

**SAFER MANAGEMENT OF CONTROLLED DRUGS:
(1) GUIDANCE ON STRENGTHENED GOVERNANCE
ARRANGEMENTS**

DEPARTMENT OF HEALTH

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SAFER MANAGEMENT OF CONTROLLED DRUGS: (1) GUIDANCE ON STRENGTHENED GOVERNANCE ARRANGEMENTS

Introduction

- 1 The purpose of this guidance is to promote the safe and effective use of all controlled drugs. The guidance sets out strengthened governance arrangements for controlled drugs in England. These new arrangements are underpinned by the Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) regulations 2006 (“the Controlled Drugs Regulations”) made under provisions in the Act.¹ The guidance is for:
 - PCTs, NHS and Foundation Trusts, and the independent healthcare sector – organisations who have a responsibility for ensuring that systems are in place for the safe and effective management of controlled drugs and that these are working effectively
 - Other individuals and organisations in the health and social care sectors who may have their use of controlled drugs monitored and inspected
 - ‘Inspectors’ - individuals who will be monitoring and inspecting controlled drugs and arrangements for their safe management.

The guidance may also help patients and the public understand how controlled drugs should be managed and how concerns about controlled drugs in the health and social care sector will be handled. Guidance on the new arrangements in Scotland will also be made available.²

- 2 Guidance is also available on prescribing and dispensing, non-medical prescribing, record-keeping, and destruction issues. Practical guidance on information-sharing will also be made available. Guidance can be found at: <http://www.gov.uk/controlleddrugs>. This website contains the latest developments in the management and use of controlled drugs and links to other relevant documents.
- 3 Controlled drugs are an essential part of modern clinical care. They are medicines used to treat a wide variety of clinical conditions including:
 - the relief of acute pain after a heart attack or fracture
 - the relief of severe chronic pain
 - palliative care, for example for patients with terminal cancer
 - the treatment of drug dependence
 - anaesthesia.

¹ See <http://www.opsi.gov.uk/acts/acts2006/20060028.htm> for the Act and <http://www.opsi.gov.uk/si/si2006/20063148.htm> for the regulations

² This will be made available through a link on the Department of Health’s controlled drugs website: <http://www.dh.gov.uk/controlleddrugs>

We have seen major advances in the therapeutic use of controlled drugs in the last few years, and their importance is recognised in clinical guidelines on their use in a range of settings.³

- 4 Controlled drugs are however subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. In response to the case of Dr Harold Shipman, the Government has introduced strengthened measures to make sure controlled drugs are managed safely. These governance arrangements are to be implemented in a way that supports professionals, and encourages good practice and the use of these important medicines when clinically required by patients.
- 5 Central to the Government's measures for the safe management of controlled drugs are new monitoring and inspection arrangements which will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. This guidance explains how these arrangements will work.

The background

- 6 The Government's response to the Shipman Inquiry's Fourth Report⁴ was set out in *Safer management of controlled drugs - the Government's response to the Fourth Report of the Shipman Inquiry*⁵. The response accepted the need for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs.
- 7 The strengthened system will work within and alongside existing governance arrangements, and place the management of controlled drugs within the overall context of clinical quality. It will build on the expertise of organisations that currently monitor and inspect aspects of the management of controlled drugs. It will also maximise the ability to detect poor practice in controlled drugs management by combining this with information on other aspects of clinical practice.
- 8 The new arrangements will result in a significant improvement to the current piecemeal arrangements, being better co-ordinated and integrated within the overall framework for improving quality in

³ For example, see Joint Royal Colleges Ambulance Liaison Committee Clinical Practice Guidelines, the British Pain Society's *Opioids for persisting non-cancer pain: recommendations for best clinical practice*, and *Drug Misuse and Dependence – Guidelines on Clinical Management*. The Royal College of General Practitioners runs a training programme specifically on the management of drug misusers (see <http://www.rcgp.org.uk/drug/index.asp>).

⁴ See *The Regulation of Controlled drugs in the community, The Fourth Report of the Shipman Inquiry* (<http://www.the-shipman-inquiry.org.uk/fourthreport.asp>)

⁵ See *Safer management of controlled drugs, the Government's response to the Fourth Report of the Shipman Inquiry* (http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4097904&chk=isA3Eo)

healthcare. The arrangements are intended to encourage good practice in the management of controlled drugs as well as help to detect unusual or poor clinical practice or systems, criminal activity or risk to patients.

