlled Drugs (Supervision of Management and Use) Regulations 2006*[3].

The sharing of the information may be through the quarterly LIN meetings, although if there is a major concern, it may be necessary to share the information more urgently outside of the regular meeting.

AOs should endeavour to meet with the organisation's Information Governance lead to ensure the legislation regarding information sharing and storing is adhered to. However, Information Governance leads may be unaware of the specific duties and powers of AOs and may try to limit them. AOs must be sure that this does not happen. The Chair of the LIN will also be responsible for ensuring processes used for information sharing within the confines of the LIN are also compliant with legislation. It may be helpful for an expert in this field to attend a LIN meeting to review the processes involved relating to data management by the LIN.

When dealing with information, the police service is also required to work to the *Guidance on the Management of Police Information*[7] (MOPI). It is recommended that Chairs of LINs make contact with their local police force and ensure that Information Sharing Agreements (ISAs) are in place.

A Memorandum of Understanding (MOU) has been agreed between the Association of Chief Police Officers (ACPO), Crown Prosecution Service (CPS), Nursing and Midwifery Council (NMC), and General Medical Council (GMC) in order that these organisations may co-operate to promote public and patient safety. The aim of the MOU is to promote public and patient safety and sets out the principles of joint working between the signatories. The MOU also contains details of how the information will be shared and managed. *http://www.gmc-uk.org/about/partners/joint_agreement.asp*

The General Pharmaceutical Council (GPhC) has MOU for the sharing of information with government and national agencies and representatives from the Council work with other bodies on joint projects and co-operate on investigations at a local level. Details of the agencies GPhC work with can be found on their website. *http://www.pharmacyregulation.org/aboutus/whoweworkwith/governmentandnationalagencies/index.aspx*

Further details regarding aspects of information governance can be found on the Information Commissioner website. *www.ico.gov.uk*

2.11 Incident or concern reporting and recording

All incidents or concerns involving the safe use and management of CDs must be reported to the organisation's AO. It is important to differentiate between purely clinical incidents involving CDs (which might be serious for clinical reasons) and 'process' incidents which could help to identify a misuse problem. The organisation will already have a system for recording and evaluating clinical incidents (for example, the *Datix* system used by many NHS trusts), however, the AO should ensure that they see these reports.

The details of the incident or concern should be recorded and investigated where appropriate using locally agreed procedures. The information must be recorded on an internal secure database with restricted access. Often incidents in isolation may not require wider investigation but should still be recorded and stored for future review for trends that may develop. Incidents that are considered to be serious enough should be reported as an organisational Serious Incident (SI). The AO should establish a risk assessment process for determining the seriousness of an incident or concern. The process should be capable of assessing the risk to patient or public safety and the likelihood of that risk becoming reality. There are a number of assessment tools in use throughout the health and social care sectors, although the AO should seek advice from the organisation's clinical governance or patient safety lead on which tool to adopt.

The outcome of the risk assessment for the incident or concern will determine whether

the matter should be reported as a SI and if immediate action is required. The assessment may indicate that the matter is unlikely to cause serious harm or is unlikely to be repeated and therefore it may be sufficient for the details of the assessment to be recorded on the quarterly occurrence report submitted to the PCT AO and subsequently the LIN. However, AOs should exercise caution when using some of the risk assessment tools established within some organisations and should review all CD incidents. The rigid use of a risk matrix might mean some potentially very serious incidents are not thoroughly investigated because their occurrence is rare or other incidents where the possible consequences seem minor, however if a number of apparently minor incidents are considered together, then it can provide a very different picture.

Further details of risk assessment processes within healthcare settings can be found on the National Patient Safety Agency (NPSA) website. *http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/risk-assessment-management/*

Where concerns are serious and patient safety is at risk or a professional's fitness to practise may appear to be impaired, local measures will usually be taken immediately while a swift investigation takes place. Those findings will then dictate whether the relevant regulatory body is informed. In the case of a medical practitioner on a PCT performers list, the Responsible Officer for that PCT should be consulted. Where concerns appear to be minor, further local investigation may be more appropriate.

The National Clinical Assessment Service (NCAS) provided through the NPSA has been established to help healthcare managers and practitioners (doctors, dentists and pharmacists) to understand, manage and prevent performance concerns. The service can be contacted by AOs for advice and guidance where there is concern regarding the professional practice of a practitioner. *http://www.ncas.npsa.nhs.uk/*

The AO must establish effective communication channels within their organisation to ensure they are made aware of relevant incidents or concerns reported from all areas. Occasionally, a colleague of a health or social care professional may have serious concerns about the actions of that person relating to patient safety or diversion of CDs. The Public Interest Disclosure Act[8] gives employees protection under the law to raise any concern they may have with their employer. This has been further backed up by the NHS Constitution[9], which incorporates the right of all staff who report wrongdoing, often referred to as *whistle blowing*[10], to be protected. Each organisation responsible for the provision or commissioning of healthcare or social care should have a whistle blowing policy that should be known to all personnel working within that environment or for the organisation. The AO should ensure this policy is embedded within the organisation and effective systems are in place to put policy into practice. All staff must understand the ways through which they can raise a concern.

This can pose a challenge to AOs, especially in large organisations with multiple departments and service providers. Senior management colleagues must be made aware of the statutory responsibilities of the AO and support this function by disseminating communications regarding incident or concern reporting or whistle blowing policies and procedures through their teams.

Information regarding potential risks to patients from the use or management of CDs may be passed to the AO in the form of a concern or a reported incident. Concerns may be raised through a variety of routes. In some circumstances the AO may receive verbal information from a staff member or a patient who may be unwilling to make a formal written report. The AO will need to assess the validity of the information received without compromising the anonymity of the informant.

The AO must report all relevant incidents and concerns to the LIN through the lead AO. It is for the LIN lead AO, in consultation with colleagues, to decide whether any issues reported require

further joint or cross sector investigation. In situations where LINs are made up of more than one PCT, each of the PCT AOs will be responsible for deciding whether any incidents reported in their specific PCT requires further investigation.

2.12 Investigating concerns and incidents

Whichever route or system is used to identify the issue or concern, the AO will need to initiate an investigation. The extent and scope of the investigation will be determined based on the initial facts presented, although there will need to be some flexibility to the scope as additional facts emerge. A risk assessed approach should be taken by the AO for the invesztigation of incidents reported such as accidental spills, irreconcilable CD register balances of exceptionally small quantities or one-off prescriptions for quantities in excess of prescribing recommendations.

The AO should follow agreed organisational procedures for conducting an investigation and may wish to seek advice and guidance from professional regulatory bodies and the police CDLO at the earliest opportunity regarding issues such as:

- who (which body) would be most appropriate to conduct the investigation
- recommended actions to avoid compromising an investigation
- the process for gathering evidence, and
- processes for recording and storage of evidence.

The advice of the professional regulator (and/or the appropriate Responsible Officer) will be essential if a determination of professional malpractice and removal from a professional register is a potential outcome. Equally the advice of the CDLO will be essential if the outcome of the investigation may lead to a criminal prosecution. Where this is the case, the CDLO should be consulted **before** any investigation is commenced so as to avoid the risk of compromising evidence.

It is advisable for the AO, at the start of any investigation, to maintain a contemporaneous record of hand written notes in a hard bound book. The entries should be dated and signed and all amendments should be initialled. The record of actions by the AO could be a valuable aide-memoire, and in some circumstances be used as evidence, in the event of further action being necessary by either a criminal investigation team or a professional regulator.

Some incidents may require the involvement with other organisational leads such as performance or contract monitoring and clinical governance when reviewing the incident at the outset and when carrying out the investigation.

If an investigation is to proceed the AO should convene an incident panel, in accordance with organisational policies, to adjudicate on the case. The terms of reference and membership of the panel should be established at the start of the investigation process, including any specific expertise necessary, together with an agreed procedure for an appeals process if deemed appropriate. The outcome of the investigation must be reported to the LIN that will, in turn, decide if further cross sector investigations and expert panels are required.

There are a number of support tools that can be used to identify the source of an issue and one that is often used within healthcare settings is the '*Root Cause Analysis*'[11] tool. This can be used alone or in combination with a *'cause and effect'* flow chart. Further information on appropriate tools for investigation can be found on the NHS Institute for Innovation and Improvement website. *http://www.institute.nhs.uk/quality_and_service_improvement_tools/*

The key to a successful investigation is to seek advice from people with appropriate expertise, avoid assumptions and logic traps and encourage the investigating team to keep drilling down to the real root cause. The processes and personnel involved in the investigation and subsequent decision-making regarding the outcome and actions from an incident or concern must be clearly separated.

Organisations that currently do not have procedures for conducting investigations should endeavour to develop these as soon as practicable to ensure they are agreed and adopted throughout the organisation in advance of the start of any investigation. AOs may find the shared resources section of the NPC website helpful when considering the development of such procedures.

2.13 Occurrence reports

Legal Requirement **– The Controlled Drugs (Supervision of Management and Use) Regulations 2006** ***Regulation 29***

All AOs are required to produce quarterly reports of their CD occurrences and submit the report to their PCT AO. The PCT AO will submit these reports to the LIN.

It is the responsibility of each PCT AO to provide CD occurrence reports, in accordance with agreed procedures, relating to the organisations that he or she is responsible for, to the LIN.

PCT AOs must establish effective mechanisms for receiving the following from the AOs of the designated bodies operating within the geographical boundaries of the PCT:

- regular reports of incidents or concerns (a minimum data set of information should be adopted for this purpose)
- 'nil' reports where no CD occurrences have been reported
- exception reports outside of the quarterly cycle that require rapid response.

Where the LIN is made up of more than one PCT the lead PCT must ensure all participating PCTs submit the appropriate occurrence reports on the dates required. It is the responsibility of the PCT AO leading the LIN to have a mechanism for receiving occurrence reports from all the PCT AOs and have an efficient process for receiving and documenting exception reporting outside of this cycle. The role of the PCT AO leading the LIN is covered in more detail in section 3.1.5

The occurrence reports will be reviewed at the LIN meeting, in accordance with LIN procedures, to cross reference concerns between organisations and to ensure appropriate action has been taken by each organisation. LINs should endeavour to focus attention on the sharing of intelligence and developing appropriate actions rather than scrutinising operational details of every CD incident.

Many LINs use an adapted version of the template occurrence form that was originally developed by the previous Healthcare Commission. This document can be found in Appendix 2 of the handbook. Some LINs are also developing new methodologies for occurrence reporting.

