Safer Management of Controlled Drugs (CDs): Changes to Record Keeping Requirements

Guidance (For England only)

Department of Health

Safer Management of Controlled Drugs (CDs): Changes to Record Keeping Requirements

(For England only)

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DH Information Reader Box			
Policy HR/Workforce Management Planning Clinical		Estates Performance IM & T Finance Partnership working	
Document purpose:			
ROCR ref:		**Gateway ref:**	8712
Title:	Safer Management of Controlled Drugs (CDs): Changes to Record Keeping Requirements (For England Only)		
Author:	DH – Medicines, Pharmacy & Industry – Controlled Drugs Team		
Publication date:			
Target audience:	NHS and private prescribers; community pharmacies (NHS and private); hospital pharmacies; dispensing doctors; Strategic Health Authority prescribing and pharmacy leads; Primary Care Trust prescribing and pharmacy leads; healthcare professional representative organisations; patient representative organisations; patient representative organisations; substance misuse services; relevant inspectorates		
Circulation list:	DH Website		
Description:	This guidance informs and supports relevant healthcare professionals and organisations in implementing changes to the record keeping requirements for Controlled Drugs (CDs) required by changes made to 'The Misuse of Drugs Regulations 2001' set out in SI 2006/1450 and SI 2006/2178 ….. This guidance also informs and supports relevant healthcare professionals and organisations in implementing changes required to the format of the Controlled Drugs Register (CDR) and the headings/titles of the columns used to capture the mandatory fields of information.		
Cross ref:	N/A		
Superseded docs:	Interim guidance issued October 2007		
Action required:	N/A		
Timing:	Arrangements described in the document will come into effect on 1 February 2008		
Contact details:	Department of Health MPI-CCE Room 406A, Skipton House 80 London Road London SE1 6LJ		
For recipient's use:			

First published October 2007, revised February 2008
Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/publications

SAFER MANAGEMENT OF CONTROLLED DRUGS (CDs):
CHANGES TO RECORD KEEPING REQUIREMENTS
(FOR ENGLAND ONLY).

For action/information

- **NHS and private prescribers**
- **Community pharmacies (NHS and private)**
- **Hospital Pharmacies**
- **Dispensing doctors**
- **Strategic Health Authority prescribing and pharmacy leads**
- **Primary Care Trust prescribing and pharmacy leads**
- **Healthcare professional representative organisations**
- **Patient representative organisations**
- **Substance misuse services**
- **Relevant inspectorates**

Purpose

1. The purpose of this guidance is to inform and support relevant healthcare professionals and organisations in implementing changes to the record keeping requirements for Controlled Drugs (CDs) required by changes made to The Misuse of Drugs Regulations 2001 set out in SI 2006/1450 and SI 2006/2178 (September) and SI 2007/ .Copies are available from the following web links:
www.opsi.gov.uk/si/si2006/20061450.htm
www.opsi.gov.uk/si/si2006/20062178.htm
www.opsi.gov.uk/si/si2007/
This guidance also informs and supports relevant healthcare professionals and organisations in implementing 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 change made to The Misuse of Drugs Regulations 2001 following the outcome of the Home Office led review & public consultation on proposed changes to The Misuse of Drugs regulations 2001 and The Misuse of Drugs Regulations (Northern Ireland) that closed on 6th July 2007.

Commencement

2. The regulatory changes come into force on 1st February 2008.

Scope

3. Changes to The Misuse of Drugs Regulations apply to England, Scotland and Wales. The Department of Health and Social Services Northern Ireland, will be considering similar changes to the corresponding regulations for Northern Ireland. This guidance is for England only.

Background and Introduction

4. This guidance reflects the outcome of a comprehensive review of the CDR format – unchanged since 1973 – undertaken by the Home Office in partnership with the Department of Health, designed to produce a revised CDR that provides a modern comprehensive format fit for the 21st century. It updates the final guidance issued by the Department of Health in October 2006 (Gateway Reference:7187) to reflect and explain the changes required to the prescribed format of the CDR, the headings/titles of the columns used to capture the mandatory fields of information in the CDR and the terminology used to describe the headings.

5. CDs are important for the management of a variety of clinical conditions. They are subject to special legislative controls because of the potential for them to be abused or diverted and cause harm.

6. This guidance sets out the changes to professional practice and standing 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 and social care sectors. This guidance explains how the new record keeping requirements work. It reinforces the requirement introduced in early 2008, to record information in the CDR about the identity of the person who may be collecting a CD. This helps to minimise the risk of abuse or harm that may be caused to patients and the public through diversion of CDs.

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

RECORD KEEPING REQUIREMENTS FOR CONTROLLED DRUGS

Legal requirements

8. 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 will be deleted on 1st February 2008.