Overview of new arrangements

- 9 At local level, all healthcare and social care organisations are accountable for ensuring the safe management of controlled drugs. Organisations directly providing clinical services may be required by the relevant Primary Care Trust, the Healthcare Commission or the Commission for Social Care Inspection (CSCI) (whichever is the appropriate monitoring body) to complete a self-assessment and declaration on whether they use controlled drugs. Registered pharmacies may be requested to provide similar assessments and declarations by the Royal Pharmaceutical Society. These assessments will inform occasional random inspections to provide an additional check that controlled drugs are managed safely.
- 10 PCTs, NHS Trusts, Foundation Trusts and the independent sector must have arrangements in place for the monitoring of the use and management of controlled drugs by all healthcare professionals who they employ or with whom they contract. They will do this in part through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads or prescribing advisers). Where one organisation provides services to another, the commissioner of the services has responsibility for ensuring that appropriate governance arrangements are specified in the contract.
- 11 Designated bodies (Primary Care Trusts, NHS Trusts, Foundation Trusts and independent hospitals⁶) are required to appoint an Accountable Officer to monitor the use of controlled drugs within their organisation and take appropriate action where necessary. The Accountable Officer will be responsible for ensuring the safe and effective use and management of controlled drugs within local organisations subject to their oversight.
- 12 In the private and voluntary sector, registered managers of hospitals will continue as part of that role to have responsibility for the day-to-day management of controlled drugs. The Healthcare Commission and Commission for Social Care Inspection (CSCI) will assess the management of controlled drugs as part of their regular inspections, ensuring compliance with legal requirements and taking appropriate action. The police retain responsibility for the investigation of crime and misuse of drugs offences that may arise.
- 13 A legal duty of collaboration is also included in the Health Act 2006. This enables local agencies to share information and intelligence, within

⁶ An independent hospital is as defined in regulation 2(1) of the Controlled Drugs (Management and Use) Regulations 2006

certain constraints, about the use of controlled drugs in the health and social care sector. The local agencies required to cooperate include healthcare organisations, the police, social service authorities and relevant inspectorates (Healthcare Commission, CSCI, and the Royal Pharmaceutical Society of Great Britain (RPSGB)).

- 14 To put this duty into practice, Accountable Officers in PCTs will act as the hub of a local network involving the key local agencies. We envisage that networks will normally be established on the basis of a health community, and could span PCTs. SHAs may wish to facilitate arrangements. Members of the network should communicate regularly to agree and update protocols and to review trends. The network will also enable agencies that have a cause for concern about the activities of any healthcare professional or organisation to share them as soon as possible with any other local agencies who may be affected or who may have complementary information. Where several agencies are concerned, the PCT Accountable Officer may consider setting up an Incident Panel of relevant agencies or individuals to consider specific serious concerns. Each agency will retain responsibility for taking appropriate action where required.
- 15 At national level, in England, the new arrangements are subject to external scrutiny by the Healthcare Commission. The Commission will ensure that local governance arrangements, intelligence networks and provisions for incident panels are satisfactory. Where appropriate the Commission will use its existing powers to inspect or investigate systems failures, or registration issues in the private and voluntary sector. The Commission will monitor national trends and innovation in the management of controlled drugs, publish its findings and promote improvement. As part of this role, the Commission is leading a small group involving the National Patient Safety Agency, the Prescribing Support Unit, the RPSGB, the National Clinical Governance Support Team and the police to look at national trends in controlled drugs use.
- 16 The Controlled Drugs Regulations come into force in England on January 1 2007. The Healthcare Commission will start its full year assessment of how organisations are fulfilling their duties under the Regulations from April 1 2007, but will also look at how organisations are following the current (March 2006) guidance in the year 2006/07.

Routine monitoring and inspection

The role of the 'Accountable Officer'

- 17 Under the Health Act, and regulations 3 and 4 of the Controlled Drugs Regulations, PCTs, NHS Trusts, Foundation Trusts and independent hospitals have a statutory duty to nominate a specific individual – an Accountable Officer - to be responsible for a range of measures relating to the monitoring of the safe use and management of controlled drugs in their organisation. The Accountable Officer's responsibilities are set out in the Controlled Drugs Regulations (regulations 8-18).
- 18 The Accountable Officer can be a stand-alone or additional role depending on local circumstances. Organisations of the same type may jointly appoint an Accountable Officer if this is appropriate; where for example two organisations are planning to merge (regulation 5). We do not expect there to be many such joint appointments.
- 19 The Accountable Officer must be a 'fit, proper and suitably experienced person' who does not 'routinely supply, administer or dispose of controlled drugs as part of his or her duties' (regulations 4 and 5). An organisation can have an Accountable Officer who has occasional exceptional need to use controlled drugs (for example, in emergencies), but if this is the case, their use of controlled drugs 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. In the case of NHS trusts, PCTs and Foundation trusts, they must be an Executive Director or report directly to an Executive Director (regulation 5). For independent hospitals, the Accountable Officer must be the registered manager or an officer or employee reporting to the registered manager (regulation 5(1)(a)). Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet the above criteria. Accountable Officers should make it clear, as part of their monitoring systems, who people should approach if they have concerns about the practice of their own Accountable Officer.
- 20 A designated body can remove its Accountable Officer from office if he or she no longer meets the requirements in regulation 5 or is unfit to be an Accountable Officer (regulation 6).

Who needs an Accountable Officer?

- 21 Primary Care Trusts, NHS Trusts, Foundation Trusts and independent hospitals are required to have an Accountable Officer (regulations 3 and 4). The Accountable Officer is required to ensure the safe and effective management of controlled drugs within local organisations subject to their oversight. Where a doctor or other healthcare professional works mainly for the NHS but also for the private sector, the Accountable Officer or their local PCT is responsible for carrying out periodic inspections of the premises that are used for their private practice, if these are not subject to inspection by the Healthcare Commission, CSCI or the Royal Pharmaceutical Society. However, monitoring purely

private health care provision that is provided neither by nor under arrangements made with an NHS body is not otherwise part of an NHS Accountable Officer's normal remit. That said, healthcare professionals who are working away from hospitals or premises of NHS contractors in a purely private capacity are nevertheless "relevant persons" who are covered by the information sharing arrangements and the duty of cooperation between responsible bodies. PCTs will receive information on private prescriptions for controlled drugs dispensed in the community pharmacy through the Prescription and Pricing Division of the Business Services Authority and should monitor and assess that appropriately.

