

Dear Colleague

**SAFER MANAGEMENT OF CONTROLLED DRUGS:
A. CHANGES TO RECORD KEEPING REQUIREMENTS
B. DESTRUCTION OF CONTROLLED DRUGS – NEW ROLE
FOR ACCOUNTABLE OFFICERS
C. ACCOUNTABLE OFFICERS – CONTACT DETAILS
(UPDATED)**

Action

NHS Boards are asked to copy this letter and Annexes to:

- **all general practices, all dentists and community pharmacy contractors on their lists, nurse prescribers, pharmacist independent prescribers, supplementary prescribers and all staff involved in the management and use of controlled drugs. The guidance must also be copied to the Board's Accountable Officer.**

Purpose

1. The annexes to this letter provide information about changes to the record keeping requirements for controlled drugs; a new role for Accountable Officers which enables them to authorise people or groups of people to witness the destruction of controlled drugs; and an updated list of Accountable Officers in Scotland.

Background

2. The fourth report of the Shipman Inquiry "*The Regulation of Controlled Drugs in the Community*" made recommendations to strengthen and improve current systems for the management and use of controlled drugs. The Government's response to the report set out a programme of work to address the shortcomings identified by the Inquiry. The Health Act 2006 and Regulations made under the Act – the Controlled Drugs (Supervision of Management and Use) Regulations 2006 – introduced new governance arrangements for controlled drugs.

3. Full guidance on the new governance arrangements for controlled drugs can be found in [Circular NHS HDL \(2007\) 12 dated 14 February 2007](#)¹.

21 December 2007

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
Medical Directors, NHS Boards
Directors of Nursing, NHS Boards
General Practitioners
Dental Practitioners
Community Pharmacists
Directors of Pharmacy, NHS Boards

For information

Chief Executive, NHS QIS
Chief Executive, NHS NSS
Chief Executive, NHS NES
Scottish Commission for the
Regulation of Care
Royal Pharmaceutical Society of
Great Britain, Scottish Division
SGPC
Community Pharmacy (Scotland)

Email Enquiries to:

cdenquiries@scotland.gsi.gov.uk

Pharmacy Division
Room 1E.01
St Andrew's House
EDINBURGH
EH1 3DG

<http://www.scotland.gov.uk>

¹ <http://www.show.scot.nhs.uk/publicationsindex.htm>

4. A copy of this letter is being sent separately to Accountable Officers in the independent sector.

Yours sincerely

Bill Scott

PROFESSOR BILL SCOTT
Chief Pharmaceutical Officer

Record Keeping Requirements for Controlled Drugs

Purpose

1. The purpose of this guidance is to provide information to healthcare professionals and organisations about changes to the record keeping requirements for controlled drugs (CDs) required by amendments made to the Misuse of Drugs Regulations 2001 set out in SI 2006/1450 and SI 2006/2178 and SI 2007/2154.²

2. The guidance also provides details of changes required to the format of the Controlled Drug Register (CDR) and the headings/titles of the columns used to capture the mandatory fields of information. This is required as a result of further changes made to the Misuse of Drugs Regulations 2001 which come into force on 1st February 2008. This guidance may need to be reviewed and amended at that time.

Background

3. The guidance sets out the changes to professional practice and standard operating procedures (SOPs) required as a result of further change made to the legislative framework. The key focus remains to strengthen the audit trail including the record keeping arrangements for CDs across the NHS and independent healthcare sectors. It explains how the new record keeping requirements work and also reinforces the requirement to be introduced in early 2008, to record information in the CDR about the identity of the person who may be collecting a CD. This will help to minimise the risk of abuse or harm that may be caused to patients and the public through diversion of CDs.

4. This guidance should be read in conjunction with the amended regulations and accompanying Home Office circulars and other guidance sign-posted in this document.

Legal requirements

5. Legislation requires that records of the receipt and supply of schedule 2 CDs must be kept in a CDR. All healthcare professionals who hold schedule 2 CD stock must keep their own CDR and are personally responsible for keeping this accurate and up to date. At the present time, CDRs may be maintained either in a paper bound or electronic format.

6. The format and requirements for CDRs are specified in regulations 19, 20 and Schedule 6 of the Misuse of Drugs Regulations 2001 as amended. Schedule 6 of the regulations, which specifies the form of the CDR, will be deleted on 1st February 2008 when it will no longer be a legal requirement to maintain a CDR in a prescribed format. The regulations will specify only the headings/fields to be used in the CDR. It will be seen as good practice to be working towards meeting the new requirements in order to achieve full compliance with the regulations by 1st February 2008.