Aide-memoire checklist # 1 — AO core role

(Always complete checklist # 1 before completing any further checklists)

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Starting point for the role	I have read the relevant legislation within the Controlled Drugs (Supervision of Management and Use) Regulations 2006				
	I have read and understood the responsibilities and tasks required of the AO for my organisation *'Safer management of Controlled Drugs: (1) guidance on strengthened governance arrangements (January 2007)'*				
	I have reviewed the CQC self-assessment tool provided for my organisation (NHS Primary Care Trusts and NHS Acute Trusts) The tool should be completed by .....[insert date]				
	The following people provide advice and support to the AO				
	Name / **Role** / **Email** / **Telephone**				
Notify the CQC	The CQC have been notified of the appointment of the AO				
Establishing and delegating tasks and duties	The Board will require the following report/s (Tick all that apply) :				
	Annual				
	Quarterly				
	Monthly				
	Other:				
	Each report must contain the following information as a minimum: (Tick all that apply)				
	Name of the current AO				
	Update in internal monitoring activity/reporting				

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
	Dates of LIN meetings since last report (optional to include copies of minutes)				
	Dates of any regional AO meetings / other meetings attended				
	Current investigations (but not any confidential detail)				
	Confirmation that all statutory requirements are met				
	Confirmation that all official guidance is met or proposals made to meet the guidance				
	A quarterly occurrence report is provided to the PCT AO and must contain the following information as a minimum:				
	Nil concerns (if applicable)				
	Brief description of concerns				
	How each concern has been managed				
	Date each concern became known				
	The following groups of people have been informed of the name and contact details of the AO:				
	Chief Executive Officer				
	Senior management team				
	Clinical managers				
	Governance leads and Responsible Officer				
	PCT AO				
	PCT AO leading the LIN (if different from above)				
	Independent practitioners (PCT AO only)				
	External stakeholders (local authority, CDLO, Police, GPhC)				
	Other:				
Process mapping	A comprehensive process mapping exercise has been carried out to identify all areas of CD related activities within the organisation				
	Each of the activities has been risk assessed				
	Each of the activities identified through this process has a standard operating procedure (SOP)				

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
	The following groups of staff/clinicians are involved in CD related activity				
	List all identified (e.g. doctors, community nurses, nurse prescribers, prison healthcare manager, ward nurses, paramedics, porters)				
Safe operational systems and practices	Procedures have been established for: Regular assurance of SOPs used within the organisation and by organisations/personnel providing services for the organisation				
Audit and monitoring of activity	Procedures have been established for the regular monitoring through audit/information systems/other methods (include all identified activities):				
	CD prescribing [state process and frequencies……..]				
	CD supplies				
	CD administrations				
Sharing information	Procedures have been established for:				
	Safe storage of information				
	Secure transfer of information between relevant organisations/personnel				
	All procedures and polices for storage and sharing information comply with the Data Protection Act and Caldicott Guidance for patient-identifiable information				
	Information sharing policies include a procedure for the sharing of personal information to take precedence over the Data Protection Act if necessary				
	The information governance lead for the designated body has reviewed the policies for information storage and sharing in the light of the requirements of the *Controlled Drugs (Supervision of Management and Use) Regulations 2006*				

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Incident or concern reporting and recording	Procedures have been established for:				
	CD incident reports to be sent to the AO				
	Raising a concern (either verbal or written) relating to the safe management and use of CDs to the AO				
	Safe storage of incident reports/concerns				
	Serious CD issues to be escalated to the LIN for urgent attention				
	Collating information to include within quarterly report to PCT AO				
	Providing a route for exception reporting				
	Providing a route for individuals to raise confidential verbal concerns				
	Providing a route for reporting from external providers (such as community pharmacies, dispensing doctor practices, social care home support personnel)				
	Other:				
Investigating concerns/issues	The organisation has a policy for:				
	Conducting/investigating complaints/concerns or serious incidents involving CDs				
	Convening an incident panel				
	Escalation processes to LIN/Police/Professional regulator/PCT Performance Decision Making Committee				
	Appeals process				

Appointment of approved witnesses for destruction of CDs

The following witnesses have been approved for CD destruction

Name	Organisation	Email	Telephone	Profession or date of CRB check	Date SOP signed	Date of review

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Education and training	Induction training is provided to all personnel working with CDs				
	Regular update training is provided to all personnel working with CDs				
	A newsletter or some form of regular news briefing is provided to all personnel working with CDs				
	Where a particular issue is identified ad hoc training will be provided for example one-to-one sessions, small team talks				

AO core role personal action plan		
Action identified	**To be completed by**	**Date completed**

Section 3

Information relating to specific bodies

Section 3

This section of the handbook contains information relating to specific healthcare environments that would require the AO of that organisation to undertake duties in addition to the core tasks outlined in the previous section.

The types of healthcare environments identified within this handbook are not exhaustive and further information will be added as the scope of those organisations registered with CQC expands and the health and social care landscape develops.

3.1 What this means for Primary Care Accountable Officers

3.1.1 The extended scope of the PCT AO role

The PCT AO has a number of additional responsibilities as set out in the *Controlled Drugs (Supervision of Management and Use) Regulations 2006* by virtue of the PCT being the statutory NHS commissioning body for a defined geographical area.

If a healthcare organisation or private practice[c] is not identified as a controlled drug designated body (see section 1) it will therefore not require an AO. Assurance of the safe use and management of CDs for that organisation or practice operating within the defined geographical area will become the responsibility of the PCT AO for that area unless subject to another regulator for this purpose, e.g. GPhC for community pharmacies. All healthcare professionals will be accountable to their own professional regulator for the standard of their professional practice.

The responsibility of the AO will include ensuring the governance, systems and processes adopted by these organisations and/or practitioners are satisfactory to assure the safe management and use of CDs in whatever circumstances they are being used, stored, transported, prescribed or dispensed.

For example, the PCT AO has responsibility for (list not exhaustive):

- GP practices,
- Dispensing doctor practices
- Community Pharmacies contracted to provide a specific service other than a Part 2 Pharmaceutical Service[d]
- Dental practices
- Private providers of healthcare services
- Private clinic environments not required to appoint their own AO
- Prison health
- Practitioners in Mountain Rescue teams

The responsibility of the PCT AO spans all NHS activity as well as private activity within environments that are not otherwise registered with CQC. In some cases, depending on the healthcare activity being provided in a private environment, the lead clinician may be a medical practitioner who provides services for an NHS organisation for some of his professional time. In these situations, the organisation may not be required to register with CQC, although this will be dependant on the nature of the healthcare activity being undertaken.

The core functions (section 2 of the handbook) of an AO's role will apply to the PCT AO for each of the identified service providers such as outlined above. Sometimes identification of the full range of providers can be difficult and PCT AOs will need to adopt effective methods to map the prescribing, supply, administration and movements of CDs around the area. Each of the providers or environments that have any involvement with CDs, however minimal, will be required to establish and maintain robust SOPs for the activities being undertaken.

[c] A private practice may operate with one or a number of practitioners providing private service/s

[d] Part 2 Pharmaceutical Service refers to services provided by community pharmacists under the NHS terms of service as laid out in The National Health Service (Pharmaceutical Services) Regulations 2005

3.1.2 Essential links and contacts for the PCT AO

The PCT AO should form collaborative links with professional standards panels within the PCT that deal with performance and conduct issues of health professionals. There may be overlap between general performance of a healthcare professional and the management, administration or prescribing of CDs. In particular the PCT AO should establish collaborative processes and an information sharing agreement with the *Responsible Officer* appointed for the organisation.

The Responsible Officer will be a licensed senior doctor in a healthcare organisation, who takes personal responsibility for those aspects of the local clinical governance systems which deal with the performance, professional competencies and conduct of doctors. In order to carry out their duty, Responsible Officers will need to work closely with the GMC over issues relating to the professional revalidation and to the fitness to practise of individual doctors[12].

Issues of concern relating to the safe management and use of CDs by a doctor, where the doctor's fitness to practice is in question, should be shared with the Responsible Officer in order that appropriate actions can be taken to ensure patient safety. Equally, information obtained by the Responsible Officer relating to CDs should be reported to the AO. Where a practitioner is the subject of an investigation, decision making will need to be undertaken jointly with the chairman of the PCT Performance Decision Making Committee. Further information regarding the Performers List Regulations (2004) can be found in the guidance document *Primary Medical Performers Lists – Advice for Primary Care Trusts on List Management* on the Department of Health website.

PCT AOs should secure links with senior commissioning managers responsible for the annual contract monitoring of all independent contractors. Strong links with the professional standards inspector of the GPhC, other professional regulators and Police CDLOs are essential to ensure the relevant information is shared with the AO.

3.1.3 Processes for PCT AO assurance of safe management and use of CDs

As outlined in section 3.1.1, the PCT AO is responsible for assuring the safe management and use of CDs by a number of healthcare providers commissioned or contracted to provide services by the NHS or providing private services within the geographical area of the PCT. An example of a private sector commissioned service handling CDs would be the pharmaceutical supply service provided by a community pharmacy, commissioned by the PCT for the local prison or private paramedic services working alongside staff from an NHS Ambulance Trust (Independent Ambulance Services will be required to be registered with CQC from 1st April 2011)

Irrespective of the sector or organisation providing the service, the regular assurances required to the PCT AO of safe operating and handling procedures for CDs remains the same. Assurance processes should cover all activities including the prescribing by all identified prescribers both NHS and private medical services, the dispensing and supply of CDs from pharmacies/dispensing practices (through a requisition or private prescription process) and the supply of CDs to patients (or patient representatives).

The following methods of assurance should be adopted by PCT AOs in order to identify unusual trends of practice that may require further investigation or identification of concerns involving misuse of CDs.

- **Provider submission of self-assessment declaration – Regulation 12**
  The AO may request that a declaration of assurance of appropriate CD management for the prescribing, possession and administration of CDs is made by:
  - All general medical and dental practitioners on the PCT's performers

lists. This is covered by Regulation 12 of *The Controlled Drugs (Supervision of Management and Use) Regulations 2006*
- o Other service providers operating within the area (other than those inspected by GPhC or CQC). Although not covered within the regulations, it would be considered good practice for the AO to request a declaration of assurance from these providers.

DH guidance for monitoring and inspection in primary care is available and provides AOs with best practice guidance for carrying out inspections and monitoring of primary care providers. '*Monitoring and Inspection guidelines: Core Activities for CD Monitoring and Inspection Work – Primary Care.*' Department of Health, January 2007. *www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4132228*

- **Routine and ad-hoc premise inspection by AO – Regulation 19**
  Whether or not declarations are received, the AO must either inspect personally, or authorise an individual to inspect, the GP and dental practices as well as all provider services (other than those inspected by GPhC or CQC) and other premises where CDs are managed or used.

  The inspection must ensure that the CDs are stored appropriately, the correct documentation is used and SOPs are in place for the management of CDs. The inspection can be unannounced, although the AO may wish to arrange the inspection in advance. Following the inspection, the practice/organisation should receive a written report with any actions to be taken. Follow-up may be required if there are concerns. It is recommended that standard inspection templates are used. A self-declaration and inspection template is included within the DH guidance for monitoring and inspection (see above). The review should be based on benchmark analysis derived from existing information, incident reports, the provider's self-assessment and declaration (for GP and dental practices) and reports from any routine visits carried out by the professional regulator and/or the AO.

  An NPC competency framework for the monitoring and inspection of CDs in Primary Care was developed in anticipation of the 2006 Regulations and remains a useful tool for AOs today.
  www.npc.co.uk/prescribers/resources/cdi_competency_framework.pdf

- **Prescription monitoring through electronic data analysis systems such as ePACT[b]**
  The ePACT data analysis system is one of the tools provided to the NHS by the NHSBSA for the purpose of monitoring the prescribing and dispensing of all prescriptions across England for almost all treatments listed within the British National Formulary (BNF) and some non BNF products. The system allows the detailed mapping of prescribing trends and activities at regional, PCT, practice and prescriber levels. To use the system effectively AOs may require the assistance of support personnel within the PCT for the monitoring of CD prescribing and dispensing.

  With the introduction of private CD prescription forms (FP10PCD) in 2006, the ePACT system was adapted to allow analysis of both NHS and private prescribing of all Schedules 2 and 3 CDs.

  To support AOs, their support teams and commissioners, The Information Centre (IC) has produced two key guidance documents to help with utilising ePACT to maximum benefit:

  - o Monitoring the prescribing of CD injections using ePACT.net
  - o Monitoring the prescribing of unusual or abnormally high quantities of Schedule 2 and 3 CDs using ePACT.net

  Both documents can be accessed from the IC website:

http://www.ic.nhs.uk/services/prescribing-support-unit-psu/using-the-service/support/controlled-drugs

Once the specified data has been downloaded from the ePACT system the challenging part is trying to identify anomalies in prescribing, such as high quantities on individual prescriptions or trends in prescribing of CDs from one particular practice or prescriber. The system will only provide raw data; it is for the AO or support personnel to interpret the data and investigate activities or concerns that come to light. It is worth trying to relate changes in prescribing data to changes at practice level, such as practitioners arriving and leaving or going on extended leave. Preliminary investigations can include scrutiny of GP prescribing systems, enquiries with community pharmacists or, where necessary, recall of prescription forms.
It is recommended that prescribers are made aware that their prescribing is reviewed on a regular basis and the methods used by the AO for the review.