Support for the Accountable Officer

- 22 The Accountable Officer needs to possess or have access to certain skills and expertise, including data analysis, investigative skills and networking. They require some investigative and administrative support and need support from others such as the clinical governance lead, Chief Pharmacist or prescribing adviser as appropriate. The National Prescribing Centre is producing a modular training package to support the training and development of those working with controlled drugs.⁷
- 23 Accountable Officers need to develop and implement systems for routinely monitoring the use of controlled drugs, through pro-active analysis and identifying triggers for concern, and taking action (regulation 11). Accountable Officers also need to ensure that appropriate arrangements for assessing and investigating concerns are in place and that they are alerted to any significant findings (regulations 11 and 16).
- 24 PCTs are encouraged to consider consortia arrangements to support Accountable Officers in areas such as data analysis and investigative skills. Decisions on the arrangements will be for local determination and be influenced by previous history of concerns about controlled drugs misuse, predictions of the likely workload and the need for coterminosity with partner organisations, such as the police service, SHAs and Healthcare Commission and CSCI regions. Individual organisations are responsible for ensuring that systems are in place and that Accountable Officers are appointed and supported. Organisations in England must notify the Head of Operations of the Healthcare Commission of the name of their Accountable Officer and let her know of any changes. They can do this using a web form that can be found at: <http://www.healthcarecommission.org.uk/serviceproviderinformation/controlleddrugs.cfm> and the Commission will publish a national list on their website. NHS organisations should also notify their SHA.
- 25 Healthcare organisations should integrate the structures set up for the Accountable Officer with existing local performance structures. They should also consider how the Accountable Officer should relate to any

⁷ This should be available at the end of January 2007. See http://www.npc.co.uk/modular_training.htm

existing groups such as Drugs and Therapeutic Committees, clinical governance committees, medicines management teams, and shared care-monitoring groups.

- 26 PCTs may wish to draw on the NCAS's toolkit for considering performance procedures (<http://www.ncas.npsa.nhs.uk/toolkit>). For NHS trusts, *Maintaining High Professional Standards in the Modern NHS* provides a framework for investigating serious concerns about performance.⁸ The Government will be issuing more general guidance on investigations as part of its response to the Fifth Report of the Shipman Inquiry, expected early in 2007.
- 27 A toolkit developed by the Clinical Governance Support Team, the NCAS and the RPSGB⁹ provides further support on how Accountable Officers might routinely monitor the use of controlled drugs and take action. This is predominately for general practice, though it can be used in other settings.

Routine monitoring

- 28 Routine monitoring of the use of controlled drugs will help to drive up quality as well as detect potential concerns. Accountable Officers must ensure the use of controlled drugs is monitored through routine processes such as data analysis, audit and clinical governance, as an integral part of normal governance arrangements (regulation 11). For PCTs, relevant data to be analysed would include prescribing data; for secondary care, supply details; and for out-of-hours services, signed orders. The ePACT.net service from the Prescription Pricing Division provides an electronic tool for auditing prescribing data. The data are from the prescriptions processed by the PPD and will include private prescriptions sent to the PPD.¹⁰
- 29 Accountable Officers should also make sure that their organisation and their contractors have suitable arrangements in place for the disposal of controlled drugs (regulation 10). They should also check that systems are in place to identify and act on other triggers such as a patient complaint, police intelligence or a healthcare professional raising a concern (regulation 11).

Self-assessment and controlled drugs declarations

- 30 The regulations enable Accountable Officers of PCTs, the Healthcare Commission, CSCI and the Royal Pharmaceutical Society to require healthcare organisations providing clinical services and relevant social care organisations within their remit to complete a periodic declaration (this is planned to be at least every two years). The declaration will

⁸ See

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4072773&chk=ol83Ov

⁹ See http://www.cgsupport.nhs.uk/Primary_Care/Resources.asp#drug_management_toolkit

¹⁰ See http://www.epact.ppa.nhs.uk/systems/sys_main_epact.htm. The PPA became the Prescription Pricing Division (PPD) of the NHS Business Services Authority in April 2006.

cover whether or not their organisation keeps stocks of controlled drugs, and whether there are any special circumstances that might explain any seemingly unusual patterns of prescribing or supply.

- 31 Those organisations that do hold stocks of controlled drugs will be required to complete a self-assessment of their management of controlled drugs. They will also be asked to draft an appropriate Standard Operating Procedure (SOP). The Healthcare Commission will assess and monitor SOPs. The declaration and self-assessment questionnaire will be sent to organisations by the relevant agency, and may be included in other assessments or planning tools, for example the Healthcare Commission’s core standards assessment or where PCTs request practice development plans. The relevant agency will determine the frequency of self-assessment. A model for declaration and self-assessment for primary care is available at <http://www.dh.gov.uk/controlleddrugs>.
- 32 Failure to provide information, or providing false information, could lead to investigation and further action.