7. From 1st February 2008, the regulations will require the following information to be recorded in the CDR, under the following specified headings, when CDs are obtained:

- Date supply obtained
- Name and address from whom obtained (e.g. wholesaler, pharmacy)
- Quantity obtained

2. www.opsi.gov.uk/si/si2006/20061450.htm
www.opsi.gov.uk/si/si2006/20062178.htm
www.opsi.gov.uk/si/si2007/20073654.htm

8. When CDs are supplied to patients (in response to prescriptions) or to practitioners (in response to requisitions), the regulations require information to be recorded in the CDR, under the following specified headings:

- Date supplied
- Name and address of person or firm supplied
- Detail of authority to possess – prescriber or licence holder’s details
- Quantity and form in which supplied

9. From 1st Feb 2008 there will also be additional record keeping requirements which are outlined in paragraphs 24-26.

10. The CDR may set out “entries to be made in case of obtaining” and “entries to be made in cases of supply” on the same **or** separate pages. Two separate pages will no longer be required. This supports the increasing use of electronic registers and maintenance of running balances. Separate pages (in paper) or sections for each strength and form of an individual drug will be required. Each page must specify the strength and form of the drug at the head of the page, together with the name of the drug to which the entries on the page of the CDR relate. In the case of electronic registers, they must be capable of printing or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout.

Additional information that may be recorded

11. The regulations make it clear that the record keeping requirements for CDRs set out in the regulations are a minimum. They do not prevent any person required to keep a CDR from including additional related information that will help to guarantee the integrity and accuracy of the audit trail.

12. The following information **may** (not must) be recorded in the CD register:

- Running balances
- Prescriber identification number (i.e. the NHS prescriber or private prescriber code) and/or the professional registration number of the prescriber where known and also the name and professional registration number of the healthcare professional supplying the CD.

13. Once electronic registers and electronic prescribing for CDs are in widespread use and subject to parliamentary approval, the UK Government will mandate the inclusion of running balances and prescriber and supplier identification. Since CDs supplied by pharmacies can involve several pharmacists, if these are being recorded it should be the name of the pharmacist who makes or supervises the supply of the CD to the patient or his/her representative, whose name and professional registration number are entered in the CDR.

Computerised CDRs

14. The regulations require that entries made in computerised CDRs must be attributable and capable of being audited. Full details of the requirements for computerised CDRs are in SI 2005/2864 ³.

Maintaining a running balance of stock

15. Healthcare professionals who supply CDs should maintain a running balance of stock in their CDR as a matter of good practice, as the regulations allow. The Royal

³ . www.opsi.gov.uk/si/si2005/20052864.htm

Pharmaceutical Society of Great Britain (RPSGB) issued professional guidance⁴ in May 2005 on maintaining a running balance in the CDR.

Physical reconciliation with stock levels

16. The running balance recorded in the CDR should be checked with the physical amounts of stock at regular intervals. The decision on how often to carry out stock checks should be taken in line with guidance from professional representative bodies and undertaken after a risk assessment has been carried out. Frequency of reconciliation may alter according to local circumstances but will be specified in the SOPs that have been drawn up for the relevant healthcare professional and his/her working environment.

17. Accountability for maintaining the running balance of CD stock and dealing with any discrepancies lies with the health care professional in charge of the healthcare working environment/premises where CDs are received, stored and supplied from.

Preservation of records

18. CDRs, requisitions and orders for CDs must be preserved for two years. The 2001 regulations allow the information contained in these records to be preserved in the original paper form, or in an electronic form. From 1st January 2008, original requisitions or orders (NHS and private) for schedule 1, 2 and 3 CDs supplied in the community must be sent to NSS. Guidance on this topic is contained in "Safer Management of Controlled Drugs (CDs): Private requisition forms for Schedules 1,2 and 3 CDs (NHS CEL (2007) 16) issued on 6th November 2007.

19. Safeguards must be put in place to make sure that all data contained in the CDR and all electronic requisitions and orders for CDs cannot be altered at a later date once a record has been made. It must be possible to retrieve all the data for audit purposes, make adequate backups and put systems in place to minimise the risk of unauthorised access to the data held.

