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Addresses

For action
Chief Executives, NHS Boards
Chief Executive, Scottish Ambulance Service Board
Chief Executive, State Hospitals Board for Scotland
Chief Executive, National Waiting Times Centre Board
Chief Executive, NHS QIS
Chief Executive, NHS NES
Chief Executive, NHS NSS
Chief Executives, Independent Hospitals
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Dear Colleague

Safer Management of Controlled Drugs: Guidance on Strengthened Governance Arrangements

Purpose

1. The fourth report of the Shipman Inquiry "*The Regulation of Controlled Drugs in the Community*" made recommendations to strengthen and improve the current systems for the management and use of controlled drugs. "*Safer Management of Controlled Drugs*", the Government response to the fourth report, set out an action programme to address the shortcomings identified by the Inquiry. The programme promised new legal requirements to promote the safe and effective use of controlled drugs. These requirements have been introduced in the UK Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (the Controlled Drugs Regulations).

2. The three key elements of the new legislation are: the appointment of Accountable officers; cooperation between health bodies and other organisations for controlled drug purposes; and new powers of entry and inspection.

Action

3. NHS Boards are asked to put into effect the new arrangements explained in the attached guidance. Although the Controlled Drugs Regulations are to come into effect in Scotland from 1 March 2007 we recognise that Boards will require more time to prepare for the changes. However, Accountable Officers must be in place by 1 July 2007.

4. NHS Education for Scotland (NES) will provide training to support Accountable Officers in undertaking their new role and Boards should pass the contact details of their Accountable Officer to NES for training purposes and to Pharmacy Division, SEHD, Room 1E-01, St Andrews House, Regent Road, Edinburgh, EH1 3DG. The Executive will publish a full list of Accountable Officers in Scotland in due course.

5. Further guidance is being developed to support the requirements in the legislation regarding the need to develop Standard Operating Procedures as explained in Annex C.

6. A copy of this letter is being sent separately to independent hospitals including hospices.

Yours sincerely

Paul Gray
Director of Primary Care and Community Care

Safer management of controlled drugs – guidance on strengthened governance arrangements

Introduction

1. This guidance sets out strengthened governance arrangements for the management and use of controlled drugs in Scotland. These new arrangements are underpinned by the UK Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (the Controlled Drugs Regulations).

2. The Fourth Report of the Shipman Inquiry[1] identified a number of serious shortcomings in the systems used for the management of controlled drugs and made recommendations to improve their management. The Inquiry recommended the creation of a controlled drugs inspectorate comprising small multi-disciplinary inspection teams, operating regionally but co-ordinated nationally.

3. The Government responded to these recommendations in *Safer Management of Controlled Drugs - the Government's response to the fourth report of the Shipman Inquiry*[2]. The Government agreed that the current systems needed strengthening but considered that a separate controlled drugs inspectorate outside of existing governance arrangements would not be the best option. Such a discrete inspectorate could lead to duplication of work and inspections and cut across existing governance arrangements.

4. The Government favoured instead a system which will work within and alongside existing governance arrangements and build on the expertise of organisations that currently monitor and inspect aspects of the management and use of controlled drugs.

5. The new system will result in a significant improvement to current arrangements, being better co-ordinated and integrated within the overall framework for improving quality in healthcare. It is 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.

Legislative changes

6. The Government considered that new legislation was necessary to respond to a number of the recommendations in the Shipman Inquiry report. Therefore, the Health Act 2006, which received Royal Assent in July, includes measures to improve and strengthen the management and use of controlled drugs. To ensure that patients in Scotland are similarly safeguarded, these provisions extend to Scotland.

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[1] See *The Regulation of Controlled Drugs in the Community, The Fourth Report of the Shipman Inquiry* (http://www.the-shipman-inquiry.org.uk/4r_page.asp)

[2] See *Safer management of controlled drugs, the Government's response to the fourth report of the Shipman Inquiry* http://www.dh.gov.uk/assetRoot/04/09/79/06/04097906.pdf

7. Regulations made under the Health Act - the Controlled Drugs (Supervision of Management and Use) Regulations 2006[3] - have been introduced in the UK Parliament. The Regulations will come into effect in Scotland from 1 March 2007.

8. The new governance arrangements need to be implemented in a way that will support healthcare professionals and encourage good practice and will not deter the use of controlled drugs when clinically required by patients. Furthermore it is essential that the new arrangements ensure that potential criminality is identified and reported to the police at the earliest opportunity.

9. The following sections describe how the new requirements will be implemented in Scotland.

Implementation in Scotland

10. The three key elements of the new legislation are: the appointment of Accountable Officers; cooperation between health bodies and other organisations for controlled drug purposes; and new powers of entry and inspection.

11. The Health Act requires "designated bodies" to appoint or nominate an Accountable Officer, either one per organisation or, within parameters, shared between organisations. For the purposes of the Act "designated bodies" are those that are "directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service)", or "otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs".

12. In Scotland, NHS Boards, the State Hospitals Board for Scotland, the National Waiting Times Centre Board, the Scottish Ambulance Service Board and independent hospitals (including hospices)[4] will be designated bodies.

13. The Act also introduces a duty of cooperation which enables a range of organisations, including healthcare organisations, NHSScotland Counter Fraud Services, the Royal Pharmaceutical Society of Great Britain (RPSGB), the police and local authorities to share information and intelligence about the management and use of controlled drugs.