Who sends the declaration and self-assessment?	
Contracted services in primary care (except community pharmacies)	PCT
NHS Trusts, PCTs (for provider services) and independent healthcare	Healthcare Commission
Care Homes	CSCI
Community pharmacies	RPSGB

- 33 Organisations should return their declaration and self-assessment to the agency responsible for monitoring their use of controlled drugs. For example, where a general practice is contracted to provide services to the PCT, the declaration/self-assessment should be returned to the PCT. Community pharmacies should return their self-assessment to the RPSGB who will send these before routine visits. NHS Trusts and the private and voluntary healthcare sector should return their declaration/self-assessment to the Healthcare Commission. Care homes should return their declaration/self-assessment to CSCI. This is summarised in the table above.
- 34 Self-assessment will help inform other monitoring and inspection activities.
- 35 As part of monitoring and audit arrangements, we recommend that the PCT’s Accountable Officer carry out a formal review once a year of primary care providers contracted with the PCT (for example, GP surgeries and community pharmacies). This review would be based on benchmark analysis derived from existing information, the organisation’s self-assessment and declaration, and reports from any routine visits by

prescribing advisers and/or clinical governance leads. The review can be conducted as part of existing clinical governance reviews.

- 36 For NHS Trusts and the private and voluntary healthcare sector, the Healthcare Commission will use their existing self-assessment methods to assess whether healthcare organisations are meeting national standards. A core standard in the national *Standards for Better Health* is that 'Healthcare organisations keep patients, staff and visitors safe by having systems to ensure medicines are handled safely and securely'. The Healthcare Commission will corroborate the self-assessment/declaration with local organisations such as the SHA, the patients' forum and the local authority's overview and scrutiny committee. Information will be checked against other regulator's findings and national data before making a decision on further action. The Healthcare Commission will use C24 from the National Minimum Standards for independent healthcare.
- 37 In care homes, controlled drugs are prescribed, dispensed and supplied for individual residents and in very few cases will a care home offering nursing care obtain a stock of controlled drugs. CSCI already regularly inspects care homes and other types of residential establishments which may use controlled drugs. The inspection process has been altered to reflect a more proportionate approach. Intelligence will be collated from the self-assessment by the care-provider; service user questionnaires; complaints and reports of untoward incidents. CSCI does not have a regulatory function to monitor prescribing patterns in care homes. Controlled drug prescribing for care home residents is captured in prescribing data for individual practitioners and therefore falls within PCT governance.
- 38 Registered midwives may supply and administer, on their own initiative, any of the substances specified in medicines legislation under midwives exemptions, provided it is in the course of their professional midwifery practice and they have received appropriate training. A midwife's records related to administration of medicines should be regularly audited by their named supervisor of midwives and any concerns should be reported to the Accountable Officer, and the Local Supervising Authority Midwifery Officer.

Routine inspections

- 39 The Health Act 2006 contains a power of entry and inspection for certain designated persons to inspect controlled drugs and associated records. Formal inspection of healthcare and social care providers involving an 'on-site' visit to the provider's premises is only part of the new monitoring and inspection arrangements. Nonetheless, inspection remains a useful tool to check physical arrangements for the storage, record keeping and management of controlled drugs, to support individual and organisational development, and to identify and investigate concerns.

40 Inspections should comply with the ten principles of inspection set out in *The Government's Policy on Inspection of Public Services*.¹¹

41 Inspections will take place in various settings:

Primary care

42 As part of their monitoring and auditing arrangements, PCTs should arrange for a small number of routine inspections of a random sample of those GP practices and other contracted primary care providers where controlled drugs are stored, dispensed, supplied or used on the premises. Whilst the power of inspection in the Health Act and the controlled drugs regulations (regulation 19) does not require inspections to be notified, we recommend that routine inspections are announced. They can be combined with other visits (such as QOF and clinical governance visits) where appropriate.

43 To avoid duplication, the RPSGB will include inspection of controlled drugs in their routine inspections of community pharmacies. Inspections will be informed by self-assessment, controlled drugs reviews and other monitoring.

44 Prescribing advisors or clinical governance leads should continue to visit all GP practices to provide advice and support on a wide range of issues, including the safe and effective prescribing of medicines and the development of practice formularies. They can discuss controlled drugs issues on these visits if appropriate and use information from these visits to share good practice and to inform monitoring and inspection activities.

NHS Secondary care

45 The Healthcare Commission will report specifically on any points of concern about controlled drugs in secondary care, including hospital pharmacy. They will do this as part of their routine assessment of whether a Trust is meeting core standards and through their clinical audit programme. They will start their full assessment of how organisations are complying with the controlled drugs regulations from April 1 2007. Trusts may also wish to arrange mutual audits with other Trusts or invite other agencies to inspect them. At their own cost, Trusts can also invite the RPSGB to carry out occasional inspections or inspect a pharmacy where they have concerns.

Independent healthcare sector

46 Private and voluntary healthcare providers are generally required to register with the Healthcare Commission and are subject to periodic inspection as a condition of their continued registration. As part of these regular inspections, the Healthcare Commission will include an assessment of the adequacy of arrangements for the management of controlled drugs. The Healthcare Commission will also assess standard

¹¹ See <http://www.cabinetoffice.gov.uk/opsr/documents/pdf/policy.pdf>

operating procedures for GPs in private practice and assess compliance.