Analysis of CD injections and oral preparations should be scrutinised separately. Ideally practices should be compared in terms of quantities prescribed. Prescriptions thought to be for quantities greater than 30 days supply, based on a defined maximum daily dose (BNF or other appropriate clinical guidance), should be analysed further, though the 30-day limit is only guidance and not a legal requirement.

- **Limitations of ePACT**
  As with any data analysis system, there are some limitations due to data coding inputting errors, search criteria or historical data capacity. AOs should adopt a system for archiving ePACT reports as every month, when the new data arrives, the oldest month is removed as the ePACT system only covers the last 5 years. This may be vital when investigating incidents that may have been over a long time period.

  In some cases the prescriber may state that they have not prescribed the item in question and a dispensing report can be run on ePACT to find out where the item was dispensed. Further investigation may highlight a coding error when the data was inputted within the ePACT system.

- **Use of NHSBSA Prescription Services PCT Prescribing Reports for the monitoring of private CD requisitions**
  With the introduction of standardised CDs requisition forms (FP10CDF) in 2008, the *PCT Prescribing Reports* system can be used to examine CDs supplied from requisitions submitted to community pharmacies.
  The community pharmacies will submit the FP10CDF to the NHSBSA and the information from the form will be included for data collation. However, the use of the standardised form is not a legal requirement and as a result of the system allowing for the option for not using the standardised form, some information may be missing and the data collated within the *PCT Prescribing Reports* will be incomplete. AOs should make efforts to ensure all practitioners likely to be requisitioning CDs for use in their practice have ready access to the FP10CDF requisition form.

  If there is a specific concern or occurrence reported regarding the prescribing or requisitioning by a private practitioner then a report detailing prescriber name, where the prescriptions/requisitions were dispensed and, if applicable, the form numbers should be produced. This information will help with the retrieval of prescriptions or requisitions from NHSBSA Prescription Services where required.

  Any concerns raised with regards to private CD prescribing or requisitioning should be included within the quarterly occurrence report and discussed at the CD LIN as appropriate, unless the risk assessment of the issue indicates more timely action. The AO may also wish to determine within which PCT the prescriber is included on a performers list, and inform the AO of that PCT, although care

should be taken to avoid compromising any criminal investigation. Regulation 27 requires that a responsible body that is disclosing or to which is being disclosed any information, the disclosure must be made by or to the AO or his staff (and not by or to any other person who may act on behalf of the responsible body).

Input from the Police CDLO, CQC, professional regulatory body and additional specialist service representatives should be obtained at the LIN. Any further action to be taken may also be agreed at the LIN, although LIN agreement is not necessary for the PCT AO to take independent action, such as writing to the private prescriber to request comment or reasoning for the prescribing. In some cases this can be followed by a meeting between the PCT AO and the prescriber concerned.

Monitoring prescribing for substance misuse
Due to the complex nature of prescribing for the treatment of substance misuse, it is likely that there will be regular queries and incidents relating to prescriptions for some CDs such as methadone and buprenorphine. This is particularly likely when there are shared care schemes in place for GPs and non-medical prescribers to prescribe for substance misusers. When monitoring prescribing in these circumstances, the AO will need to be aware of some of the high doses and combinations of treatments as stated within treatment guidelines but equally should be vigilant for the prescribing of excessive quantities, or frequent issue of duplicate prescriptions.

Guidance for prescribers is available from the National Treatment Agency website and *Drug misuse and dependence: UK guidelines on clinical management (2007)* commonly called 'the Orange Book'.
http://www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf

Community pharmacists and prescribers should be encouraged to report incidents or concerns to the AO. This can be facilitated by providing local guidance for practitioners working in this speciality together with a simple and effective route for reporting. Many PCTs have substance misuse representatives attending the LIN.

AOs may wish to consider the following common issues when reviewing ePACT data for prescriptions for substance misuse:

- *Are the quantities of CDs being prescribed appropriate — local policies could consider setting a 'limit' agreed with specialist providers and review all prescriptions that exceed this limit*
- *Is there a local prescribing policy for the use of methadone concentrate and injection — do prescriptions comply with this policy?*
- *Local policies for the prescribing of benzodiazepines should include recommended strengths, doses and duration of prescriptions*
- *Which drugs are included in the local formulary for substance misuse — do prescribers comply with this?*
- *Have substance misuse prescribers undertaken additional appropriate training? This will be most applicable to GPs providing shared care treatment services or non-medical prescribers from a nursing or pharmacy background.*

- **Monitoring prescribing for palliative care**
  A significant proportion of CD prescribing in primary care will be for palliative care prescriptions. In a similar way to substance misuse services, there is likely to be a locally agreed policy for prescribing for palliative care patients and the recommended medicines to prescribe. For most of the medicines it will not be possible to state maximum doses. The ePACT guidance provided by the Information Centre describes what a usual palliative care prescribing pattern may look like and how to identify unusual prescribing of CD injections. Local guidance should discourage prescribers from prescribing large quantities on individual prescriptions, whilst allowing for anticipatory prescribing should a patient's condition deteriorate.

  Key issues for consideration (list not exhaustive):

- Unusual prescribing of CD injections
- High quantities on individual prescriptions
- Prescribing of patches — do quantities on prescriptions reconcile with patch formulation.

- **Monitoring internal supply of CDs in other healthcare organisations including prisons**
  Review and monitoring of CDs issued through internal supply arrangements in private clinics, prisons and other environments that are not identified as CD designated bodies will be the responsibility of the PCT AO. Depending on the CD governance and supply arrangements in place for that organisation the requisition data may or may not be captured through the NHSBSA information system and therefore the AO will need to consider the most appropriate mechanism for monitoring activity.

  The CD arrangements within prisons (both state run and private sector) may require particular attention as the model for the delivery of healthcare and medicines supply arrangements is likely to vary from prison to prison. The AO should map the processes used within the prison and the personnel involved for all CD related activities and ensure that appropriate and up-to-date SOPs are in place. The AO should establish links with the prison senior healthcare manager to ensure effective communication and reporting processes are also in place.

- **Monitoring the activities of other healthcare professionals operating within the geographical boundary of the PCT**
  As the PCT AO is responsible for assuring the safe use and management of CDs by all healthcare professionals operating within their area who do not have their own AO, a system of assurance processes should be established to review, monitor and inspect the activities of these professionals.

  Having identified all organisations and individuals operating within the area, the AO should arrange to have regular communication to enable the review of SOPs and the monitoring of activities. The AO must also ensure that an effective reporting mechanism is established to allow individuals and organisations to report any CD issues or concerns.

3.1.4 Possession, supply and administration of CDs by private paramedics

The CD related activities of private paramedics is worthy of particular note and consideration by the PCT AO. The legislative frameworks that allow for the activities of private paramedics is more complex than for other healthcare practitioners as a result of the extended nature of their role in providing emergency treatment.

The Misuse of Drugs Regulations 2001: Group Authority to Registered Paramedics, authorised by the Secretary of State, January 2008[13], makes provision for registered paramedics to possess and supply or offer to supply to any person who may lawfully possess any of these drugs – morphine sulphate (in the form of morphine sulphate injection to a maximum strength of 20mg and oral morphine sulphate) and to possess diazepam and/or morphine sulphate preparations – for the purpose of administration for immediate and necessary treatment of the sick and injured persons.

Paramedics employed by an NHS Ambulance Trust will fall within the remit of the Ambulance Trust AO (see section 3.5). Paramedics employed by private Ambulance Services will be subject to regulation by CQC from 1st April 2011. Individual private practitioners will fall within the remit of the PCT AO. Paramedics must be registered with the Health Professions Council (HPC), as the regulatory body, and all issues relating to professional conduct or practice should be referred to the regulator.

3.1.5 Establishing, operating and leading the LIN – Regulation 18

The PCT AO has the specific responsibility for leading and managing the LIN, and establishing

an effective communication network amongst the members so that concerns can be shared quickly if necessary.

Many established LINs meet on a quarterly basis, although some now meet on a six monthly basis with arrangements embedded within the operating procedure of the LIN to receive the occurrence reports from all AOs within the PCT geographical boundary prior to the meeting, so that the contents can be discussed with the LIN members. Irrespective of the time interval between LIN meetings all AOs must submit their quarterly occurrence report from their organisation to the PCT AO.

LINs will normally be established on the basis of a health community, and may include more than one PCT. This is more likely to be the case in urban locations where PCTs have relatively small geographical areas and may border a number of other PCTs. Prescriptions for CDs written in urban areas will often be dispensed in neighbouring PCT pharmacies, and therefore intelligence sharing across the boundaries enables the LIN to function more effectively. Where more than one PCT is included in the network, a collective decision is required to indentify the 'lead' PCT. The AO from this PCT will then take responsibility for the organisational management of the LIN.

An essential element of the LIN is to allow concerns about the activities of any health or social care personnel or organisation to be shared as soon as possible with any other local agencies who may be affected or who may have complementary information. The PCT AO leading the LIN should ensure discussions concerning reports of relatively minor issues do not dominate the agenda and allow potentially more serious concerns of malpractice to be mentioned and discussed in confidence between the network members. Members must be supported to discharge their duty of sharing information relating to the practice and activities of health and social care personnel and necessary steps should be taken to protect information sources.

Where there are concerns over the use of CDs by any healthcare or social care professional or care worker employed by a health or social care organisation or in contract with it, or working privately as a doctor, dentist, pharmacist, paramedic, nurse or midwife, this information (including the name) should be shared and recorded in accordance with robust information sharing agreements established from the outset of the LIN.

In the event of a concern or issue being raised at the LIN that requires collaboration from multiple agencies, the PCT AO should consider setting up an incident panel of relevant individuals. Each agency will retain responsibility for taking appropriate action where required. The LIN should have a procedure in place, initiated by the PCT AO leading the LIN, for setting up an incident panel including the individuals who should be involved and their roles.

Additional information relating to the code of practice for primary medical service providers and PCT for confidentiality and disclosure of information can be viewed at *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4107304.pdf*

Appendix 3 sets out the various parties that have involvement in LIN engagement.

3.1.6 Membership of the LIN

The membership of the LIN may vary depending on the needs of the local area. A suggested starting point would be the inclusion of the following:

- AOs from PCTs within the agreed geographical area of the LIN
- AOs from all NHS and Foundation Trusts (including ambulance [see note in section 3.5] and mental health Trusts)
- Strategic Health Authority (SHA) representative
- Professional regulatory body representative (e.g. GPhC, GMC, NMC, HPC)
- Care Quality Commission
- AOs from local Independent hospitals and hospices

- Local police services — usually the CDLO
- NHS Counter-Fraud and Security Management Service
- Local authority representative.

When drafting or reviewing the LIN terms of reference, the network may also consider including an option for inviting guest representation as and when appropriate for example from the following suggested list of organisations. However, inclusion of such organisations that are not Responsible Bodies may restrict information sharing.

- The local authority's vulnerable adult or child protection team
- Drug action teams
- Local supervising authority midwifery officers
- The independent sector, a dental representative
- The Home Office Drugs Inspectorate and Regional Directors of Public Health.

The PCT AO leading the LIN may find it helpful and constructive to meet with representatives from these and other appropriate organisations outside of the LIN meeting.