14. The Act contains a new power of entry and inspection for certain authorised persons to inspect controlled drugs and associated records. The inspection process is intended to identify and investigate concerns, monitor compliance, educate, improve quality and support individual and organisational development.

Training and development

15. Educational material is being prepared and, when appointed, Accountable Officers will be contacted about training arrangements.

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[3] The Regulations can be accessed at www.opsi.gov.uk/si/si2006/20063148.htm

[4] An independent hospital is defined under the Regulation of Care (Scotland) Act 2001

16. More detailed information on each aspect of the Health Act requirements is given in the Annexes.

Annex A	- Accountable Officer
Annex B	- Duty of Cooperation
Annex C	- Monitoring
Annex D	- Entry and Inspection
Annex E	- Investigations
Annex F	- Declaration Statement/Self-Assessment

Annex A

Accountable Officer

1. The Health Act 2006 and the Controlled Drugs Regulations require "designated bodies" to nominate or appoint an Accountable Officer (regulation 4) to be responsible for a range of measures relating to the monitoring of the safe use and management of controlled drugs within the organisation and take appropriate action where necessary. In Scotland, NHS Boards, the Scottish Ambulance Service Board, the National Waiting Times Centre Board, the State Hospitals Board for Scotland and independent hospitals are designated bodies.

2. An Accountable Officer 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.

3. Two or more NHS designated bodies which are of the same type may jointly nominate or appoint one person to be their Accountable Officer so long as that person meets the criteria at paragraph 2 above in relation to one of the designated bodies. Each designated body must be satisfied that the Accountable Officer can discharge his/her responsibilities in relation to both.

4. In the case of an independent hospital, the Accountable Officer must be its manager[5] or one of its officers or employees who is answerable to its manager. If the Accountable Officer is the manager, s/he must be answerable to the Chief Executive, Chairman or Managing Director of the hospital.

5. Two or more independent hospitals can nominate or appoint one manager to be the Accountable Officer for both or all the hospitals if the manager is the manager of both or all the hospitals.

6. 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 their duties. A designated body can nominate or appoint an Accountable Officer who has an occasional, exceptional role in the use of controlled drugs (for example, in emergencies). However, 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. Individuals such as

[5] "Manager" means the person notified to the Care Commission as the manager under Regulations 17(1) and Regulation 23 (1)(b) of the Regulation of care (Requirements as to Care Services) (Scotland) Regulations 2002.

Medical Directors, Pharmacy Directors or Directors of Nursing, can be appointed as Accountable Officers if they meet the above criteria. The Accountable Officer can be a stand-alone or additional role depending on local circumstances. Designated bodies 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.

7. A designated body (or, in the case of a joint appointment, the designated bodies acting jointly) must remove its Accountable Officer if s/he no longer satisfies the conditions set out above or if s/he is no longer considered fit to be an Accountable Officer (regulation 6). For the purposes of the Regulations, an Accountable Officer is found to be unfit if s/he wilfully, negligently or through lack of competence breaches her/his duties as an Accountable Officer. A designated body must have in place a procedure (which may be part of its internal disciplinary procedures) for due consideration of matters which may lead to the removal of its Accountable Officer.

8. Designated bodies must provide their Accountable Officer with sufficient funds and other resources such as information systems, accommodation and staff to enable them to carry out their duties (regulation 7).

9. Designated bodies must inform the Scottish Executive Health Department in writing of their nomination or appointment as Accountable Officer and of any subsequent changes. The Scottish Executive Health Department will publish, from time to time, a list of Accountable Officers in Scotland (regulation 4(5)).

Accountable Officer Responsibilities

10. The Controlled Drugs Regulations set out Accountable Officers' responsibilities. Accountable Officers need to develop and implement systems for routinely monitoring the management and use of controlled drugs through pro-active analysis and identifying triggers for concern, and taking action (regulation 11). They also need to ensure that appropriate arrangements are in place for assessing and investigating concerns and that they are alerted to any significant findings (regulations 11 and 16). Where criminality is suspected the police should be notified.

11. Accountable Officers must themselves establish, operate and review appropriate arrangements for the management and use of controlled drugs within their designated body or ensure that the designated body does so. They must also ensure that any person or body acting on behalf of, or providing services under arrangements made with their designated body establishes, operates and reviews appropriate arrangements for the management and use of controlled drugs. The Accountable Officer's responsibilities are set out in the Controlled Drugs Regulations (regulations 8-18).

12. The Accountable Officer will need to have or be able to access certain skills and expertise, including data analysis, investigative skills and networking. They will require some investigative and administrative support and will need support from others such as the clinical governance lead, prescribing adviser, or the police as appropriate (see Annex C).

13. Designated bodies may wish to consider consortia arrangements to support Accountable Officers in areas such as data analysis and investigative skills. These arrangements will be for local determination and should take into account any previous history of concerns about controlled drugs misuse and predictions of the likely workload.