Care Homes

- 47 At present, regular inspections by CSCI look at arrangements for managing controlled drugs. In future, self-assessment and other corroborating information will be used to determine whether a targeted visit should take place. Targeted controlled drug inspections will be undertaken by CSCI pharmacist inspectors.

Standards

- 48 To ensure consistency in the new arrangements, common guidelines for inspection visits have been developed. A working group of representatives from the RPSGB, Healthcare Commission, CSCI, the police and the NHS has agreed the guidelines. They set out the core activities that should be included in an inspection and cover areas such as ensuring safe storage arrangements and proper record keeping. They also suggest a frequency for visits: a minimum ten per cent random sample to be inspected each year. We recommend notice is given of routine inspections. The guidelines can be found at: <http://www.gov.uk/controlledrugs>.
- 49 A competency framework is also available setting out the competencies that those involved in monitoring and inspection will need.¹²
- 50 Accountable Officers, or those authorised by his or her organisation to carry out an inspection, must make a record of visits and inspections (regulation 19(4)) and a report should be made available to the inspected premises as soon as possible after a visit. Where concerns are raised, the relevant Accountable Officer must be made aware of this and given a copy of the report.

Information-sharing

Duty of collaboration

- 51 To maximise the effectiveness of the new arrangements, it is important that healthcare organisations, police services, the inspection bodies (RPSGB, Healthcare Commission and CSCI), regulatory bodies and others work together to share intelligence on controlled drugs issues. To reinforce this need for co-operation, the Controlled Drugs Regulations place a statutory duty of collaboration on healthcare organisations, police forces, social services authorities, and the relevant inspection and regulatory bodies to enable them to share information about potential controlled drugs offences and potential or actual systems failures (regulation 24).
- 52 The duty allows specified organisations (responsible bodies specified in regulation 22) to share information which gives rise to concern over the use of controlled drugs by any healthcare or social care professional or

¹² See http://www.npc.co.uk/pdf/CDI_Competency_Framework

careworker employed by a health or social care organisation or in contract with it, or working privately as a doctor, dentist, pharmacist, nurse or midwife. Under the duty, organisations can ask other organisations whether they have any information related to the concern (regulation 26).

- 53 In sharing information, organisations must have regard to the Data Protection Act 1998 and codes of practice on confidentiality, in particular the Caldicott principles, namely:
- Justify the purpose.
 - Don't use patient identifiable information unless it is absolutely necessary.
 - Use the minimum necessary patient identifiable information.
 - Access to patient identifiable information should be on a strict need to know basis.
 - Everyone should be aware of their responsibilities.
 - Understand and comply with the law.
- 54 A toolkit to provide practical guidance on information-sharing is being prepared by the Department, Healthcare Commission and Association of Chief Police Officers.¹³ NHS organisations, those contracted to provide NHS services, and the independent sector may find the *Confidentiality and disclosure of information: GMS, PMS and APMS Code of Practice* helpful.¹⁴
- 55 Confidential information which relates to a patient should be anonymised where possible (regulation 25(2) and 26(3)). If it is not possible to remove patient identifiable information from confidential information, then the patient's consent should be sought wherever practicable (regulation 25(3) and 26(4)).
- 56 Care should also be taken with sharing information about identifiable health and social care professionals and where possible, they should be made aware of concerns raised about them. Intelligence networks may wish to agree a code on information-sharing and nominate a person to be responsible for ensuring the code is followed.
- 57 Organisations are also required to co-operate in taking appropriate action within their individual remits (regulation 24). Action might include the further investigation of issues of concern or the initiation of processes to protect the safety of the public, including professional disciplinary processes. Each organisation will be separately accountable for action within its own remit. If a responsible body shares information under regulations 25 and 26 that shows a concern about inappropriate or unsafe use of controlled drugs by a relevant person, the

¹³ This will be available on <http://www.dh.gov.uk/controlledddrugs>

¹⁴ See

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107303&chk=GiJc0B

relevant Accountable Officers may make recommendations to the Accountable Officer as to the actions that should be taken. For these purposes, the relevant Accountable Officer would be the Accountable Officer of any designated body responsible for entering into any arrangements (either directly or through another individual or body) with the person to provide services. The relevant responsible body is any responsible body that could take appropriate action, including regulatory bodies and the police. Where there is no relevant Accountable Officer, that is the person doesn't provide services to a designated body, the Accountable Officer leading the network must take reasonable steps to protect the safety of patients and the public, and may refer the matter to an appropriate responsible body (regulation 30).

Intelligence network

58 In addition to the duty of collaboration, PCT Accountable Officers will be responsible for establishing and operating an intelligence network for sharing information (regulation 18). Membership of the network will need to be decided locally. Networks will often be based on a locally recognised health community and SHAs may wish to help facilitate arrangements. Current organisational changes may mean that networks may take a while to be established, so consideration will need to be given to ensure relevant information is shared appropriately in the interim.

59 Networks may involve:

- Local PCTs
- NHS and Foundation Trusts (including ambulance and mental health trusts)
- RPSGB inspectors
- Healthcare Commission (through regional and area teams)
- CSCI (through regional teams)
- Local police services
- NHS Counter-Fraud and Security Management Service
- Local authorities
- SHA
- Lay involvement, such as a PCT non-executive director

A number of bodies that can be included in a network are listed in regulation 18(3), though this list is not exhaustive, and it is for local networks to consider which bodies should be involved.