It is essential to check the register of AOs on a regular basis in case new services have been established in the locality and AOs have been appointed, e.g. new private hospital registrations, so that the new AOs can be contacted and become involved with the LIN as soon as possible.

3.1.7 LIN governance arrangements

The LIN must adopt an agreed terms of reference and code of practice that ensures it remains fit for purpose, truly representative and responsive to the challenging and changing health and social care environment.

LINs should be reminded that their core function is to share information and build up a database of concerns and that where the safety of patients is a concern, there is a duty to share information, including, if necessary, sharing concerns about named individuals.

An operating policy will be required for the management of the LIN to clearly document:

- The roles and responsibilities of specific LIN members particularly where there is more than one PCT AO on the LIN
- Agenda setting with procedures for circulating draft agendas to allow for additional items to be considered
- How records will be made and stored and who will have access to them
- Processes for review of protocols, procedures or other time limited documents used by the LIN or approved by the LIN for wider implementation
- Processes for delivery of meeting notes to members, in particular arrangements to be used if papers contain sensitive or confidential information
- Collection and disposal of sensitive or confidential information when no longer required
- Process for action follow up
- Optional training and development requirements for LIN members as and when appropriate

The operating policy should be reviewed regularly with appropriate auditing arrangements undertaken to inform the process. The frequency of the review interval should be determined by the LIN members and stated within the terms of reference. The PCT AO leading the LIN may wish to seek advice from both the information governance lead within their PCT and the police when developing and reviewing the operating policy.

3.1.8 Information Sharing Agreements

Legal requirement – *The Controlled Drugs (Supervision of Management and Use) Regulations 2006* Regulations 18, 24, 25, 26, 29 and 30

The regulations require that the PCT AO must establish and operate appropriate arrangements for ensuring the effective sharing of information regarding the management and use of controlled drugs. The regulations also require that responsible bodies co-operate with each other and report any concerns to the PCT AO.

The essential function of the LIN is to allow information to be shared effectively between AOs within the network, professional and health and social care regulators, CDLOs and other appropriate members the LIN has included within its terms of reference. An Information Sharing Agreement (ISA) between all parties will set out the procedures to be adopted by the LIN. ISAs should be detailed documents that specify exactly what information will be shared, by whom, when and how. They are key to ensuring that the LIN complies with data handling requirements and legislation.

Depending on the organisation or individuals the LIN will be sharing information with, it may be possible that more than one ISA is in operation during the life of the network. Each ISA must be agreed by the organisation/s cited within the agreement before the representative from that organisation is included within the LIN meetings or has sight of LIN documents.

The ISA(s) should be reviewed on a regular basis, as determined by the LIN members or as required by the member organisations to ensure it remains a valid agreement, fit for purpose and that the LIN is complying with the terms of the agreement. It is the joint responsibility of the PCT AO leading the LIN and LIN members to ensure strict governance of all such agreements and take the necessary steps to instruct any review or audit of LIN information sharing procedures.

3.1.9 Communicating the work and function of the LIN

The PCT AO needs to make the appropriate organisational senior managers and commissioned or employed health and social care professionals aware of the LIN functions. It should be part of the general information that the AO provides about their role. Ensuring the information is disseminated through organisations can be difficult and different methods of communication may be appropriate depending on the environment.

It can be useful for the PCT AO to attend local professional body meetings, voluntary sector networks and also engage with the local professional representative committees to allow the professions an opportunity to understand the role of the AO, the function of the LIN and to raise the awareness of the safer management of CDs agenda.
Some PCT AOs have used a factsheet or newsletter to advise of their role. This can serve as a good reminder even if the role is already well established but the individual AO or member of support team has changed.

3.1.10 Care Quality Commission – Safer Management of Controlled Drugs annual reports

Each year the CQC report on The safer management of controlled drugs to government.

The 2007 report (published by the Healthcare Commission) made several recommendations relating to LINs:

- LINs should be encouraged to:
  - develop arrangements for intelligence sharing within and between networks
  - review their functions to ensure that they are effectively discharging their responsibilities
  - develop arrangements for sharing good practice with each other
- LINs should be reminded that, where PCTs have joined together for a LIN, there needs to be clear leadership to ensure that intelligence is handled and stored appropriately. Leadership should be clearly identified where LINs serve more than one PCT
- LINs should be reminded that the regulations require information to be shared among responsible bodies and this cannot happen if the membership of the LIN is too wide.

The 2008 Safer Management of Controlled Drugs Annual Report was published by the CQC in September 2009. There were four recommendations in this report for AOs to consider, of which the third and fourth directly relate to the LIN and its leadership. These are

summarised here but the full report should be viewed to gain maximum insight into the work of the CQC and the evidence behind their recommendations to AOs and designated bodies.

- Healthcare organisations should ensure they have AOs in place at all times and mechanisms to replace AOs immediately when they leave. The CQC must be notified of changes to AO
- A robust workable method should be devised to ensure that 72-hour fentanyl patches are applied at appropriate intervals to ensure patients are not left in pain and the patches are not used wastefully
- PCT AOs should collaborate more effectively with other PCTs and national bodies to ensure that suitable numbers of authorised witnesses are available for destroying obsolete drugs
- LINS must ensure that all their designated bodies are kept up-to-date with the formation and leadership of the network and that they know where to submit their reports. Membership and working arrangements of LINs should be kept under review.

The 2009 annual report stated the following three recommendations for the safer use and management of CDs:

- Chief executives and AOs should continue to keep the safe management of CDs a high priority on twheir organisation's agenda
- The Royal Colleges should develop guidance on appropriate use of opioids and amphetamines for all sectors, to ensure best practice across all areas
- The Department of Health should revisit the requisition regulations and guidance to ensure that they capture and identify the purchase of CDs by all individual doctors and healthcare professionals, in line with the original policy intent.

Aide-memoire checklist # 2 — PCT AO role

(Always complete checklist # 1 before completing any further checklists)

Handbook section heading				Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Extended scope of PCT AO role	For which organisations/practitioners am I responsible for assuring the safe use and management of CDs? (complete table below)						
		Number	Comments				
	GP/dispensing practices						
	Community pharmacies (see section 3.1.1)						
	Dental practices						
	Prison health						
	Private midwives						
	Commisioned services that are not Designated bodies						
	Private clinics/practitioners						
Essential links	**Key contacts**	**Role**	**Email**				
Processes required for assurance	Regular checks in place to find new designated bodies and new CD users that are not designated bodies, including private paramedics and private midwives						
	Arrangements exist for the ambulance trust AO to assist with finding private paramedics						
	Private practitioners informed of the need to notify all CD issues to the PCT AO						
	Procedure established for issue and receipt of self assessment declaration forms						
	Procedure established for routine and adhoc premises inspections of services managing or using CDs						

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
	Links made with senior commissioning managers responsible for the annual contract monitoring of all independent contractors				
	Procedures established for routine monitoring of prescribing through ePACT system, including non-medical prescribers				
	Annual reviews of primary care contractors undertaken				
	Contracts and SLAs for services received from other organisations specify the requirement to have CD governance arrangements in place				
	Procedure established for monitoring of prescribing and supply of CDs within other organisations				
	Make arrangements to receive occurrence reports from all the Designated Body AOs in the PCT area				
	Collaborative links established with professional standards panels within the PCT, the Responsible Officer, and the PALS/Complaints Team				
Establishing, operating and leading the LIN	The LIN is established and is meeting regularly				
	The LIN is chaired by an appropriate person and a deputy is nominated				
Membership of the LIN	Membership includes at least those members suggested in section 3.1.6				
	Members (or appropriate deputies) attending regularly				
LIN governance arrangements	Terms of Reference agreed				
	Regular review of Terms of Reference				
Information Sharing agreement	Information sharing agreement accepted by all				
	Regular review of information sharing agreement				
Communicating the work and function of the LIN	Arrangements in place to ensure awareness of the LIN and its work in the local health economy				
CQC annual reports	Report recommendations discussed at the LIN				

AO core role personal action plan		
Action identified	**To be completed by**	**Date completed**

3.2 What this means for Secondary Care Accountable Officers

This section is intended to help point new AOs, appointed by a secondary care designated body, in the right direction in carrying out their responsibilities and as a reference for existing AOs.

The volume of CDs used and the number of personnel involved in handling CDs within many secondary care environments highlights that the task of controlling their journey and assuring the safe use and management through the system can be a complex one. CDs are ordered and stored within the pharmacy department then supplied to wards and other clinical areas as stocks or dispensed directly to patients. Each step in the process requires its own SOP, having regard to best practice. Existing SOPs need to be regularly reviewed and updated in the light of changes to organisational delivery of services, legislation, published guidance and patient safety alerts.

The core elements of the role of the AO are detailed within section 2 of this handbook and should be read first. Communication processes must be established so that Trust personnel have the ability to raise a concern about a colleague in confidence, and senior management staff within the Trust are aware of the procedures required for reporting a CD related incident or concern.

The DH and Royal Pharmaceutical Society (RPS) guidance – *Safer management of Controlled Drugs: A guide to good practice in secondary care (England)*[17], published October 2007 provides detailed guidance for the management of CDs in and around the secondary care environment. The document provides a step wise approach to the complete journey of CDs including transportation to and from the pharmacy department and around the estate, management of CDs on the wards and operating theatres as well the requirements for storage both at ward level and in the pharmacy department. The guidance is an essential reference source for personnel involved in the tasks of supporting the AO.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618

Additional guidance for the management of all medicines within specific areas of a secondary care Trust are provided within *The safe and secure handling of medicines: A team approach 2005*. Revision of the 1988 Duthie Report[18].

3.2.1 Safe operational systems and practices in secondary care

The AO must be aware of the range of CD related activities within the Trust and what SOPs are required to ensure safe use and management of CDs for that activity. A process mapping and risk assessment exercise as outlined in section 2 will be required to track the CD journey in and around the Trust estate (and beyond if the trust is providing services to another organisation), identify the personnel involved in all aspects of CD use as well as the individual environments and the specific requirements for those areas. As non-medical prescribing develops through national policy, the range and numbers of prescribers of CDs continues to increase. The AO will need to identify the clinical areas where prescribers and nurses are working with CDs and ensure Trust policies are in accordance with clinical guidelines and regulations for the safe use and management of CDs.

The AO should ensure a thorough and regular review of existing CD-related SOPs as well as an audit of CD documentation, storage areas and authorised signatory lists for the requisitioning of CDs. By maintaining a concerns log the AO can document progress and inform the quarterly occurrence reports required for the LIN.

3.2.2 Monitoring CD activity and identifying concerns

The prescribing, requisitioning and administration from ward/unit stock must be tightly monitored and scrutinised on a regular basis to identify inappropriate prescribing patterns or indications of poor clinical practice. The electronic dispensing and stock management systems within most Trust pharmacies will also allow for analysis of CDs supplied from the pharmacy. However, electronic ward prescribing systems allow for analysis of activity that has been recorded within the system but will not capture handwritten instructions. Where stock has been supplied in response to a handwritten instruction, there will be no electronic record to enable reconciliation. Since the audit trail is dependant on accurate recording of administration and stock reconciliation on the ward/unit the AO should work with senior Trust managers to develop suitable methods for monitoring activities when no electronic audit trail is possible.

Where the AO is not the Trust chief pharmacist, the AO will need to work very closely with the pharmacy team, particularly with regard to audits and assurances about day-to-day compliance with policies and SOPs.

Where the AO is the senior clinician for a professional group (e.g. Chief Pharmacist, Nurse or Medical Director) there may need to be contingency arrangements to support investigation of concerns relating to that discipline.