14. 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 works in the private sector, the Accountable Officer of their local NHS Board is responsible for carrying out periodic inspections of the premises that are used for private practice, if these are not subject to inspection by the RPSGB or have their own Accountable Officers i.e. independent hospitals. However, monitoring purely private health care provision that is provided neither by nor under arrangement with an NHS body is not otherwise part of an NHS Board's 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 nonetheless "relevant persons" who are covered by the information-sharing arrangements and the duties of cooperation between responsible bodies. NHS Boards will receive information on private prescriptions for schedule 2 and 3 controlled drugs dispensed in the community through the Information Services Division (ISD) of NHS National Services Scotland and should monitor and assess that information appropriately.

15. The Accountable Officer should also make sure that their designated body and contractors have suitable arrangements in place for the disposal of controlled drugs (regulation 10).

16. The structures set up for the Accountable Officer should integrate with existing local performance structures and should relate to groups such as Area Drugs and Therapeutic Committees and clinical governance committees.

17. At national level, NHS QIS has agreed to support and facilitate a network of Accountable Officers. A key purpose of the national network will be to maximise learning and share lessons across NHSScotland and the UK.

NHS Board Accountable Officers

18. As part of the arrangements for ensuring the proper sharing of information, Accountable Officers in NHS Boards will act as co-ordinators for local intelligence networks involving key local agencies (regulation 18). Membership of the network will be decided locally and can change depending on the circumstances. For example, the Regulations suggest that network members should include the police, NHS QIS, the Care Commission, NHSScotland Counter Fraud Services as well as regulatory bodies and representation from local authorities e.g. the vulnerable adult or child protection team. The Accountable Officer may also want to involve others as appropriate such as Drug Action Teams, Local Supervising Authority Midwifery Officers, a dental representative, the Home Office Drugs Inspectorate. A number of the bodies that can be included in a network are listed in regulation 18. However, this list is not exhaustive and it is for local networks to consider which bodies should be

involved. More information about the statutory duty of cooperation is given in Annex B.

19. Members of the network should communicate regularly to agree and maintain information-sharing protocols, perhaps drawing on any existing guidelines, and to review emerging trends. The network will enable agencies that have concerns 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 involved the NHS Board Accountable Officer leading the network 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.

20. The Accountable Officer leading the network will need to establish mechanisms to share information quickly between network members, including how best to contact organisations (possibly outside normal working hours) and make cover arrangements for holidays and sickness leave.

Occurrence Reports

21. Accountable Officers in the Special Health Boards and independent hospitals must provide the NHS Board Accountable Officer leading their local intelligence network with a quarterly occurrence report (regulation 29). This report should provide details of any concerns that the designated body may have identified regarding its management or use of controlled drugs or confirm that it has not identified any such concerns.

Annex B

Duty of Cooperation

1. To maximise the effectiveness of the new arrangements, it is important that healthcare organisations, police services, and others work together to share intelligence on controlled drugs issues. The Controlled Drugs Regulations place a statutory duty of cooperation on specified organisations ("responsible bodies" set out in regulation 22) to share information giving rise to concerns over the management or use of controlled drugs by any "relevant person" (regulation 23). The Health Act and the regulations made under the Act define the term "relevant person" and include any individuals whether or not healthcare professionals who are involved in any way (NHS or private) with the management or use of controlled drugs[6].

2. In Scotland, responsible bodies are: designated bodies; police forces; local authorities; regulatory bodies; NHS National Services Scotland (i.e. NHSScotland Counter Fraud Services, the Information Services Division and the Practitioner Services Division) (regulation 22).

Information-Sharing

3. A responsible body may disclose to any other responsible body any information which may help identify cases where action may need to be taken in respect of the management or use of controlled drugs. This enables bodies that have a cause for concern to share them as soon as possible with any other bodies who may be affected or who may have complementary information.

4. Confidential information about patients should be anonymised where possible (regulation 25 & 26). If it is not possible to remove patient identifiable information from confidential information, then the patient's consent should be sought wherever practicable (regulations 25 & 26). Where information is provided to NHSScotland Counter Fraud Services patient consent should not be sought – there is an exemption from the requirements of the Data Protection Act 1998 relating to the investigation of crime. Section 29(3) of the Act includes exemptions for the prevention or detection of crime and for the apprehension or prosecution of offenders.

5. In sharing such information, responsible bodies must have regard to the Data Protection Act 1998 and codes of practice on confidentiality - in particular the Caldicott principles i.e.

- 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.

[6] See clause 19 of the Health Act 2006 and regulation 23 of the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

6. Care should also be taken when sharing information about identifiable health and social care professionals and, where possible, individuals should be made aware of concerns raised about them.

7. NHS organisations, those contracted to provide NHS services, and the independent sector may find the following documents helpful: *Confidentiality and Disclosure of Information: General Medical Services (GMS), Section 17C Agreements and Health Board Primary Medical Services (HBPMS) Code of Practice; NHS Code of Practice on Protecting Patient Confidentiality;* and *A Good Practice Guide on Consent for Health Professionals in NHSScotland.*

8. Where the information to be shared relates to a possible fraud against the NHS, the information may only be shared in accordance with the Partnership Agreement between NHSScotland Counter Fraud Services and NHS Boards and Special Health Boards which sets out the roles and responsibilities of each NHS body in relation to fraud.

Request for Additional Information

9. There may be instances when a responsible body considers that it may require additional information from another responsible body in order to determine whether or not action is necessary (regulation 26). This additional information may not be specific to the management or use of controlled drugs but could be, for example, fitness to practise information. Where a responsible body has received such a request in writing it must decide within a reasonable period of time whether or not to disclose the additional information. If a decision is taken to disclose the information the paragraphs above relating to confidentiality apply.