60 There may be instances where the Accountable Officer may consider the involvement of the local authority's vulnerable adult or child protection team. The Accountable Officer may also want to involve 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.

- 61 The PCT's Accountable Officer (or an Accountable Officer on behalf of a cluster of PCTs) will act as the hub of the network and assist with setting up and managing the network. They will need to establish mechanisms to share information quickly between relevant partners. This will include considering how best to contact organisations (possibly outside normal working hours), and making cover arrangements for holidays and sickness leave. They will also need to set up a forum of all members of the network to agree and maintain joint protocols and to review trends. Accountable Officers must give the PCT Accountable Officer leading the local network quarterly occurrence reports detailing any concerns they have about the management of controlled drugs, or confirmation that they have no concerns (regulation 29).

Investigating concerns

- 62 The Accountable Officer will need to ensure that robust systems are in place to enable concerns about controlled drugs to be raised, to log these concerns, to alert themselves where appropriate and to initiate investigations (regulations 15 and 16). Where possible, existing mechanisms for identifying and managing concerns about performance should be used. *Maintaining high professional standards in the modern NHS* and the NCAS toolkit provide guidance on performance procedures in general practice and the NHS.¹⁵ Guidance on investigating patient safety incidents involving unexpected death or serious untoward harm, and liaising between the NHS, the police and the Health and Safety Executive is available.¹⁶
- 63 Concerns may be raised through a variety of routes – including routine monitoring of prescribing data, a routine inspection, a patient complaint, police intelligence or from a health or social care professional. Where concerns are serious, if for example, patient safety is at risk or the professional's fitness to practise may be impaired, they should be passed on to the relevant body immediately (see paragraph 67 and section on escalating concerns). Where concerns appear to be minor, further local investigation may be more appropriate.
- 64 Care should be taken to ensure that any evidence collected during the course of an investigation is preserved in an appropriate manner to ensure its integrity in case it is required at a later stage for proceedings instituted by the police, other enforcement agencies and/or regulatory bodies. In such circumstances, it is strongly recommended that early advice be sought from the police or another appropriate enforcement

¹⁵ See

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4072773&chk=ol83Ov

¹⁶ *Guidelines for the NHS in support of the Memorandum of Understanding Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association and the Health and Safety Executive*

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4140659&chk=LhbzT3

authority. Criminal investigations will usually take precedence over other investigations.

- 65 Accountable Officers should ensure that there is a clear separation between investigating and decision-making.
- 66 The Clinical Governance toolkit for controlled drug management in primary care may be a useful tool for investigating concerns.¹⁷ The document sets out a standard approach to investigating problems, covering routine monitoring of controlled drugs, investigating specific concerns and taking action once the investigation is completed. Whilst the document focuses on primary care, it will also be useful for other settings. The Accountable Officer may wish to obtain information and advice from others in the local controlled drugs network.
- 67 Where the concern relates directly to a doctor or dentist, the National Clinical Assessment Service can offer help and run a 24-hour help-line. The NCAS can also carry out formal assessments to help PCTs with their decision-making.¹⁸ The General Dental Council, the General Medical Council, the Nursing and Midwifery Council, and the Royal Pharmaceutical Society of Great Britain offer guidance on when to involve the regulatory body. Useful guidance can be found on their web-sites and some helpful documents are listed below. Support and guidance can be obtained from the General Social Care Council where concerns relate to a social care professional. For some professionals it may be necessary to also contact other individuals or organisations, such as the superintendent pharmacist where a pharmacist is working in a large multiple organisation or the Local Supervising Authority for midwives.

General Dental Council, *Our Guide to Local Practitioner Advice and Support Schemes*

http://www.gdc-uk.org/NR/rdonlyres/9F525505-9AAC-4507-A148-A5E48DA37932/15677/guide_to_pass.pdf

General Medical Council, *Referring a doctor to the GMC: A guide for individual doctors, medical directors and clinical governance managers*

http://www.gmc-uk.org/probdocs/fitness_to_practise_guidance/factsheets/guide_for_directors.pdf

Nursing and Midwifery Council, *Reporting unfitness to practise: A guide for employers and managers,*

http://www.nmc-uk.org/nmc/main/publications/Reporting_unfitness.pdf

¹⁷ See http://www.cgsupport.nhs.uk/Primary_Care/Resources.asp#drug_management_toolkit

¹⁸ See the consultation document 'Back on track' at <http://www.ncas.npsa.nhs.uk/backontrack>

Royal Pharmaceutical Society of Great Britain, *Interim guidance - Identifying and Remediating Poor Pharmacist Performance in England and Wales* <http://www.rpsgb.org/pdfs/pharmpoorperf0501.pdf>
The RPSGB also run a legal and ethical telephone advice line for pharmacists.