All issues or concerns identified should be risk assessed and urgent action taken if necessary to protect the public. This may require discussing the matter with senior Trust colleagues, the CDLO and the professional regulatory bodies. All matters should be included on the quarterly occurrence report for the LIN.

For Mental Health Trusts (and all acute trusts) many CD prescriptions are written by the Trust's clinicians but are dispensed by community pharmacies, thereby adding an additional complexity to the task of monitoring. There can be added problems for the Trust because of the restrictions on the number of FP10 cost centres that the NHSBSA can provide, consequently teams of prescribers may be allocated one cost centre. As a result, the monitoring of the prescribing of individual prescribers may not be possible within the current system. In some areas local arrangements have been made between the provider Trust of the substance misuse service and the local PCT to overcome this situation. Further discussion between the AOs for the respective organisations would be required.

3.2.3 Sharing information

Information disclosed at the LIN should be treated in accordance with the LIN operating policy and the information sharing agreement between LIN members (see section 3.1.8). Since many specialist practitioners work across geographical boundaries it may also be necessary for some information to be shared more widely so that neighbouring LINs can be alerted to concerns relating to the misuse of CDs or poor professional practice.

LIN attendance and information sharing by Trust AOs is of particular importance as a secondary care Trust will generally be a very large local employer and will have employed and contracted personnel who may also be working elsewhere in the health economy, including in private practice. As each LIN has an information sharing agreement the AO for all designated bodies included within the network will need to ensure the agreement has their Trust's organisational approval.

3.2.4 Ordering CDs from suppliers

The CD journey begins with the pharmacy department who are responsible for ordering CDs that are on the hospital formulary from the pharmaceutical supplier. All aspects of CD ordering require a SOP including setting out who is authorised to order CDs, and under what circumstances. As with all SOPs staff should be trained appropriately. The AO should ensure there is regular review and audit of the SOP and daily practice within the pharmacy.

3.2.5 Receiving CD orders from suppliers

Receiving CD orders into the pharmacy department is associated with a number of issues that can raise concerns for an AO. The receipt of the CDs occurs at an interface between a variety of organisations both NHS and non-NHS. When CDs are delivered by a pharmaceutical wholesaler, their delivery drivers will be required to hand the CD personally to the designated pharmacy staff. The wholesaler will have systems and processes for their drivers to follow, however, the pharmacy must also ensure the SOP for receipt of CDs details the requirements for the pharmacy staff.

3.2.6 Recording CDs received and dispensed

SOPs should clearly specify how the CD register, whether as manual or electronic, should be maintained and by whom. The SOP should specify exactly when in the receipt or dispensing process entries should be made. In busy pharmacy departments it is possible for an entry to be omitted in error, making audits and investigations problematic. Therefore it is recommended that frequent reconciliation of CD balances is undertaken to minimise discrepancies becoming difficult to track. Electronic recording systems are to be encouraged and in addition many organisations are introducing electronic CD semi-automatic stores with bar code readers that can facilitate audit and tracking of items.

Frequent causes of error within a hospital pharmacy can include:

- Booking out dose units rather than full packs on the computer
- Simple subtraction and addition errors
- Not entering an order
- Not entering in returned stock (onto the computer and/or the register)
- Not entering out expired stock on destruction.

3.2.7 Stock control in the pharmacy

Stock control processes need to be well thought through and addressed in SOPs. They should include regular and frequent stock checks, register reconciliations and procedures for dealing with discrepancies.

The AO should be informed of all discrepancies, including those that can be accounted for. Although the stock may have been accounted for, incidents such as these, if they appear to be happening on a relatively frequent basis may indicate a pattern of concern for the AO and/or a training need requirement for some staff. It is a matter for the AO to identify trends or issues of concern relating to missing or unaccounted for stock. All such matters should be included on the quarterly occurrence report to the LIN, although the LIN should adopt a risk assessed view of whether frequent register discrepancies indicate a need for review of SOPs and training or if further investigation is required.

3.2.8 CD stationery

Arrangements for controlling CD stationery, e.g. ward stock books, and maintaining an authorised signatory list of who is authorised to order CDs on behalf of a ward or other clinical areas must be in place.

3.2.9 Safe storage

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007[19] apply to community pharmacy and care homes. For other settings they are now considered as a minimum standard and the level of security should be risk assessed.

Further detail of requirements for storage in the pharmacy and on the wards is given in section 3.2.12.

CD medicines dispensed to the ward must be stored securely and away from other non-CD medicines. AOs should regularly review ward storage arrangements to ensure compliance with local policy.

Effective key holding and transfer policies are an essential element of the safe and smooth running of a ward or unit. The keys for the CD storage

cupboard should be held by the most senior member of the nursing staff and daily key transfer records should be completed and made available to the AO in the event of an investigation or audit.

3.2.10 Ward and other clinical areas

Tracking and monitoring CD related activities can become complex when considering the use of these medicines in wards, theatres and in other clinical areas. As a result, the tasks required to provide the necessary assurances for the AO can be detailed and require input from a range of senior managers. The numbers of staff and staff groups who have access to CDs can be significant in large busy hospitals with levels of CD prescribing and administration sometimes complex to monitor. It is highly recommended that ward matrons/ ward sisters take an active part in reviewing CD control on his/her ward for example by regularly reviewing the CD register to check that SOPs are being adhered to, that all signatures are identifiable and that the doses of CDs are in accordance with multi professional prescribing policies.

The prime focus for nurses and doctors is the well being of their patients, and the importance of CD security may not always be a priority. A lack of vigilance and poor compliance with SOPs at ward or clinic level can provide an opportunity for diversion of CDs by healthcare professionals or other Trust staff.

AOs must ensure that ward/clinic SOPs are reviewed regularly to ensure they remain relevant to the environment, compliance with the SOPs is audited and staff are made aware of the risks associated with CDs through appropriate training and communications.

To add to the complexities associated with CD use on busy wards and regular movements of CDs around (and, possibly, beyond) the Trust estate, the AO must also consider the processes involved in emergency care both on the ward and also within the accident and emergency unit. Emergency care practitioners are required to make quick clinical decisions at the point of care and complete necessary documentation in a risk assessed timely manner. Effective management and robust policies for the ordering, storage, disposal and recording of CDs will ensure the potential risk of diversion from the unit will be minimised.

When patients are transferred between wards/ units in the same hospital or between hospitals their medicines may be transferred with them. This activity could be viewed as an area of risk for CD management reinforcing the need for the AO to ensure policies and procedures are in place and complied with.

Palliative care patients merit particular consideration for the AO. These patients are, on occasion, discharged home during the last stage of their illness, which may in some cases be for a matter of only days. In order to make this time as comfortable as possible some Trusts send these patients home with a box containing all the medication that they are likely to require. Much of the contents are pre-prepared in readiness for a rapid discharge. The AO should ensure that CDs are prescribed appropriately for the patient in accordance with Trust prescribing policies.

A further situation for an AO to consider in a Trust with childrens' wards is that a patient's parents or carers are encouraged to stay with their child/ charge. On occasion a Trust may have parents or carers within the ward/unit who are substance misusers receiving prescribed treatment who attend with their own supply of CDs. To effectively manage situations such as these the hospital should develop a policy and a system for securing and accounting for these personal CD medicines.

Further guidance on the safe storage of personal CD medicines and patients own medicines can be found in the DH guidance; *Safer management of controlled drugs: a guide to good practice in secondary care (England)*[17]. October 2007.

3.2.11 Ordering and collection of CDs by ward staff

An AO will need to be assured that appropriate systems have been put in place to ensure that

CDs are only ordered by those authorised to do so, and that collection from the pharmacy department and suitable secure transport arrangements are in place. The pharmacy should retain a list of authorised signatories for personnel who have been given the authority from a senior manager to collect the CD, which must be checked before the CD is issued.

The AO should discuss with Trust senior managers who should be authorised. Particular consideration should be given if the ward is off site and a courier/taxi firm is used. As a safeguard, the same member of staff that ordered the CD should not collect the CD from the pharmacy.

3.2.12 Safe storage and stock control on the wards/unit

The AO will need to ensure that each ward has suitable CD storage cupboards that either meet the British Standard (BS2881: 1989 security level 1) or have been approved by the pharmacy department and that a robust stock control system is in place. Provision for security of keys needs to be considered and that ward CD records and stock levels are maintained diligently with discrepancies being reported to the AO in a timely fashion. Audits should be carried out regularly to show compliance with SOPs, as mentioned previously, this could be delegated to the ward matron/nurse in charge.

An example of such an audit can be found on the password protected section of the NPC CD web pages. *www.npci.org.uk/cd*

A view should be taken by the AO in discussion with senior Trust managers on how to store Schedule 3 CDs that are not subject to storage requirements under the Misuse of Drugs Act but which Trusts may wish to store securely.

3.2.13 CD destruction

Patients own CDs brought on to the ward or maintained on the ward that are no longer required, do not legally require destruction by an authorised witness; however the AO should ensure that local SOPs provide an auditable process for either transferring the items to the pharmacy or destruction on the ward. If destruction is to carried out on the ward appropriate denaturing kits must be used that will render the CD irretrievable so that it cannot be reconstituted or re-used.

Ward stocks of CDs no longer required or out of date should be returned to the pharmacy for destruction. The ward or department should keep a record of the items returned, which may be in the form of a returns advice note with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

Particular care is needed if the trust provides services to another organisation, for example under a contract or Service Level Agreement (SLA), that includes return and destruction of waste CDs. The conditions of the Environments Agency's regulatory position statement must be followed. Further details regarding the denaturing of CDs at a place other than the premises of production can be found at: *http://www.environment- agency.gov.uk/static/documents/Business/MWRP_RPS_004_v2_denaturing_drugs_final_08-07-10.pdf*

3.2.14 Temporary transfer of CDs

There are occasions when wards or units need to close temporarily, for example for weekend cleaning or maintenance. The CD stock should not remain on a closed ward and should be transferred back to the pharmacy. The AO should ensure a SOP is in place to cover such eventualities and the correct documentation is completed by the appropriate authorised signatories.

3.2.15 Illegal drugs on Trust premises

Occasionally staff within the Trust may find drugs brought in by members of the public and patients. This could be anything from a small amount of an unidentifiable suspicious substance to a complete cannabis plant. The local police CDLO will be able to advise the AO on formulating a strategy to handle these eventualities.

3.2.16 Involving the police

Experience has shown that it is essential that all staff are aware of the Trust's process for reporting CD incidents to the police. Reporting (where required) should be via the AO, or a nominated deputy, to the local Police CDLO and not through any other Trust function or department.

Aide-memoire checklist # 3 — Secondary Care AO role

(Always complete checklist # 1 before completing any further checklists)

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Process mapping	A comprehensive process mapping exercise has been undertaken including any services provided to another organisation				
	Written assurances about all pharmacy-related procedures have been provided by the Trust's chief pharmacist				
Monitoring CD activity	Effective monitoring systems established for Trust clinicians proving services in the community (e.g. substance misuse services)				
	Procedures in place for the review of ward level audits				
Safe operational systems and practices	SOPs include the controls and restrictions on prescribing of CDs by non-medical prescribers				
	CD SOPs cover the special needs and risks in emergency departments and operating theatres and for palliative care patients				
	CD SOPs include the temporary transfer of CDs, including in emergencies				
	CD storage and key control in wards and clinical areas comply with best practice				
	CD SOPs include arrangements for illegal drugs brought in by patients and members of the public				
	CD SOPs include process for managing patient/public's own prescribed CDs				
	Procedures are in place for reporting CD-related concerns including concerns about the private practice of a Trust employee				
Sharing information	The AO or a nominated deputy regularly attends LIN meetings				
	Trust incident recording systems, e.g. Datix, have a code for CDs				
	Quarterly occurrence reports sent to the lead PCT AO include all issues other than purely clinical errors				
	All staff are aware of who is permitted to call in the police				
Incident reporting and recording	Procedure in place for:				
	The review of incidents				
	Review of outstanding actions from previous incidents				
	Cascading information and learning from incidents to ward matron/senior nursing teams				
	Ward and department training issues identified and appropriate manager informed				

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Storage arrangements	Storage arrangements within the following areas/department have been checked to ensure they meet required standards: (List not exhaustive)				
	Wards (include numbers/names/other identification)				
	A & E department				
	Theatres (include numbers/names/other identification)				
	Diagnostic units				

AO core role personal action plan		
Action identified	**To be completed by**	**Date completed**

3.3 What this means for Hospice Accountable Officers

This section should be read in conjunction with the core tasks identified for all AOs in section 2 of this handbook. The AO will need to identify a suitable senior healthcare professional within the hospice to undertake some of the tasks associated with audit and monitoring; however, the AO cannot delegate the responsibilities of the role.