Restrictions Relating to Disclosures

10. Where a responsible body has an Accountable Officer any information disclosed under the Regulations must only be made by or to the Accountable Officer or his/her staff and may only be used for identifying cases and taking action in respect of concerns relating to the management or use of controlled drugs (regulation 27). In particular, the responsible body must ensure that appropriate measures are taken to prevent unauthorised access to or processing of the information.

Record Keeping

11. Responsible bodies must keep records (either paper or electronic) of any decisions to disclose information, details of the nature of the information disclosed, details of the responsible body to which the information was disclosed and any other relevant details (regulation 28).

12. Responsible bodies must also keep a record (either paper or electronic) of any requests received from another responsible body to disclose information, details of the nature of the information disclosed, details of the responsible body to which the information was disclosed and any other relevant details (regulation 28).

Taking Action

13. Organisations are required to cooperate 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 Accountable Officer(s) concerned may make recommendations to the responsible body 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 responsible body is any responsible body that could take appropriate action, including regulatory bodies and the police. Where the person does not provide services to a designated body, the NHS Board Accountable Officer leading the local intelligence network must take reasonable steps to protect the safety of patients and the public. This could include referring the matter to a responsible body, e.g. a regulatory body or the police (regulation 30). Further information about undertaking investigations can be found in Annex E.

Annex C

Monitoring

Routine monitoring

1. Accountable Officers must ensure that their designated body and any persons or bodies acting on behalf of, or providing services under arrangements made with the designated body, monitor the management and use of controlled drugs (regulation 11). This can be through normal governance and management arrangements such as analysing prescribing data and monitoring practice (for example, by clinical governance leads or prescribing advisers, including any contract monitoring visits). 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.

2. For monitoring purposes, data analysed could include prescribing data; for secondary care, supply details; for out-of-hours services, signed orders. The Information Services Division (ISD) of NHS National Services Scotland provides a range of analytical services related to prescribing activity and costs. One of these is a web-based system to aid local (and national) monitoring and audit. Prescription data are derived from prescriptions processed by Practitioner Services Division and now include private prescriptions for schedule 2 and 3 controlled drugs dispensed in the community.

3. A toolkit developed in England by the Clinical Governance Support Team, the National Clinical Assessment Service and the RPSGB[7] provides further support on how Accountable Officers might routinely monitor the use of controlled drugs and take action. The toolkit was developed predominantly for general practice, but can be used in other settings.

Self- assessment and controlled drugs declaration statement

4. Regulation 12 provides for certain healthcare organisations providing clinical services to complete a periodic (planned to be at least every two years) declaration on 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. Those 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.

5. The Regulations enable Accountable Officers in NHS Boards to request a periodic declaration and a self-assessment form to be completed by each GP practice on its primary medical services performers list (regulation 12). The forms will also be a useful tool to aid monitoring of other healthcare providers within their designated body e.g. hospitals. For hospitals, the RPSGB's *Safe and secure handling of medicines: a team approach* provides useful information.[8]

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[7] See http://www.cgsupport.nhs.uk/Primary_Care/Resources.asp#drug_management_toolkit
[8] See http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf

6. The Regulations also enable the RPSGB to request a periodic declaration and a self-assessment form from registered pharmacies. The NHS Board Accountable Officer and the RPSGB respectively will determine the frequency of self-assessment and it may be included in other assessments or planning tools. In all cases, failure to provide information, or providing false information, could lead to investigation and further action. A model declaration/self-assessment is attached as Annex F.

Standard Operating Procedures

7. Healthcare organisations holding stocks of controlled drugs will be asked to draft a Standard Operating Procedure (SOP). The Regulations (regulation 9) require the SOPs to cover:

- who has access to the controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- disposal and destruction of controlled drugs;
- who is to be alerted if complications arise, and
- record-keeping, including –

  (i) maintaining relevant controlled drugs registers under the misuse of drugs legislation, and

  (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

A framework for SOPs is being developed and will be available shortly.

Controlled drugs review

8. As part of their responsibilities, Accountable Officers need to review or ensure that the arrangements for the management and use of controlled drugs are reviewed in their designated body and organisations contracted to provide services. For primary care providers contracted with the NHS Board (for example, GP practices and community pharmacies) we recommend that the NHS Board Accountable Officer carries out this review once a year. The review will be based on benchmark analysis derived from existing information, the organisation's self-assessment and controlled drug declaration statement (if available) 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. Information can be checked against other findings from e.g. health care regulators.

Midwives

9. Practising 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 relating 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.

Annex D

Entry and Inspection

Routine inspections

1. The Health Act 2006 contains a power of entry and inspection for certain authorised persons to inspect controlled drugs and associated records. Formal inspection involving an 'on-site' visit 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. The inspection process is intended to identify and investigate concerns and to support individual and organisational development. Inspectors may find helpful the publication "*The Government's Policy on Inspection of Public Services*" which sets out ten principles of inspection[9].