Health Professions Council, *Making a complaint about a health professional*
http://www.hpc-uk.org/assets/documents/100008E1HPC_Making_a_complaint.pdf

Local Supervising Authority Midwifery Officers
[http://www.nmc-uk.org/\(p3bwl553c23b5fgm0sxdn2g\)/aArticle.aspx?ArticleID=1666](http://www.nmc-uk.org/(p3bwl553c23b5fgm0sxdn2g)/aArticle.aspx?ArticleID=1666)

- 68 In analysing the reasons underlying an event and determining next steps the National Patient Safety Agency (NPSA)'s Incident Decision Tree will be helpful in many cases.¹⁹ The NPSA's Incident Decision Tree can help NHS managers decide on the appropriateness of suspension (exclusion) when dealing with staff involved in a serious patient safety incident.
- 69 Use of the tool is voluntary and the tree does not aim to provide firm 'answers' or 'solutions', but rather to identify a range of possible options. The Incident Decision Tree comprises an electronic flowchart and leads the manager through a series of questions about the individual's actions, motives and behaviour at the time of the incident.
- 70 Once the user has completed the questions he or she will be led to guidance that reflects not only the care setting but also the individual's role (community pharmacist, GP etc). The current version has been issued on a 'pilot' basis and covers most of the health economy, including primary care. Versions for dentistry and locum and agency staff are in development.

Serious concerns

- 71 There may be occasions where serious concerns come to light, either initially or through further investigation of a minor concern.
- 72 Depending on the nature of the concern, various options may apply (regulation 17):
- Immediate action to protect patients
 - Initial consultation with other members of the network
 - Incident panels
 - Formal inspection

Immediate action to protect patients

¹⁹ See <http://www.npsa.nhs.uk/idt>

- 73 If patient safety is thought to be at risk, immediate action should be taken. NHS bodies should follow their local serious untoward incident procedures. Immediate referral to the relevant regulatory body should be considered where there are serious concerns about an individual's fitness to practise. Practical guidance has recently been available on investigating patient safety incidents involving death or serious untoward harm.²⁰

Initial consultation with other members of the network

- 74 Where concerns have come to light, initial consultation with other members of the network who may have relevant information may be helpful as an alternative or prior step to establishing an Incident Panel.

Incident Panels

- 75 A PCT Accountable Officer may decide to set up an Incident Panel which provides for more structured consideration. The individual membership would depend on local circumstances and the nature of the concern but should include key members of the local network. The police would normally expect to be involved at this stage if they have not been previously.

Targeted inspection

- 76 Either following an Incident Panel or as a direct result of a concern, the Accountable Officer may decide to ensure a formal inspection of the premises takes place. The formal inspection could be undertaken by any body with the power to inspect the management of controlled drugs: the PCT, RPSGB, Healthcare Commission, CSCI or police or a mixture of the above. The Health Act gives powers of entry and inspection to examine the arrangements for the safe management of controlled drugs to nominated groups, such as the police and Accountable Officers. Information-sharing between organisations will be necessary and PCTs in particular should be involved for their local knowledge. Depending on the nature of the concern, inspection teams involving members of different organisations may be helpful to bring expertise and knowledge together.²¹

Remedial actions: dealing at local level

- 77 Many concerns can be rectified at local level. Examples may be a 'false positive' where an apparent prescribing anomaly is due to the caseload of a particular prescriber. In other cases, a minor lapse may be put right locally, where for example an organisation's storage arrangements for controlled drugs could be improved. If there is a minor concern about a healthcare professional's performance, they may require support or training. Additional visits from a prescribing adviser, or

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http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4140659&chk=LhbzT3

²¹ The Royal Pharmaceutical Society of Great Britain may charge for certain types of inspection.

clinical governance lead may be sufficient to rectify any minor issues (see regulation 17(2)).

Remedial actions: escalating concerns

- 78 However there may be cases where concerns can not be resolved satisfactorily at local level and need to be formally escalated or passed on to another organisation.
- 79 The NPSA incident decision tree offers help and support in deciding how to pass on issues. The table summarises where issues should normally be referred. There may well be occasions where a concern should be passed to more than one organisation.

Concern	Refer to:
Criminality suspected	Police
Fraud suspected	NHS Counter-Fraud and Security Management Service, police
Individual fitness to practise issue	Professional regulatory body, or Local Supervising Authority Midwifery Officer for midwives
Organisational/systems issue	RPSGB (in case of pharmacy) Healthcare Commission (in case of NHS body, private or voluntary healthcare organisation) CSCI (in case of care home) Healthcare Commission and inform Monitor (in case of Foundation Trust)
For any of the above, additionally inform the SHA	

- 80 Where there are serious concerns about any element of the management and use of controlled drugs, the SHA should be informed. They will be members of the intelligence network and have a performance management role for PCTs.
- 81 If a concern is formally passed on to another organisation, the relevant Accountable Officer should record the referral (regulation 28). Where an adverse incident or potential adverse incident (near miss) has or could have taken place, then local procedures should be followed. The details of the incident or potential incident should also be shared with the NPSA via the National Reporting and Learning System (NRLS) so that wider learning can take place.

Support for healthcare professionals

- 82 Individuals raising concerns should be supported in doing so. Free and confidential advice on how to raise a concern and the protections provided by the Public Interest and Disclosure Act can be obtained from

Public Concern at Work (an independent organisation).²² Regulatory bodies may also be able to provide advice.²³

- 83 Individuals should also be supported where concerns are raised about them, or where they wish to raise concerns about their own performance. The NCAS toolkit and *Maintaining high professional standards in the modern NHS* provide some advice on supporting professionals.²⁴

Closure of cases

- 84 Cases considered by an Accountable Officer or a responsible body should be recorded with a clear account of the findings and any action taken (regulation 28). The SHA should be informed so that trends can be monitored. Where there has been serious systems failure, the Healthcare Commission will wish to return to check that action has been taken. Where there is evidence that a particular drug has been diverted, it may be appropriate to inform the manufacturer or wholesaler.
- 85 Reports containing information about the storage and movement of controlled drugs should not normally be disclosable under Freedom of Information legislation as they could aid criminal activity and so would come within the “law enforcement” exemption.