9. 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.

10. From 1st February 2008, 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. 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.

11. From 1st February 2008, the regulations 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

12. 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

* from 1st Feb 2008 there will be additional record keeping requirements which are outlined in paragraphs 25-27

Additional information that may be recorded

13. 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.
The following information MAY (not must) be recorded in the CD register:

a) Running balances
b) Prescriber identification number (i.e. the 6 digit private doctor code or the NHS 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.

Once electronic registers and electronic prescribing for CDs are in widespread use and subject to parliamentary approval, the Government will mandate the inclusion of running balances and prescriber and supplier identification. Since CDs supplied by pharmacies can involve several pharmacists, 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 SI2005/2864 which is available from the following web link: www.opsi.gov.uk/si/si2005/20052864.htm

15. Good practice guidance on the management of CDs in primary care is set out in the National Prescribing Centre's "A Guide to Good practice in the Management of Controlled Drugs in Primary care". The document is available on the NPC

website:www.npc.co.uk
Good practice guidance on the safer management of CDs in secondary care (England) is set out in the Department of Health and the Royal Pharmaceutical Society of Great Britain's "Safer management of Controlled Drugs: a guide to good practice in secondary care (England)". The document is available on the Department of Health website: www.dh.gov.uk. and the Royal Pharmaceutical Society of Great Britain website: www.rpsgb.ork.uk
The guidance makes clear that if the CDR is held in computerised form then best practice requires that:

- Safeguards should be incorporated in the software to make sure that the author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

Maintaining a running balance of stock

16. 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 Pharmaceutical Society of Great Britain (RPSGB) issued professional guidance in May 2005 on maintaining a running balance in the CDR
The most up to date version of this document is available from the following web link:
www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf

Physical reconciliation with stock levels

17. 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 their working environment.

18. 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

19. 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 for schedule 1, 2 and 3 CDs supplied in the community must be sent to the NHS Business Services Authority Prescription Pricing Division (PPD) for England, or processed as directed by its equivalent for the Devolved Administrations. The Department of Health has provided guidance on this topic in: "Changes to the

requirements in respect of requisitions used for the supply of schedule 1,2 and 3 CDs". (available on the Department's website: www.dh.gov.uk)

20. 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.

21. 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

22. 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;
- 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.

23. 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.

24. The RPSGB has issued professional guidance: *Changes to the management of controlled drugs affecting pharmacists (England, Scotland and Wales)* for their members on what forms of identification may be considered suitable and advice on circumstances where discretion should be exercised. This guidance is available from the following web link: www.rpsgb.org.uk/pdfs/cdmanagechguid.pdf

ADDITIONAL INFORMATION THAT MUST BE RECORDED FROM 1st FEBRUARY 2008.

25. It is good practice to record information to support the proof of identity requirements outlined in paragraphs 22 - 24 above. The form of identification for health care professionals should be their professional registration number.

26. 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 a mechanism that identifies malpractice and possible diversion of CDs at the earliest opportunity. 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 is a requirement, **from 1st February 2008,** to record additional information in the CDR. As specified in the amended Misuse of Drugs Regulations 2001, it is 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;
- and whether evidence of identity was provided by the person collecting the drug.

27. 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.

Where to go for more information

A guide to good practice in the management of CDs in primary care (England). This provides useful good practice guidance on record-keeping. It is available from the following web link: www.npc.co.uk/background for cd.htm

Safer management of Controlled Drugs: a guide to good practice in secondary care (England). This provides useful good practice guidance for those who are involved in the day to day management of CDs in secondary care and for those who are responsible for making

sure that CDs are managed safely and appropriately in their organisations The document is available on the Department of Health website: www.dh.gov.uk and the Royal Pharmaceutical Society of great Britain website: www.rpsgb.org

Changes to the management of controlled drugs affecting pharmacists (England, Scotland and Wales) RPSGB guidance. This is available from the following web link: www.rpsgb.org.uk/pdfs/cdmanagechguid.pdf

Filename: Record Keeping final guidance Feb 08.doc
Directory: C:\DOCUME~1\kbaah\LOCALS~1\Temp\notes99D109
Template: C:\DOCUME~1\Commsteo\LOCALS~1\Temp\p.notes.data\NHS led_DH_2.dot
Title: Main heading
Subject:
Author: DH User
Keywords:
Comments:
Creation Date: 28/01/2008 11:04 AM
Change Number: 5
Last Saved On: 28/01/2008 12:03 PM
Last Saved By: DH User
Total Editing Time: 46 Minutes
Last Printed On: 29/01/2008 11:28 AM
As of Last Complete Printing
Number of Pages: 10
Number of Words: 3,092 (approx.)
Number of Characters: 17,627 (approx.)