2. As part of their monitoring and auditing arrangements, NHS Board Accountable Officers should arrange for a small number of routine inspections of a random sample of "relevant premises"[10] where controlled drugs are stored, dispensed, supplied or used. Inspections will be informed by self-assessment, controlled drugs reviews and other monitoring of data. Whilst the power of inspection in the Health Act and the Regulations (regulation 19) does not require the inspections to be notified, we recommend that routine inspections are announced. Where inspections are announced the purposes of the visit should be made clear in advance. Inspections may, where possible, be combined with other visits such as Quality and Outcomes Framework, contract monitoring and clinical governance visits. Where there is more than one purpose to a visit, the Accountable Officer may wish to arrange for a second person to undertake the controlled drugs aspects of the visit. To avoid duplication, the RPSGB will take over responsibility from the police for the inspection of controlled drugs and will now include this in their routine inspections of community pharmacies. It is important that mechanisms are established between each Accountable Officer and the RPSGB to ensure that the police service is notified of any potential criminality at the earliest opportunity.

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

4. The Regulations enable an Accountable Officer to request in writing that another Accountable Officer from a designated body of the same type (NHS or independent) inspects any relevant premises of his/her designated body (regulation 20(6). This is intended to provide Accountable Officers with a system of mutual audit and support.

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[9] See http://archive.cabinetoffice.gov.uk/opsr/documents/pdf/policy.pdf

[10] See clause 20 of the Health Act 2006 and regulations 19 and 20 of the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

5. At their own cost, secondary care services can invite the RPSGB to carry out occasional inspections or inspect a hospital pharmacy where they have concerns.

Standards

6. Monitoring and Inspection Guidelines: Core Activities for Controlled Drugs Monitoring and Inspection Work – Primary Care have been developed identifying key areas which organisations monitoring and inspecting controlled drugs may wish to include in their work. The guidelines can be found at www.dh.gov.uk/assetRoot/04/13/22/58/04132258.pdf . The guidelines suggest a minimum 10% random sample to be inspected each year. We recommend that notice be given of routine inspections.

Records

8. A record (either paper or electronic) should be made of visits and inspections (regulation 19) and a report should be made available for routine inspections to the inspected premises as soon as possible after a visit, provided there is no mention in the report of potential fraud or other concerns which may result in a referral to a Discipline Committee, the NHS Tribunal, NHSScotland Counter Fraud Services, the police or a professional regulatory or licensing body. Where Counter Fraud Services involvement is required as a result of the visit, no report should be made to the owner or occupier of the premises until the results of the Counter Fraud Services investigation are known. Visit reports will form part of the self-assessment evidence material and should clearly document action taken in response to any concerns raised. Where concerns have been raised, the relevant Accountable Officer must be made aware of this and given a copy of the report.

Annex E

Investigations

1. Accountable Officers will need to ensure that robust systems are in place across his/her area of responsibility to enable concerns or incidents involving controlled drugs to be identified and, where appropriate, investigated (regulations 15 and 16).

2. Concerns may be raised through a variety of routes, including routine monitoring of prescribing data, a routine inspection, a patient complaint, police intelligence or a concern raised by a health or social care professional.

3. Where a concern relates to a potential fraud within or against any part of the NHS in Scotland the Accountable Officer should pass the information to the fraud liaison officer for his/her NHS body who will contact NHSScotland Counter Fraud Services in line with the Partnership Agreement. Any subsequent investigation should be carried out by Counter Fraud Services.

4. Where a concern that does not involve potential NHS fraud relates to a family health service practitioner whose name is included on a Board's primary medical performers', dental, ophthalmic or pharmaceutical list, the NHS Board Accountable Officer should discuss the matter with, and pass any relevant papers to, the Board officer responsible for onward referral. Referral could be to NHS Discipline Committees and to the NHS Tribunal and, where relevant, referral by the Board or by the Board's reference committee under the National Health Service (Discipline Committees) (Scotland) Regulations 2006 to one of these bodies or to the police or the relevant professional regulatory or licensing body.

5. The officer within the NHS Board with responsibility for referral of cases to NHS Discipline Committees or to the NHS Tribunal will have a copy of the Scottish Executive Health Department's Guidance on family health service (FHS) Disciplinary Procedures – A guide for Health Boards sent out under cover of circular 2006 PCA(M)12/PCA(P) 14/PCA(D)8/PCA(O6. This provides guidance on referral of FHS practitioners, including referral to professional regulatory or licensing bodies.

6. Where the matter does not concern an FHS practitioner but another healthcare professional, and where the matter does not concern potential NHS fraud, referral to the professional regulatory or licensing body may be appropriate. 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 websites and some helpful documents are listed below.

> General Dental Council (www.gdc-uk.org) *Our Guide to Local Practitioner Advice and support Schemes*
>
> General Medical Council (www.gmc-uk.org) *Referring a doctor to the GMC: A guide for individual doctors, medical directors and clinical governance managers*

Nursing and Midwifery Council (www.nmc-uk.org) *Reporting unfitness to practise: A guide for employers and managers*

Health Professions Council (www.hpc-uk.org) *Making a complaint about a health professional*

Local Supervising Midwifery Officers website (www.mnc-uk.org) has a range of useful documents.

The Royal Pharmaceutical Society of Great Britain runs a legal and ethical telephone advice line for pharmacists (www.rpsgb.org)

7. Where a concern relates to a social care professional, support and guidance can be obtained from the Scottish Social Services Council. In some cases it may be necessary to contact other organisations, for example, the superintendent pharmacist if a pharmacist is working for a large multiple organisation.