20. Once electronic CDRs are in widespread use, the Government intends to require any person required to maintain a CDR to preserve secure copies of the records made for up to 11 years.

Proof of identity requirements: prescriptions for Schedule 2 CDs

21. The regulations require any person who is asked to supply a Schedule 2 CD on prescription to seek to establish whether the person collecting the CD is the patient, the patient's representative or a healthcare professional acting in his/her professional capacity on behalf of the patient. This requirement conveys an important message to patients, their representatives and members of the public about the importance attached to the safe management of CDs and the priority the Government places on taking reasonable steps to minimise the harm caused through diversion of CDs in the community. Where the person collecting the CD is the patient or the patient's representative (e.g. a friend or neighbour) the dispenser may:

- request evidence of that person's identity
- refuse to supply the drug if he/she is not satisfied as to the identity of that person

Where the person collecting the prescription is a healthcare professional acting in his/her professional capacity on behalf of the patient, the dispenser:

- must obtain that person's name and address;

⁴ www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf

- must, unless he/she is acquainted with that person, request evidence of that person's identity; but
- may supply the drug even if he /she is not satisfied as to the identity of that person.

22. The regulations aim to strike a sensible balance between strengthening controls designed to minimise the risk of diversion of CDs in the community, and making sure that patients have access at all times to the medicines they need and that have been prescribed for them. The dispenser is therefore allowed:

- discretion *not* to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed;
- to dispense the prescription and supply the CD when proof of identity has not been provided without committing an offence under the regulations.

23. The RPSGB has issued professional guidance: *Changes to the management of controlled drugs affecting pharmacists (England, Scotland and Wales)*⁵ for their members on what forms of identification may be considered suitable and advice on circumstances where discretion should be exercised.

Additional information that must be recorded from 1st February 2008.

24. It is good practice to record information to support the proof of identity requirements outlined in paragraphs 21 -23 above. The form of identification for health care professionals should be their professional registration number.

25. The main purpose of the requirement to keep and maintain a CDR, is to provide an audit trail of the supply of those CDs that are considered to have the greatest potential for diversion and harm when they are abused. It provides a detailed record of the receipt, supply and stock-holding of CDs used to treat patients. The records contained in the CDR are fundamental to the wider governance and SOPs that underpin the care and safe management of CDs. When used correctly within the requirements of the regulations, they provide proof and evidence of safe and lawful practice, whilst at the same time providing at the earliest opportunity a mechanism that identifies malpractice and possible diversion of CDs. This minimises the risk of harm to individuals and supports the high level of confidence that patients and members of the public must have in the care and safe management of CDs in the community. As part of the further work that has been undertaken to strengthen the audit trail and improve further the contribution that the CDR makes to the management of CDs, it will be a requirement, **from 1st February 2008**, to record additional information in the CDR. As specified in the amended Misuse of Drugs Regulations 2001, it will be a requirement to record the following information in relation to the identity of the person collecting a schedule 2 CD supplied on prescription:

- whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient; and
- if the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address;
- if the person who collected the drug was the patient or their representative and whether evidence of identity was requested (annotated in the yes/no columns). As a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory;
- whether evidence of identity was provided by the person collecting the drug.

⁵ www.rpsgb.org.uk/pdfs/cdmanagechguid.pdf

26. The requirement to record this additional information in the CDR, confirms and endorses the good practice already followed by health care professionals. It strengthens the contribution that the CDR makes to the audit trail of CDs, and provides further proof and evidence of their safe and lawful supply. Recording additional information in relation to the identity of the person collecting a schedule 2 CD represents an important component of the governance arrangements necessary for the care and safe management of CDs in the community, and for minimising the risk of harm to patients and the public caused through diversion and abuse.