Training and development

- 86 The National Prescribing Centre (NPC) has published *A guide to good practice in the management of controlled drugs in primary care (England)* to provide support for professionals on good practice and legislative requirements in the prescribing, supply, administration, storage and disposal of controlled drugs. It is regularly updated to reflect legislative changes and good practice.²⁵ The RPSGB’s *Safe and secure handling of medicines: a team approach* also provides information on the safe management of drugs.²⁶
- 87 The NPC has also produced a competency framework for the competencies needed by individuals and teams undertaking monitoring and inspection functions under the new arrangements.²⁷
- 88 The NPC is also producing a modular training and development package to support those working with controlled drugs. Modules will cover legislative requirements, good practice, the new monitoring and

²² See <http://www.pcaw.co.uk/> or telephone 020 7404 6609

²³ See for example, the RPSGB’s guide on raising concerns:
<http://www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf>

²⁴ See <http://www.ncas.npsa.nhs.uk/> and
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4072773&chk=ol83Ov)

²⁵ See http://www.npc.co.uk/background_for_cd.htm. A new version is in preparation and should be available early in 2007.

²⁶ See <http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf>

²⁷ See http://www.npc.co.uk/pdf/CDI_Competency_Framework

inspection arrangements and the specific knowledge and skills that different professions may need.

Central oversight

- 89 At national level, in England, the new arrangements will be subject to external scrutiny by the Healthcare Commission. They will begin to formally monitor the implementation of the controlled drugs regulations from April 1 2007. The Head of Operations is the individual responsible at the Commission for ensuring that all healthcare organisations (public, private and voluntary) have satisfactory arrangements in place for the safe management of controlled drugs. This judgement will be informed by the findings of the other regulators (eg RPSGB, CSCI) and national data sets alongside the Commission's own work. The Commission will also ensure that local governance arrangements, intelligence networks and provisions for incident panels are satisfactory – this will include a review of the partnership arrangements with other agencies. Where appropriate the Commission will use its existing powers to inspect or investigate systems failures, or registration issues in the private and voluntary sector.
- 90 A small group has been set up under the leadership of the Healthcare Commission and involving the National Patient Safety Agency, the Prescribing Support Unit, the National Clinical Governance Support Team and the police to provide a central intelligence and analysis function. The group will not be involved with individual cases but will analyse national trends in the use and management of controlled drugs and recommend action where required.
- 91 In England, the Healthcare Commission will annually publish its findings on the management of controlled drugs. It will share trends both in good practice and in common systems errors.

Support

- 92 Various organisations can provide support with developing and operating the new governance arrangements for the management of controlled drugs. The NPC will be offering a range of training and development modules and its guide to good practice in the management of controlled drugs may be helpful.²⁸ The Clinical Governance Support Team/ NCAS/ RPSGB's toolkit²⁹ provides help in implementing the arrangements, and the NPSA's incident decision tree³⁰ will help with analysing the reasons behind an event and determining next steps. The DH controlled drugs website (<http://www.dh.gov.uk/controlleddrugs>) contains the latest guidance from the department.
- 93 Accountable Officers may find it helpful to network with other Accountable Officers to share their experiences. The National

²⁸ See http://www.npc.co.uk/background_for_cd.htm

²⁹ See http://www.cgsupport.nhs.uk/Primary_Care/Resources.asp#drug_management_toolkit

³⁰ See <http://www.npsa.nhs.uk/idt>

Prescribing Centre has run introductory workshops on the new arrangements and is running national networking events for PCT Accountable Officers in Spring 2007.

94 Comments or questions on this guidance should be addressed to:

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020 7972 5397

Annex A

Supporting documents

A guide to good practice in the management of controlled drugs in primary care (England)

http://www.npc.co.uk/background_for_cd.htm

Confidentiality and disclosure of information: GMS, PMS and APMS Code of Practice

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107303&chk=GiJc0B

The Controlled Drugs (Supervision of Management and Use) Regulations 2006

<http://www.opsi.gov.uk/si/si2006/20063148.htm>

Guidelines for the NHS in support of the Memorandum of Understanding Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association and the Health and Safety Executive

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4140659&chk=LhbzT3

The Health Act 2006

<http://www.opsi.gov.uk/acts/acts2006/20060028.htm>

Maintaining high professional standards in the NHS

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4072773&chk=ol83Ov

NCAS toolkit

<http://www.ncas.npsa.nhs.uk/>

NCGST/ NCAS/ RPSGB Controlled Drugs Toolkit

http://www.cgsupport.nhs.uk/Primary_Care/Resources.asp#drug_management_toolkit

NPC Competency framework

http://www.npc.co.uk/pdf/CDI_Competency_Framework

NPSA incident decision tree

http://www.npsa.nhs.uk/health/resources/incident_decision_tree

Safe and Secure Handling of Medicines: a Team Approach

www.rpsgb.org.uk/pdfs/safsechandmeds.pdf