8. A Clinical Governance toolkit for controlled drug management in primary care may be a useful tool for investigating concerns.[11] This toolkit sets out a standard approach to investigating problems and covers routine monitoring of controlled drugs, investigating specific concerns and taking action once an investigation is complete. Although it focuses on primary care it may also be used in other settings. NHSQIS, in collaboration with others as required, will review the toolkit and make it suitable for NHSScotland.

9. In all cases, care should be taken that any evidence gathered during the course of an investigation is preserved in an appropriate manner to ensure its integrity. Such evidence may be required for proceedings instituted by the police, NHSScotland Counter Fraud Services, other enforcement agencies and/or the NHS Tribunal or Discipline Committees or regulatory bodies. In these circumstances, it is strongly recommended that early advice be sought from the police, NHSScotland Counter Fraud Services or another appropriate enforcement authority. Accountable Officers may wish to make early contact with the police so that they can agree guidelines for evidence gathering to ensure that any such evidence is preserved appropriately. Criminal investigations take precedence over other investigations.

Minor concerns

10. Where concerns appear to be minor, local investigation may be all that is required. For example, an apparent prescribing anomaly may be due to the case-load of a particular prescriber or where an organisation's storage arrangements for controlled drugs could be improved. If there is a minor concern about a healthcare professional's performance, that individual may benefit from additional support or training and visits from a prescribing advisor or a clinical governance lead may be sufficient (regulation 17).

[11] See http://www.cgsupport.nhs.uk/Primary_Care/Resources.asp#drug_management-toolkit

Escalating concerns

11. There may be cases where concerns cannot be resolved satisfactorily locally and need to be escalated or passed to another organisation. The table below summarises where issues should normally be referred. On occasion concerns may need to be passed to more than one organisation. In all cases the local NHS Board should also be told.

Concern	**Refer to:**
Non-NHS fraud criminality suspected.	Police.
NHS fraud suspected.	NHSScotland Counter Fraud Services via Fraud Liaison Officer in the first instance. Counter Fraud Services will deal with the police and Procurator Fiscal on behalf the NHS Board or Special Health Board.
Issue concerning FHS practitioner which is not NHS fraud related.	Officer within NHS Board with responsibility for referral of cases to NHS Discipline Committees or the NHS Tribunal.
Individual fitness to practise issue where not concerning an FHS practitioner and not concerning NHS fraud.	Professional regulatory or licensing body or Local Supervising Authority Midwifery Officer.
Organisational/systems issue	RPSGB (pharmacy) NHS QIS

12. If a concern is passed to another organisation(s) the relevant Accountable Officer should record the referral (regulation 28).

Serious concerns

13. There may be occasions where serious concerns come to light, either initially or through investigation of a minor concern. Depending on the nature of the concern, various options may apply (see regulation 17):

- Immediate action to protect patients;
- Consultation with other members of the local intelligence network;
- Controlled Drug Incident Panel;
- Formal inspection.

14. If patient safety is thought to be at risk immediate action must be taken. NHS bodies should follow their local serious untoward incident procedures. Where a case relates to NHS fraud, whether or not involving an FHS practitioner the action in the Partnership Agreement should be followed i.e. where patient safety is involved, the person may be moved to other work or suspended. In cases involving FHS practitioners, an NHS Board may refer him/her to the NHS Tribunal for interim suspension. In cases involving optometrists or ophthalmic medical practitioners on the Board's ophthalmic lists only, the Board has the power to suspend the person from its list. (Regulatory amendments will enable Boards to suspend other FHS practitioners from their other FHS lists in due course.) Immediate referral to the NHS

Tribunal must be considered where there are serious concerns about an FHS practitioner.

15. For healthcare professionals who are not FHS practitioners, referral to the relevant regulatory body must be considered where there are serious concerns about an individual's fitness to practise. NHS QIS should be informed of any serious service failures. In the case of an independent health care service, the Care Commission should be informed.

16. Communication with local stakeholders and the local intelligence network may be helpful before establishing a Controlled Drug Incident Panel or as an alternative way forward in cases not involving NHS fraud or FHS practitioners.

17. The NHS Board Accountable Officer may decide to set up a Controlled Drug Incident Panel which provides for more structured consideration. Again, this may be suitable in cases not involving NHS fraud or FHS practitioners. Membership of the panel will depend on local circumstances and the nature of the concern or incident, but should include members of the local intelligence network. The police would normally expect to be involved if they have not been previously.

18. Accountable Officers should ensure that there is a clear separation between investigating and decision-making.

Targeted inspection

19. Either following a Controlled Drug Incident Panel or as a direct result of a concern, the Accountable Officer may decide that a formal inspection of premises is required. The inspection could be undertaken by any person or body with the power to inspect premises for the management or use of controlled drugs. Information-sharing between organisations will be necessary and NHS Boards in particular should be involved. Depending on the nature of the concern, inspection teams involving members of different organisations may be helpful so as to bring together expertise and knowledge.[12]

Raising concerns

20. Individuals raising concerns should be supported in doing so. Advice on how to raise a concern and the protections provided by the Public Interest and Disclosure Act can be obtained from Partnership Information Network (PIN) guidelines and local policies (staff governance – "whistleblowing" or "voicing concerns" policies). Cases where NHS fraud is suspected can be reported anonymously to Counter Fraud Services either by telephoning the freephone Fraud hotline on 08000 15 16 28 or on their website www.cfs.scot.nhs.uk Regulatory bodies may also be able to provide advice.[13]

21. Individuals should also be supported where concerns have been raised about them or where they wish to raise concerns about their own performance.