Destruction of Controlled Drugs

1. The UK Health Act 2006 introduced new monitoring and inspection requirements for controlled drugs. These new arrangements are designed to work within and alongside existing governance systems to promote the safe, secure and effective use of controlled drugs.
2. Regulations made under the Health Act - the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (the Controlled Drugs Regulations) - require healthcare organisations to appoint an Accountable Officer to be accountable for the safe management and use of controlled drugs in their organisation, including safe destruction and disposal.
3. Regulation 27(1) of the Misuse of Drugs Regulations 2001 requires that any person who is required to keep records with respect to a drug in Schedule 1,2,3 or 4 of these Regulations may not destroy such a drug except in the presence of and in accordance with any directions given by a person authorised (either personally or as a member of a class) to witness their destruction. An amendment to the Misuse of Drugs Regulations 2001, which came into force on 16 August 2007, permits Accountable Officers to authorise people or groups of people to witness the destruction of controlled drugs in compliance with these regulations. Controlled drugs must be rendered irretrievable prior to onward safe disposal.
4. The Controlled Drugs Regulations state that the Accountable Officer should be independent of day-to-day management of controlled drugs, therefore the amendment to the Misuse of Drugs Regulations states that the Accountable Officer cannot themselves be an authorised person to witness the destruction of controlled drugs.
5. As many of the groups of people previously authorised to witness destruction of controlled drugs in Scotland no longer exist, Accountable Officers are likely to need to authorise new people or groups of people who can witness destruction of controlled drugs. Any person authorised to witness destruction should have appropriate training and be accountable for this activity directly to the Accountable Officer.
6. In community pharmacies a large percentage of witnessing of destruction has been undertaken by police chemist inspection officers (CIOs). From September 2007, they are no longer involved as inspection of controlled drugs in community pharmacies is being undertaken by the Royal Pharmaceutical Society of Great Britain. However, the Society has stated that its inspectors will not routinely witness destruction.

Pharmacy multiples or bodies corporate

7. Accountable Officers should also be aware that given their new powers, the Home Office is to withdraw its authorisations to hospices and bodies corporate (e.g. large pharmacy chains) to witness destruction by the end of 2007. In view of this, Accountable Officers are now expected to facilitate the authorisation of witnesses for pharmacy multiples to enable them to maintain their existing internal arrangements for the safe destruction of controlled drugs.
8. Due to the need to prevent the build up of expired or unwanted controlled drugs, Accountable Officers will need to ensure that they have sufficient witnesses, and so granting applications from individuals previously authorised by the Home office may be a useful supplement to authorised persons within the NHS Board area.

9. A person authorised by the Accountable Officer should be authorised to witness the destruction of controlled drugs in any pharmacy or premises in Scotland owned by the body corporate employing the individual. It is not intended that such an individual would be authorised by the Accountable Officer in every NHS Board area in which he or she witnesses the destruction. It is suggested that applicants will have discretion in deciding which NHS Board area they should apply to. The applicant should specify the NHS Board areas in which they will require to witness destruction and that the authorising Accountable Officer should notify the Accountable Officer(s) of the other NHS Board areas.

10. Accountable Officers will wish to seek reassurance from the multiples that persons applying to be witnesses are:

- subject to a code of ethics
- appropriately trained
- have the necessary distance from the day-to-day handling of controlled drugs.

11. Appropriate records of all such witnessed destructions must be kept within the pharmacy. The record must include details of the quantity destroyed and the date of destruction and words to the effect of “Out of date stock destroyed in the pharmacy”. The authorised witness should also endorse the record with name, signature and registration number.

12. it is recommended that witnessing destruction of controlled drugs arrangements are written into standard operating procedures and should include elements such as ID requirements, record keeping and good practice for safe destruction. Good practice guidance on the destruction of controlled drugs together with advice on safe methods of destruction and disposal to comply with environmental protection legislation is available at www.rpsgb.org/pdfs/cdsafedestructionguid.pdf .

Accountable Officers: Contact details

- The following lists provide contact details for Accountable Officers in Scotland appointed under the Health Act 2006 and regulations made under the Act – the Controlled Drugs (Supervision of Management and Use) Regulations 2006.
- Please ensure that your organisation's Accountable Officer is included on the lists and that their contact details are correct. Any changes should be notified to Pharmacy Division at the address on the front of this letter.