3.3.1 Safe operational systems in the hospice

There are likely to be some similarities to the arrangements within a hospice as those adopted within a secondary care environment, in particular if there is more than one 'ward' within the hospice or if CDs are retained within the hospice as stock.

The AO should undertake a process mapping exercise to identify the CD related activities that he/she will be responsible for. The AO may wish to read section 3.2 of the handbook to identify where activities align. The DH guidance *Safer management of Controlled Drugs - A guide to good practice in secondary care (England)* – October 2007[17] will also be a useful resource to read.

3.3.2 Governance arrangements for hospices

The AO must be a senior manager and be of sufficient seniority and influence to take action regardless of how an issue is raised. It is essential that the AO is not personally involved in the routine prescribing, supply, administration or disposal of CDs. For further information on who can be an AO see section 2.2 of the handbook.

The role of the AO must fit into the clinical governance (or equivalent) framework of the hospice, ensuring that the clinical governance committee and the Board of Trustees are kept fully informed. It is suggested that reports are submitted to the committee which oversees the hospice's clinical governance issues and to the Trustees as a standing agenda item.

3.3.3 Home Office licence

Most hospices are exempt from requiring a HO licence to hold CD stock by nature of their charitable status. If a hospice is privately owned and operated, then a licence to possess a stock of schedule 2 CDs is required[20].

No licensing is required for the possession of dispensed "patient's own" medication.

Further information regarding licensing arrangements and requirements can be found on the Home Office website *http://www.homeoffice.gov.uk/drugs/licensing/*

3.3.4 Policies and procedures

The AO must ensure that the hospice has robust SOPs for all activities involving prescribing, use and management of CDs. To identify activities requiring SOPs a comprehensive process map and risk assessment should be undertaken (see section 2.6).

In addition, there must be systems in place to audit, document and effectively manage any deviation from SOPs. Policies and procedures must include a process for incident reporting, the receipt of adverse comments and complaints, whistle-blowing and managing information provided to and received from the LIN. The AO should ensure that hospice personnel have a suitable route for raising concerns confidentially. Any significant incidents must be shared with the LIN as incidents may involve healthcare professionals who may provide services for other organisations in addition to their role within the hospice.

3.3.5 Providing assurance of safe use and management of CDs

As part of their role, the hospice AO must be able to provide evidence of safe handling of CDs to the CQC to confirm that the management of CDs

complies with the misuse of drugs legislation. To help hospices to establish systems and processes for the monitoring of CD activities within the organisation and provide evidence that the hospice is compliant with the Regulations, *Help the Hospices National Audit Tools Group (NATG)* has produced two comprehensive audit tools:

- The Management of Controlled Drugs, and
- Self Assessment for the Accountable Officer.

Both of these can be downloaded from Help the Hospices website (login required). *www.helpthehospices.org.uk/our-services/clinical-governance/audit-tools/national-audit-tools-group/*

Specifically, the hospice AO must ensure that all hospice personnel involved in each stage of the handling of CDs have been trained and/or are qualified for the tasks undertaken. The performance of staff handling CDs must be both monitored and assessed and there must be clear lines of accountability for the handling of CDs.

The AO must establish systems for routinely monitoring the use of CDs by analysing data on a pro-active basis through:

- Audit – It is recommended that the Help the Hospices national audit tools are used (see earlier). They provide a baseline for anyone new to the role and if used on an annual basis will help to ensure that the hospice is working to achieve safe patient care and adhering to legislation and national guidance
- Collating information on prescribing within the hospice – through regular audits of prescribing the AO should be able to demonstrate that any signs of unusual, excessive or inappropriate prescribing have been identified and discussed with the Medical Director. Following on from these discussions, the AO may seek advice from the CDLO if an investigation is to be initiated. In the absence of an electronic prescribing system, it may be appropriate in some hospices to also collate the information from the procurement of CDs (through requisitions) to use as a proxy measure for prescribing activity
- The continuous monitoring by the AO should enable them to demonstrate that they have been able to identify triggers for concern. There must be documented evidence that the AO has taken appropriate action if there were well-founded concerns. Completing a concerns log can be helpful to document issues as they arise and use as a reference if issues continue.

3.3.6 Stock levels of controlled drugs

Hospices may hold large quantities of CDs in stock. The AO must undertake a risk assessment to determine the frequency with which this stock is checked. A stock check can be a straight forward task as the Controlled Drug Registers should have a running balance for each CD held. Many hospices carry out this check daily. However, this may be a problem in a hospice that maintains very few CDs as the Register will quickly fill up with line after line of stock check entries. In such cases it is better if stock levels are checked each time a CD is used and at less frequent regular intervals. Local arrangements should determine the frequency of stock checks required.

3.3.7 Destruction of controlled drugs

The hospice AO must authorise named individuals to witness the destruction of CDs. In respect of their role as witnesses to the destruction of CDs, these individuals are directly accountable to the AO and must be trained to undertake this role. The witnesses must not be routinely involved in any stage of the management of CDs.

Some hospices have appointed the Director of Finance, Director of Estates or similar non-clinical senior managers as witnesses.

3.3.8 Annual review by the AO

On an annual basis, the hospice AO should complete a review of the management of CDs to ensure that the hospice is compliant with the relevant legislation, regulations, guidelines and policies.

This must cover the following:

- Procurement of CDs (order, supply, receipt)
- Storage of CDs
- Destruction of CDs
- Disposal of CDs
- Record keeping of CDs
- Prescribing of CDs (including take home prescriptions)
- Administration of CDs
- Compliance with the requirements for safe custody of the keys.

Where the hospice has its own pharmacy, the pharmacist will be able to provide assurances for a number of these items.

3.3.9 Working with the LIN

A priority for the hospice AO is to ensure there is an established link with the PCT lead AO and that they become a member of their LIN. Depending upon the hospice's catchment area, the AO may need to be a member of more than one LIN.

The frequency of the LIN meetings will be determined locally but in the main will be quarterly. The meetings are aimed at setting up mechanisms for the very quick sharing of intelligence with other AOs within the LIN. At such meetings, it is likely that more than one hospice will be represented. As such, it is a useful venue for AOs to share experience and support each other.

As part of the information-sharing process, the hospice AO must provide a quarterly occurrence report detailing any concerns associated with their management of CDs, to the PCT lead AO; these reports may simply state that there have been no concerns regarding the safe management or use of CDs at the hospice (see Appendix 2). It must be understood that the hospice AO remains responsible for the management of incidents involving CDs within their own hospice. Most incidents will be minor and will be dealt with in-house but should be reported to the PCT AO and recorded on the occurrence report.

The LINs have been established to share significant information and not to take over the role of routine management of incidents. The type of incidents which should be discussed within the network usually involve incidents of a serious nature or incidents which involve any member of staff or healthcare professional who might also work for other organisations. It should also be noted that all significant incidents must be reported directly to the CQC.

3.3.10 Further support for hospice AOs

For further information on the work of Help the Hospices, visit their website. *http://www.helpthehospices.org.uk/welcome/*

Aide-memoire checklist # 4 — Hospice AO role

(Always complete checklist # 1 before completing any further checklists)

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Process mapping	A mapping exercise has been undertaken and where similarities have been identified with secondary care the relevant section of the handbook has been read and the checklist/s completed				
Governance arrangements	The AO reports directly to the registered manager (see section 2.2 – who can be an AO)				
Home Office Licence	Any necessary Home Office licences have been obtained				
Providing assurances of safe use and management	Procedures are in place for:				
	• Monitoring the arrangements for requisitions (review sample supply orders and invoices)				
	• Monitoring CDs received in to the hospice				
	• Safe storage of stock CDs				
	• Safe storage of patient's/public's own CD medicines				
Policies & procedures	Advice is given to patients/carers on how to store their medicines and disposal of unwanted supplies				
Safe systems and processes	Appropriate SOPs are in place for:				
	Obtaining supplies of CDs from the supplying pharmacy				
	Recording receipts in the Register				
	Stock balance checks				
	Destruction of stock CDs				
	Destruction of patient's own CDs				
	Arrangements for prescribing and supply of 'take home' and 'just in case' CDs has been reviewed and is acceptable				
	Staff are appropriately trained to ensure compliance with SOPs				
Working with the CDLIN	Procedures established for reporting to the lead PCT AO (LIN) incidents or causes of concern identified via patient complaints, police intelligence or healthcare professional				
	The AO attends the CD LIN				

AO core role personal action plan		
Action identified	**To be completed by**	**Date completed**

3.4 What this means for Independent Hospital Care Accountable Officers

This section should be read in conjunction with the core tasks identified for all AOs in section 2 of this handbook.

3.4.1 Safe operational systems

There are likely to be many similarities to the arrangements within an independent hospital as those adopted within an NHS secondary care environment, in particular if there are a number of wards, operating theatres and an on-site pharmacy. The AO should undertake a process mapping exercise to highlight the CD related activities that he/she will be responsible for and that require appropriate and up-to-date SOPs.

To identify activities that may appear similar to those within the NHS sector and use these to benchmark internal governance arrangements within the independent hospital, the AO should read Section 3.2 of this handbook together with the DH guidance *Safer management of Controlled Drugs - A guide to good practice in secondary care (England)* – October 2007[17].

The handbook does not specify the CD related activities that will be similar or different to the NHS sector as the nature and complexities of the arrangements within the independent hospital will vary depending on the number of beds, the medicines supply arrangements and the scope of the clinical activities. However, the core functions set out in section 2 and many of the functions of a NHS secondary care AO set out in section 3.2 will be essential for the AO to ensure the independent hospital is operating its CD related activities safely and in accordance with legislation.

One significant feature of the clinical staffing arrangements in many independent hospitals is that the specialist doctors will in the main be self-employed clinicians and will not be employees of the hospital. This can create a unique set of pressures for the AO in relation to ensuring adherence with hospital SOPs. All clinicians will, however, be required to adhere to hospital policies as part of their practicing privileges.

3.4.2 Governance arrangements for independent hospitals

The AO must be the registered manager of the hospital or answerable to the registered manager. If the person is the registered manager, he must be answerable to the chief executive, chairman or managing director of the hospital. It is essential that the AO is not personally involved in the routine prescribing, supply, administration or disposal of CDs and therefore should not be the senior pharmacy manager.

The role of the AO must fit into the clinical governance (or equivalent) framework of the hospital, ensuring that the clinical governance committee and senior management team are kept fully informed. It is recommended that regular reports are submitted to the committee which oversees the clinical governance within the hospital and to the Hospital Board as a standing agenda item.

3.4.3 Staff training

As outlined above, the unique nature of the self-employed position of many of the clinicians working within the hospital, results in a speedy turnover of clinical procedures and swift movements of clinicians in and out of the hospital. Training for the safe use and management of CDs for employed hospital personnel must be given a high priority to ensure SOPs are adhered to in all hospital environments.