[12] The Royal Pharmaceutical Society of Great Britain may charge for certain types of inspection.

[13] See for example the RPSGB's guide on raising concerns at www.rpsgb.org.uk

Closure of cases

22. 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). Where a serious systematic failure has been discovered NHS QIS will support and work in collaboration with the Accountable Officer to ensure that action has been taken and lessons learned are shared across NHSScotland and the UK[14]. Where there is evidence that a controlled drug has been diverted, it may also be appropriate to inform the manufacturer or wholesaler.

23. Reports containing information about the storage and movement of controlled drugs should not normally be disclosable under Freedom of Information legislation as this could aid criminal activity and so would come within the "law enforcement" exemption.

[14] See Paper E at http://www.nhshealthquality.org/nhsqis/qis_display.jsp?pContentID=3141&p_applic=CCC&p_service=Content.show&

Annex F

Self Assessment & Controlled Drugs Declaration Statement

This model self-assessment and declaration statement can be adapted for use by bodies involved in the monitoring and inspecting of controlled drugs. It was produced by a working group involving key stakeholders and chaired by the RPSGB on behalf of the Department of Health.

Please complete the form below:

Name of organisation	
Address of organisation	

Please complete the relevant parts of the questionnaire below. This questionnaire relates to activities within the last 12 months and relates to Schedule 2 and 3 controlled drugs (CDs) only, as these are subject to a higher level of control.

	Area of activity	**Yes/No**	**If the answer is 'yes'**
Q1	Do you prescribe CDs?		Please complete Table A (general information) and Section 1
Q2	Do you supply CDs?		Please complete Table A (general information) and Section 2
Q3	Do you administer CDs (or supervise or assist patients' own administration)?		Please complete Table A (general information) and Section 3
Q4	(i) Do you hold stock CDs either on the premises or off site e.g. in doctors' bags? (ii) Do you hold patients' CDs?		Please complete Table A (general information) and Section 4
Q5	Do you destroy or dispose of CDs (patient returns/stock)?		Please complete Table A (general information) and Section 5

Self Assessment & Controlled Drugs Declaration Statement

If you have answered YES to any of the above questions then:

a) Please complete the relevant parts of the questionnaire overleaf **before** signing the declaration below:

In **ALL** case please **delete** as applicable and sign the declaration below:

i) I declare to the best of my knowledge and belief that this *organisation/pharmacy* does not handle, use or manage Schedule 2 or 3 CDs on any premises of this *organisation/pharmacy*;

or

ii) I declare that to the best of my knowledge and belief that this *organisation/pharmacy* does/does not comply (please delete where appropriate) with the provisions of the Misuse of Drugs Act 1971 and the associated Regulations in its handling, use and management of Schedule 2 and 3 CDs.

Signature*	
Name (and registration number, if healthcare professional)	
Position within the organisation* *This form must be signed by appropriately authorised personnel, who have responsibility for the management and use of CDs within the organisation.	
Date of signing	

Please note that you must notify us of any material changes to the answers to Q1 – Q5 above within 14 days of the change.

Please return your completed declaration/self assessment to: **[insert name and address of organisation]**

Self Assessment & Controlled Drugs Declaration Statement

Please fill in the relevant tables below if your organisation prescribes, manages, uses or handles CDs. Please ensure that the information is accurate.

Table A: General Information: Please complete in ALL cases

	Yes/No	**Details**
1. Do you have written standard operating procedures or written policies covering the handling and management of CDs, appropriate to the activities carried out at the premises?		
2. Do you have in place a local procedure for dealing with a significant event* involving CDs?		
3. Do you have appropriate procedures for the initial and continuing training or development of all staff involved in the prescribing, handling, supply and administration of CDs?		
4. Are there any special factors which influence the prescribing or use of CDs by your organisation? If yes, please give details		

*Significant event includes any incident where a patient is harmed or nearly harmed and includes ‘near misses’, when things almost go wrong.

Self Assessment & Controlled Drugs Declaration Statement

Section One (ONLY complete if the answer to Q.1 above is YES)

Prescribing of CDs

	Yes/No or N/A	**Details (where applicable)**
1. Are there any specific restrictions on the CD prescribing abilities of any of the healthcare professionals involved?		
2. Have there been any patient or carer complaints* involving the prescribing of CDs?		
3. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about unusual, excessive or inappropriate prescribing of CDs?		
4. Have there been any significant events** involving the prescribing of CDs?		

*This includes complaints about failing to prescribe appropriate doses and/or appropriate medicines.

**Significant event includes any incident where a patient is harmed or nearly harmed and includes ‘near misses’, when things almost go wrong.