NHS Accountable Officers – Contact Details

NHS Board	Accountable Officer	Tel No	Email
Ayrshire & Arran	Mrs Michele Caldwell	01292 513846	michele.caldwell@aaaht.scot.nhs.uk
Borders	David J Dalglish	01896 825579	david.dalglish@borders.scot.nhs.uk
Dumfries & Galloway	Michael Pratt	01387 241526	michael.pratt@nhs.net
Fife	Dr Frances Elliot	01592 648077	frances.elliott@nhs.net
Forth Valley	Dr Gareth Davies	01786 457293	gareth.davies@nhs.net
Grampian	Professor George Downie	01224 556348	george.downie@gpct.scot.nhs.uk
Greater Glasgow & Clyde	Dr Catherine McKean	0141 201 5837/5176	kate.mckean@sgh.scot.nhs.uk
Highland	Professor John Cromarty	01463 706895	john.cromarty@raigmore.scot.nhs.uk
Lanarkshire	Ms Christine Gilmour	01236 712560	christine.gilmour@lanarkshire.scot.nhs.uk
Lothian	Ms Pat Murray	0131 536 9413	pmurray@lpct.scot.nhs.uk
Orkney	Dr Peter Baxter	01856 885400	peternicholas.baxter@nhs.net
Shetland	Chris Nicolson	01595 743000 Ext: 3372	chris.nicolson@shb.shetland.scot.nhs.uk
Tayside	Ms Angela Timoney/ Alistair Jack	01382 425685	angela.timoney@nhs.net alistairjack@nhs.net
Western Isles	Jane Adams	01851 708008	jane.adams@wihb.scot.nhs.uk

Special Health Board	Accountable Officer	Tel No	Email
National Waiting Times Centre	Kenneth Kinghorn	0141 951 5806	kenneth.kinghorn@gjnh.scot.nhs.uk
State Hospital	Dr Steve Young	01555 840293	steve.young@tsh.scot.nhs.uk
Scottish Ambulance Service	Ms Shirley Rogers	0131 446 7017 (mob: 07775 954072)	srogers@scotamb.co.uk

Independent Sector Accountable Officers – Contact Details

Organisation	Accountable Officer	Tel No	Email
Abbey King's Park Hospital, Stirling	Elizabeth Martin	01786 451669	bethmartin@abbeyhospitals.co.uk
Accord Hospice, Paisley	Helen Simpson	0141 581 2000	helen.simpson@accord.org.uk
Ardgowan Hospice, Greenock	Ros Park	01475 558881 or 01475 726830	ros.park@ardhosp.co.uk
BMI Albyn Hospital, Aberdeen	Kenneth Hay	01224 595993	khay@bmihealthcare.co.uk
Highland Hospice, Inverness	Paula McCormack	01463 243132	p.mccormack@highlandhospice.org.uk
The Glasgow Nuffield Hospital	David Snape	0141 576 2702	david.snape@nuffieldhospitals.org.uk
The Huntercombe Hospital, Edinburgh	Diane Whiteoak	01506 856023	diane.whiteoak@fshc.co.uk
The Prince & Princess of Wales Hospice, Glasgow	Audra Cook	0141 429 5599	audra.cook@ppwh.org.uk
The Priory Hospital, Glasgow	Stuart Cummings	0141 636 6116	stuartcummings@prioryhealthcare.com
Strathcarron Hospice	Marjory Mackay	01324 826222	marjory.mackay@strathcarronhospice.org
Marie Curie Hospice, Belmont Road, Glasgow	Anna Grady	0141 531 1318	anna.grady@mariecurie.org.uk
Abbey Carrick Glen Hospital, Ayr	Alison Smith	01292 288882	alisonsmith@abbeyhospitals.co.uk
St Andrew's Hospice, Airdrie	Susan Dillet	01236 766952	susan.dillet@standrews.lanpct.scot.nhs.uk
St Columba's Hospice	Margaret Dunbar	0131 551 1381	mdunbar@stcolumbashospice.org.uk
St Margarets of Scotland Hospice	Elizabeth Thomas	0141 435 7025	elizabeth.thomas@smh.org.uk
The Ayrshire Hospice	Shona Hynd	01292 269200	shona.hynd@ayrshirehospice.org
Ross Hall Hospital	David Tennent	0141 810 3151	dtennent@bmihealthcare.co.uk
Marie Curie Hospice Edinburgh	Anne Willis	0131 470 2201	anne.willis@mariecurie.org.uk
St Vincent's Hospice	Brona McGee	01505 705635	Brona.mcgee@svh.co.uk
Quarriers	Martin Cawley	01505 612224	martin.cawley@quarriers.org.uk
Children's Hospice Association Scotland (CHAS) Rachel House	Libby Gold	01577 866060	
Children's Hospice Association Scotland (CHAS) Robin House	Margaret Robertson	01389 722051	
Children's Hospice Association Scotland (CHAS)	Pat Carragher	0131 444 4015	
Bethesda Care Home and Hospice Stornoway		01851 706222	bethsдахospice@hotmail.com
Castlebeck Care	Heather Brown	01382 819910	