Aide-memoire checklist # 5 — Independent Hospital AO role

(Always complete checklist # 1 before completing any further checklists)

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Process mapping	A mapping exercise has been undertaken and where similarities have been identified with NHS secondary care sector the relevant section of the handbook has been read and the checklist/s completed				
Governance arrangements	The AO is an appropriate senior member of the hospital management team (see section 2.1 – who can be an AO)				
Home Office Licence	Any necessary Home Office Licences have been obtained				
Staff training	Staff are appropriately trained to ensure compliance with SOPs				
	Annual updates are provided for employed staff				
Safe systems and processes	Appropriate SOPs are in place for all CD related activities identified in the process mapping exercise				
	Arrangements for prescribing and supply of 'take home' CDs (if applicable) has been reviewed and is acceptable				
Working with the CDLIN	Procedures established for reporting to the lead PCT AO (LIN) incidents or causes of concern identified via patient complaints, police intelligence or healthcare professional				
	The AO attends the CDLIN and reports back to the senior pharmacist any recommendations for audit or monitoring action				

AO core role personal action plan		
Action identified	**To be completed by**	**Date completed**

3.5 What this means for Ambulance Trust Accountable Officers

The following information provides some guidance on the issues which are specific to ambulance Trusts. This section should be read in conjunction with section 2 of this handbook which details the core tasks required for all AOs. The AO may also wish to read section 3.1 of the handbook, which outlines the responsibilities and associated tasks for the PCT AO as there may be some overlap with the roles with regard to the safe use and management of CDs by private paramedics operating within the geographical area of the PCT.

Additional guidance for the safe and secure handling of all medicines in Ambulance Trusts is provided within section 18 of the 2005 revision of the Duthie Report[18].

The Ambulance Pharmacists Network is working to develop systems that ensure the safe and secure management of CDs by NHS Ambulance Trusts and contracted private providers. The network can be contacted through the NeLM communities site although a password is required for access. *http://www.nelm.nhs.uk/en/NeLM-Area/Communities/*

3.5.1 Ensuring safe operational systems

The operations of an Ambulance Trust have a number of factors that pose a different set of risks to other environments for the safe use and management of CDs. In particular, CDs are transported in Trust vehicles to scenes requiring urgent care and administered in emergency situations with retrospective recording of supply. The process mapping exercise undertaken by the Ambulance Trust AO will need to consider all likely scenarios where CDs will be used in order to ensure appropriate SOPs have been developed and are being adhered to.

Ambulance paramedics may possess, supply or offer to supply diazepam and/or morphine sulphate injection (to a maximum strength of 20mg) and/or oral morphine sulphate, for the purpose of its administration for the immediate necessary treatment of sick or injured persons in accordance with *The Misuse of Drugs Regulations 2001: Group Authority for National Health Service (NHS) Ambulance Paramedics*[21] (and employing NHS Ambulance Trusts).

Ambulance service medical, nursing and paramedics employed or commissioned by the Trust must comply with all legislation for obtaining, storage and recording of CDs as stated within the Misuse of Drugs Regulations 2001. Private practitioners working alongside ambulance staff are not employed by the Trust and therefore their CD related activity is accountable to the PCT AO for the area. Private practitioners must maintain their professional standards in accordance with the standards determined by the professional regulatory body and if commissioned by the Ambulance Trust should work according to the terms of the commissioning agreement. Ambulance Trust AOs should ensure such agreements include a requirement to work within the safe working procedures of the Trust and should performance manage this agreement on a regular basis. The Ambulance Trust AO should encourage the private practitioner to make themselves known to the PCT AO.

If private paramedic services are being provided from Trust ambulance vehicles and CDs are being transported it is important that the CDs are stored appropriately according to best practice guidelines and the private paramedics stock should not get confused with any stock held within the ambulance by an Ambulance Trust employee. All stock must be accounted for at the end of shift or call-out (whichever is most appropriate to maintain robust recording of supplies).

3.5.2 How should CDs be ordered?

CDs should be requisitioned by the Ambulance Trust from a pharmacy according to the requirements stated within the *Safer management of controlled drugs: changes to requirements for requisitions for the supply of schedule 1,2 and 3 controlled drugs (England only)*[22]. The requirements provide an effective audit trail for CDs ordered by organisations and individual practitioners that can be tracked and monitored for the purpose of reviewing the activities of personnel using CDs during the course of their duties.

Since the orders requisitioned by an Ambulance Trust will be supplied to the Trust base, the AO must ensure that accurate records are kept of all movements of the stock within the Trust and its personnel.

The following two documents may provide some additional guidance:

- *Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)* October 2007. Department of Health[17]. Section 7.11 of the document provides further guidance for the requirements for supply of CDs to external units or other health and social care bodies
- *A guide to good practice in the management of Controlled Drugs in primary care (England)*, 2009, National Prescribing Centre[23].

3.5.3 Supply of CDs to doctors

The Group Authority mentioned earlier allows paramedics to possess and supply diazepam and/or morphine sulphate injection (to a maximum strength of 20mg) and/or morphine sulphate oral for the purpose of its administration for the immediate necessary treatment of sick or injured persons. This enables paramedics to supply an attending medical practitioner or any person who may lawfully have the CDs in their possession for the purpose stated. It does not allow Ambulance Trusts to supply morphine sulphate or diazepam to a doctor or other person for any other purpose.

Alternatively doctors working for Ambulance Trusts may wish to obtain and carry their own stocks of CDs. The doctor must be fully compliant with the requirements within legislation for safe custody both when off-duty (in particular if CDs are stored in the doctors home or bag) and when transporting the CDs during the course of his duties. The doctors must maintain accurate records of all receipts and supplies of the CDs.

Doctors can requisition CDs in two ways:

- Register with the PCT as a private prescriber, and order CDs using the standard requisition form (although this is not currently a legal requirement, it is good practice to always use one wherever possible)
- Requisition CDs using a signed order, from a registered pharmacy or a wholesale dealer (such as a hospital with a wholesale dealers licence).

3.5.4 Requisitions made on behalf of the Ambulance Trust

It would significantly assist the maintenance of an effective audit trail for the requisitioning of CDs, used by employees of the Trust or doctors contracted to provide medical services, if an Ambulance Trust set up an account with an agreed supplier and used a standard order form so that all supplies can be tracked. The requisitions would be signed by the Trust Medical Director or appropriate senior medical practitioner employed by the organisation.

3.5.5 Storage of CDs

As with many environments where CDs are stored there are no specific regulations relating to the storage requirements in ambulance vehicles and ambulance bases. However, it is strongly recommended that the requirements set out in the *Misuse of Drugs (Safe Custody) Regulations 1973* are considered and British Standard BS 2881 is applied as a minimum where appropriate. Benchmarking of local practice with other ambulance services and informed by discussions with the local police force can also provide some additional guidance.

The requirements for safe storage need to take

account of all buildings and vehicles used by the Trust as well as the range of services being provided. The AO should ensure all storage procedures for both within the base and on all vehicles operated by Trust personnel are regularly reviewed and audited.

3.5.6 Recording

All movements of CDs, requisitioned on behalf of the Trust, into and out of the Ambulance Trust base must be recorded in an appropriate CD register. All paramedics and doctors requisitioning their own supplies of CDs should record in their own personal registers and maintain personal responsibility for keeping this accurate and up-to-date. The senior medical officer for the ambulance base is responsible for ensuring all Trust records are accurate and up-to-date. At the present time registers may be maintained either in a paper bound or electronic format, provided they contain the specific information as stated within the legislation.

3.5.7 Destruction

As for Secondary Care Trusts, Ambulance Trusts must have a process in place for the destruction of stock CDs. The AO is not able to witness the destruction and the appointed witness must be independent from the day-to-day management of CDs. Similarly the paramedics are not permitted to destroy CD stocks when they may have been involved in the administration or supply process. Private paramedics will need to contact the PCT AO if they have stocks that need destroying. The PCT AO will provide the name of an approved witness for this purpose. (An example of an authorisation template is provided at Appendix 1).

3.5.8 Stock checks

Stock checks should take place at least once a week, and discrepancies should be followed up. It is important to record all discrepancies, including those that have been resolved, so that process problems can be identified. The AO must be informed of all CD related issues or concerns. Irreconcilable balances of CD stocks should be risk assessed and investigated. The outcome of the risk assessment will indicate if urgent action needs to be taken and the LIN Chair needs to be informed. All CD irregularities should be included on the quarterly occurrence report,

Individual practitioners with their own personal supply must conduct their own stock checks. Any discrepancies should be reported to the PCT AO who will take a decision on what actions need to be taken, although informing the Ambulance Trust AO can be helpful in ensuring any suspicions of diversion or malpractice relating to practitioners employed or commissioned by the Trust are handled appropriately.

3.5.9 Review and audit of CD related activities

All CD related activities within the Ambulance Trust must be monitored. In particular, where morphine is being stored and taken out in emergency care vehicles, movements should be regularly scrutinised so that patterns of errors can be identified.

Data for the supply of CDs to stations can be recorded electronically to enable unusual trends to be identified.

To provide the necessary assurance of safe use and management of CDs within the Ambulance Trust the AO must undertake regular reviews of SOPs and audits of practice. The activities of private paramedics and private medical practitioners operating alongside NHS Trust colleagues should be included within the reviews and audits, although any cause for concern relating to their professional practice should need to be referred to the PCT AO for appropriate action.

3.5.10 Admission of patients to hospital

There is no specific guidance for the transportation of patient's own CDs by ambulance crews when patients are being admitted to hospital. It is not expected that Ambulance Trust staff will record all the patient's

medicines, they may not have the appropriate skills, and in an emergency they will not have the time. Ideally, all the medicines should be placed in a bag and taken to hospital with the patient (and wherever possible in the patient's possession).

3.5.11 Patients discharged from hospital

Wherever possible, medicines should be given directly to the patient at discharge, and should be in the patient's possession (in the same way as their personal valuables). Non-emergency transport staff should not be asked to sign for specific medicines such as CDs, as this may put them in the situation of signing for something they are not in a position to understand.

Where it is not possible for a patient to take possession of their medicines, it would be reasonable to record that the medicines were given to the driver, together with the time, date and the name of the person handing over the medicine.

Some hospitals have a system where a sealed box is signed for when issued and the receiving health facility sign for the box on receipt, and the paperwork is matched up. This process works well in integrated care environments, but may not be appropriate for discharges into the community and care homes.

3.5.12 LINs

Ambulance Trusts will usually have several LINs established within the geographical area they cover. Each LIN usually has between two and four meetings a year and may have different ways of working.

Where it is not practical to attend all the LINs covered by an Ambulance Trust, it may be useful to agree across the Trust area that one LIN will be the lead, and the Ambulance Trust AO will attend all meetings of the lead LIN. This should usually be the LIN based in the PCT that is the commissioning lead for the ambulance service but when there are specific issues in another LIN area, the AO (or his/her delegated representative) will attend the local LIN. The AO for the PCT that is the lead commissioner for the ambulance service should share ambulance service related information with other AOs covered by the Ambulance Trust.

It may be appropriate for the Ambulance Trust AO to attend a regional meeting in addition to, or instead of, one specific LIN meeting.

In all these cases, the Ambulance Trust AO must still send quarterly occurrence reports to each PCT AO in the Ambulance Trust area.