Self Assessment & Controlled Drugs Declaration Statement

Section Two (ONLY complete if the answer to Q.2. above is YES)

Supply of CDs

	Yes/No or N/A	**Details (where applicable)**
1. Do you supply CDs to addicts?		
2. Do you supply CDs against private prescriptions: (a) from addiction services? (b) elsewhere?		
3. Do you supply controlled drugs: (a) to doctors? (b) to others (not including patients)?		
4. From where do you obtain your stocks of CDs?		
5. Do you provide advice to patients on the safekeeping and disposal of unwanted CDs?		
6. Are patient returned medicines ever re-used?		
7. Are patient information leaflets supplied to all patients receiving CDs?		
8. Have there been any patient or carer complaints involving the supply of CDs?		
9. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the supply of CDs from the organisation/pharmacy?		
10. Have there been any significant events* involving the supply of CDs?		

*Significant event includes any incident where a patient is harmed or nearly harmed and includes ‘near misses’, when things almost go wrong.

Self Assessment & Controlled Drugs Declaration Statement

Section Three (ONLY answer if the answer to Q.3 above is YES)

Administration of CDs (This excludes supervision of CDs consumed by addicts)

	Yes/No or N/A	**Details (where applicable)**
1. Are the CDs used for administration: (a) stock CDs? (b) patient's own CDs? (c) both a) and b)?		
2. Do you maintain records of administration? If yes, where? (Register, MAR chart etc)		
3. Is administration of CDs witnessed? If not, what risk management policies are in place to cover administration?		
4. Have there been any patient or carer complaints involving the administration of CDs?		
5. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the administration of CDs?		
6. Have there been any significant events* involving the administration of CDs?		

*Significant event includes any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong.

Self Assessment & Controlled Drugs Declaration Statement

Section Four (ONLY complete if the answer to Q.4 above is YES)

A) Security and safe custody of CDs on premises

	Yes/No or N/A	**Details (where applicable)**
1. Do you store CDs in: (i) a central store? (ii) doctors' bags? (iii) other places (please detail)?		
2. Do you have any current Chief Constable exemption certificates in operation for your CD storage facilities?(NB Not all premises will need exemption certificates for CD storage facilities)		
3. Are all CDs kept under lock and key (including patient returned CDs or unwanted/obsolete CDs)?		
4. Is access to CDs controlled? If yes, then how?		
5. Do you utilise the CD storage facilities for storage of anything other than CDs? If so, please state.		
6. How often does date checking of CD stock take place? Give details of date checking procedures.		
7. How often does date checking of CD stock in doctors' bags take place? (where applicable) Please give details of date checking procedures.		
8. Are all stock CDs kept in the original container?		

9. Are dispensed patients' medicines appropriately labelled?		
10. Are different strengths of the same medicine segregated in any way?		
11. Do you have out of date or obsolete **stock** CDs currently stored?		
12. Are out of date/obsolete/patient returned CDs segregated from other CDs?		
13. Are patient returned medicines ever reused?		

B Security and safe custody of CDs in transport

	Yes/No	**Details (where applicable)**
14. Do you transport or are you responsible for the transport of CDs (this includes sending CDs using third party carriers such as delivery drivers and postal system)? If **NO**, please move on to section C.		
15. What procedure do you have in place for the transport of CDs?		
16. Are CDs routinely kept under lock and key during transport? If no, then please provide details.		
17. What records are maintained of CDs in transport?		

C Registers

	Yes/No	Details (where applicable)
18. Do you keep an up to date CD register?		
19. Do you keep running balances of stock CDs held? (a) If yes, do you audit your running totals? (State how often and date of last audit) (b) Are the running totals audited by outside management staff (area/regional managers)? (State how often and date of last audit)		
20. Have you identified any discrepancies between running totals and actual CDs held in the last 12 months? If yes, what was the explanation for the discrepancy? What action was taken?		
21. Do you maintain records of all receipts and supplies of CDs? If yes, for how long do you keep records?		
22. Have there been any patient or carer complaints involving the storage, transport or record keeping of CDs?		
23. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the storage, transport or record keeping of CDs?		
24. Have there been any significant events* involving the storage, transport or record keeping of CDs?		

*Significant event includes any incident where a patient is harmed or nearly harmed and includes ‘near misses’, when things almost go wrong.

Self Assessment & Controlled Drugs Declaration Statement

Section Five (ONLY complete if the answer to Q5 above is yes)

Destruction or disposal of CDs

	Yes/No	**Details (where applicable)**
Patients' CDs		
1. What records do you keep of CDs returned to you by patients for disposal (where applicable)?		
2. Do you routinely destroy patients' old or obsolete CDs?		
3. What systems do you have in place to dispose of patients' old or obsolete controlled drugs?		
4. Is the destruction of patients' old or obsolete CDs witnessed? If yes, by whom?		
5. Do you keep records of the destruction of patients' old or obsolete CDs?		
Stock CDs (if applicable)		
6. How often do you aim to destroy out of date or obsolete stock CDs?		
7. Do you have any out of date or obsolete stock CDs currently awaiting destruction?		
8. Who usually witnesses your stock destruction?		
9. When was the last-witnessed CD stock destruction?		
10. Are records of stock destruction kept in the CD register?		
11. Have there been any patient or carer complaints involving the destruction or disposal of CDs?		

12. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the destruction or disposal of CDs?		
13. Have there been any significant events* involving the destruction or disposal of CDs?		

*Significant events includes any incident where a patient is harmed or nearly harmed and include ‘near misses’, when things almost go wrong.