3.5.13 CDs transported in non-NHS vehicles such as air ambulances, helicopters

Emergency care and rescue transport vehicles may be operated and provided by a range of organisations that will work in partnership with the ambulance service paramedics and doctors. An example of such an arrangement would be the air ambulance helicopters operated by the Royal Air Force (RAF) or off-road rescue vehicles operated by the Mountain Rescue Service. It is difficult to categorise the many different arrangements that have developed over time and each Ambulance Trust AO must ensure they are fully aware of the responsible organisation providing the transport vehicle and be satisfied that appropriate governance arrangements for the transportation of CDs are in place. In the case of RAF, neither the PCT AO, nor the Ambulance Trust AO are responsible for the CD activities undertaken by any of Her Majesty's Armed Forces.

Aide-memoire checklist # 6 — Ambulance Trust AO role

(Always complete checklist # 1 before completing any further checklists)

Handbook section heading		Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Process mapping	A mapping exercise has been undertaken and unique arrangements have been identified such as with emergency transport vehicles				
Governance arrangements	The AO reports directly to the most senior member of the Trust management team (see section 2.1 – who can be an AO)				
Safe storage requirements	All Ambulance Trust CD stock is subject to safe storage requirements:				
	In the base				
	Ambulance Trust vehicles				
Monitoring of activities	The Trust has appropriate procedures in place for monitoring the activities of:				
	Paramedics operating under the group Authority for NHS paramedics				
	Doctors employed or commissioned to provide services for the Trust				
	All movements of CDs in and out of ambulance trust vehicles				
	Regular stock checks				
	Transport of patient's own CDs (either to or from hospital)				
Private paramedics	The AO has had an active involvement in the drafting of the service agreements for services commissioned by the Trust				
	The AO has encouraged private paramedics to make contact with the PCT AO for their area				
Attendance at CDLIN	Does the geographical area of the Trust cover more than one CD LIN? if so, which ones				
	An agreement has been reached between the LIN Chairs for which network meeting the Ambulance Trust AO will attend				
	Arrangements are in place for sending occurrence reports to the PCT AOs for each of the LINs within the operating area of the Trust				

Handbook section heading				Date completed	Further actions or procedure review required	Date actions to be completed by	By whom?
Non-NHS transport vehicles	Emergency transport vehicles provided by non-NHS organisations List below						
	Vehicle type	**Operating organisation**	**AO responsible (if not armed forces)**				

AO core role personal action plan		
Action identified	**To be completed by**	**Date completed**

Section 4

Appendices

Appendix 1:

Template letter for authorisation of destruction of Controlled Drugs

Background

Under the Misuse of Drugs Regulations 2001, Regulation 27, those required to maintain a CD Register are not allowed to destroy Schedule 1-2 CDs which are surplus or out of date stock, without the destruction being witnessed by an authorised person. From the 16th August 2007 the Trust AO is empowered to nominate individuals who are authorised to witness the destruction of these CDs.

Witness for the destruction of Controlled Drugs

The AO is not able to witness the destruction as they must be independent from the day-to-day management ofCDs. Similarly a Pharmacy Advisor or senior medical officer may not be permitted to destroy CDs where they may have been involved in the administration or supply process.

From [date] the AO has nominated the following individuals to be authorised witnesses for the destruction of CDs according to the Regulations.

Name	Title	Profession or date of CRB check	Date SOP signed

Further individuals may be authorised by the AO – an updated list may be obtained from the AO — Name, job title.

Authorisation by Accountable Officer

I, name, Accountable Officer for …….. authorise the following individuals to witness the destruction of Controlled Drugs in accordance with the amendment to The Misuse of Drugs Regulation 2001 which came into force on the 16th August 2007.

The individuals are:

Signed: _____

Date: _____ / _____ /_____

Name, Accountable Officer, organisation name

With thanks to Oxfordshire Primary Care Trust for this template.

Appendix 2:

Occurrence Report – Controlled Drugs Concerns

This draft 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). It has been produced by the Healthcare Commission Controlled Drugs regulation team, and should be further developed within the local intelligence network in the light of experience in use.

Name of designated body	
Name of Accountable Officer	
Report for three-month period	
Name of Local Intelligence Network (LIN)	
Name of LIN lead Accountable Officer	
I confirm that my designated body has **no / the following** (delete as appropriate) concerns regarding its management or use of controlled drugs during this period	
Accountable Officer signature	
Date signed	

Description of concern[e]	Date aware[f]	Actions taken[g]

[e] *Short description of the cause for concern, including date(s). Details may be attached in a separate document. Note regulations 25 and 26 regarding the need not to disclose information which relates to and can identify a patient.*

[f] *Date the Accountable Officer of the designated body became aware of the concern.*

[g] *Action already undertaken (if any) within or outside the designated body e.g. as part of internal incident investigation process, including the reference number within the internal incident investigation process (where relevant), and whether the incident is closed or still open.*

Notes

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 came into force in England on 1 January 2007, see:
http://www.opsi.gov.uk/si/si2006/20063148.htm#29

Regulation 29 concerns occurrence reports, and is shown in full below. In brief, regulation 29 requires Accountable Officers to give an occurrence report to the Accountable Officer for the PCT that is leading their Local Intelligence Network (LIN). This should contain details of any concerns that their

designated body has regarding its management or use of controlled drugs (or confirmation that it has no concerns to report).

Occurrence reports

29. — (1) An Accountable Officer (other than an Accountable Officer nominated or appointed as Accountable Officer for a Primary Care Trust or Health Board) must give, on a quarterly basis, an occurrence report to the Accountable Officer nominated or appointed as Accountable Officer for the Primary Care Trust or Health Board that is leading any local intelligence network of which he or his designated body is a member.

(2) The occurrence report may contain the following information—

(a) details of any concerns that his designated body has regarding its management or use of controlled drugs; or

(b) confirmation by his designated body that it has no concerns to report regarding its management or use of controlled drugs.

(3) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

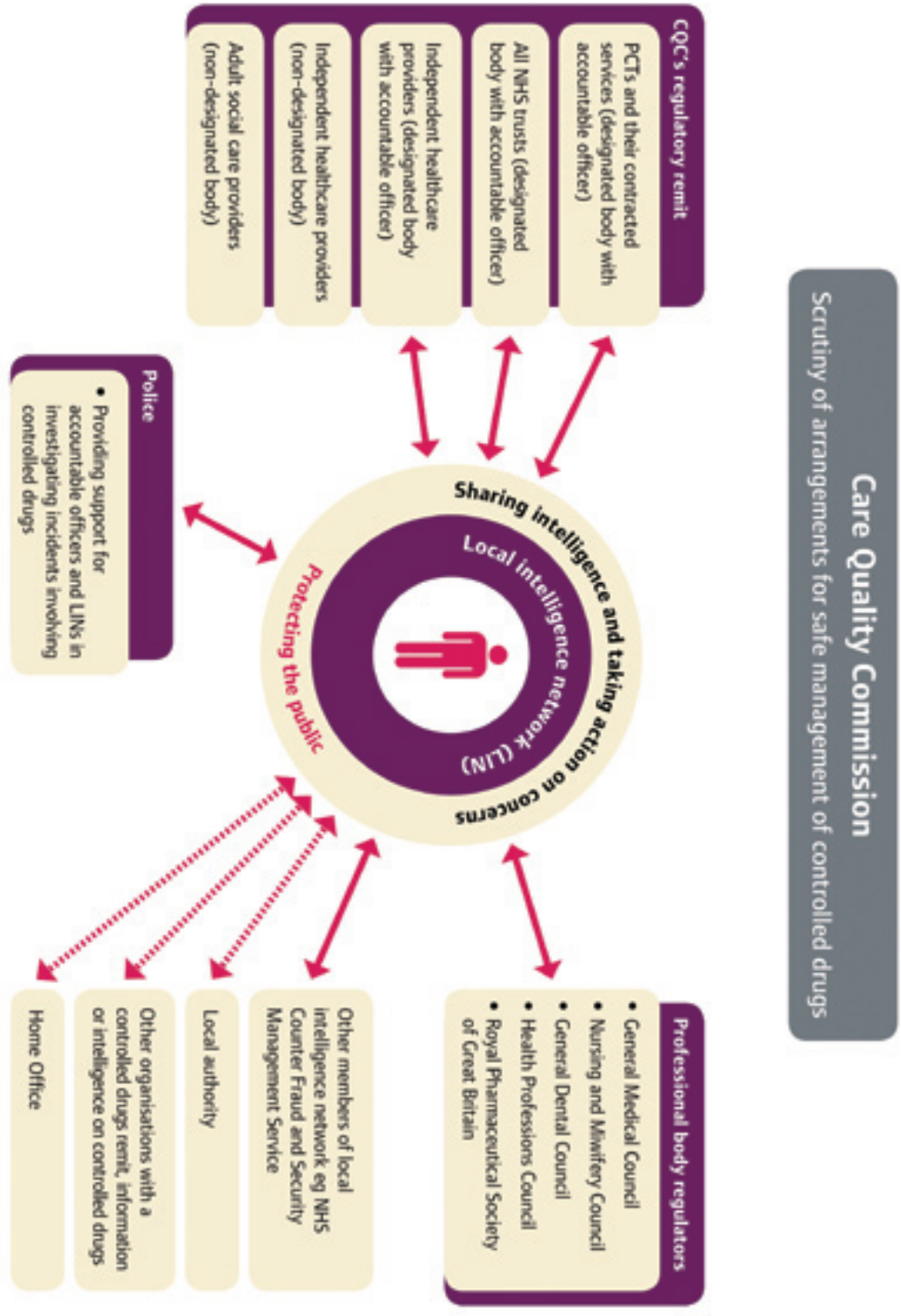
(4) In determining for the purposes of paragraph (3) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998 by virtue of section 35(1) of that Act (disclosure required by law or made in connection with legal proceedings etc.), it is to be assumed that the disclosure is required by this regulation.

Some designated bodies (such as Ambulance Trusts that cover a large area) may relate to more than one LIN. They need to discuss engagement with the LIN leads and the reporting of concerns; perhaps sending a copy of their occurrence reports to all.

This document will be held securely by the LIN lead in accordance with the LIN agreed local policies for handling information.

Appendix 3:

The diagram shows that protecting patients and the public is central to the safer management arrangements for controlled drugs and the regulators and agencies that have a key role.



With thanks to the CQC for their permission to reproduce this diagram.

Appendix 4:

Glossary of abbreviations

ACPO	Association of Chief Police Officers
AO	Accountable Officer
BNF	British National Formulary
CD	Controlled Drug
CDLO	Controlled Drugs Liaison Officer
CPS	Crown Prosecution Service
CQC	Care Quality Commission
CRB	Criminal Records Bureau
DH	Department of Health
GMC	General Medical Council
GPhC	General Pharmaceutical Council
HPC	Health Professions Council
ISA	Information Sharing Agreement
LIN	Local Intelligence Network
MOPI	Management of Police Information
NATG	National Audit Tools Group
NHSBSA RxS	NHS Business Services Authority – Prescription Services
NMC	Nursing and Midwifery Council
NPC	National Prescribing Centre
NPSA	National Patient Safety Agency
PALS	Patient Advice and Liaison Service
PCT	Primary Care Trust
SHA	Strategic Health Authority
SOP	Standard Operating Procedure
SI	Serious Incident

Appendix 5:

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Mark Seaton	*Head of Medicines Management & Accountable Officer for Controlled Drugs, South Staffordshire PCT*
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Annabel Wickens	*Acting Quality and Risk Manager, Sue Ryder*
Authors	*Catherine Baldridge, Associate Lead Medicines Management and Accountable Officer for Controlled Drugs, NHS South of Tyne and Wear*
	Harriet Lewis, Head of Implementation and Project Support, National Prescribing Centre
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Ground Floor, Building 2000, Vortex Court, Enterprise Way, Wavertree Technology Park,
Liverpool L13 1FB
Tel: 0151 295 8671
www.npc.nhs.uk