SAFER MANAGEMENT OF CONTROLLED DRUGS (CDs):

CHANGES TO RECORD KEEPING REQUIREMENTS

Guidance for Implementation

Department Of Health
Gateway Reference: 6819

June 2006 (Interim Guidance)

INTERIM GUIDANCE

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SAFER MANAGEMENT OF CONTROLLED DRUGS: CHANGES TO RECORD KEEPING REQUIREMENTS

For action/information

- Community pharmacies (NHS and independent sector)
- Hospital pharmacies (NHS and independent sector)
- Dispensing doctors
- Strategic Health Authority prescribing and pharmacy leads
- Primary Care Trust prescribing and pharmacy leads
- Healthcare professional representative organisations
- Patient representative organisations
- User representatives for substance misuse treatment 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 required by recent (November 2005 SI 2005/2864) and forthcoming (July 2006 SI 2006/1450) changes to the Misuse of Drugs Regulations 2001.

Scope

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

Introduction

3 Controlled drugs 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. This guidance is part of the post-Shipman changes to this legislative framework - a key focus is to strengthen the audit trail including the record keeping arrangements for controlled drugs across the NHS and independent healthcare sector. This guidance explains how the new record keeping requirements will work. It should be read in conjunction with the amended regulations and accompanying Home Office circular (available at www.homeoffice.gov.uk) and other guidance sign-posted in this document.

RECORD KEEPING REQUIREMENTS FOR CONTROLLED DRUGS

Legal requirements

4 The format and requirements for Controlled Drug Registers (CDRs) are specified in Regulations 19, 20 and Schedule 6 of the Misuse of Drugs Regulations 2001 as amended (the 2001 Regulations).

5 Records for Schedule 2 controlled drugs must be kept in a CDR. All healthcare professionals who hold personal CD stock must keep their own CDR and are personally responsible for keeping this accurate and up to date.

6 For CDs received into stock, the following details must be recorded in the register:

- date on which the supply was received;
- name and address of the supplier (eg. wholesaler, pharmacy);
- amount obtained;
- name, form and strength of the CD

7 For CDs supplied to patients (in response to prescriptions) or to practitioners (in response to requisitions) the following details must be recorded in the CD register:

- date on which the supply was made;
- name and address of person or organisation supplied;
- particulars of the license or authority of person or organisation supplied to be in possession;
- quantity supplied;
- name, form and strength in which the CD was supplied.

RECORD KEEPING REQUIREMENTS : KEY CHANGES

Minimum requirements

8 The 2001 Regulations are being amended from July 2006 to make clear that the record-keeping requirements of the CDR outlined in the Regulations are a minimum and do not prevent any person required to keep a register from including additional related information. **The Department of Health is aware that the Home Office are working towards a root and branch review of the format of the CDR set out in Schedule 6 of the 2001 Regulations - this interim guidance will be reviewed in due course to take account of any further regulatory changes that may result.**

From July 2006, the following additional information MAY (not must) be recorded in the CD register :

a) running balances (see paragraphs 11-14);

b) prescriber identification number or professional registration number where known; name and professional registration number of the dispenser (paragraphs 18-20).

Subject to Parliamentary approval, the Government intends to mandate the additional entries at (a) once electronic registers are in

widespread use and at (b) when electronic systems which automatically capture the data are in common use.

Computerised Controlled Drug Registers

9 The definition of a Controlled Drug Register in the 2001 Regulations was amended in November 2005 to **allow - not require at this stage** - the register to be held on a computerised system which complies with specified best practice guidance. The Regulations require that entries in computerised registers must be attributable and capable of being audited. Full details of the requirements for computerised CDRs are in SI 2005/2864, available at www.opsi.gov.uk/si/si2005/20052864.htm

10 The current specified best practice guidance is the National Prescribing Centre's *A Guide to Good practice in the Management of Controlled Drugs in Primary Care, available at* www.npc.co.uk/background_for_cd.htm which makes clear that if the CDR is held in computerised form:

- safeguards should be incorporated in the software to ensure 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

11 The Shipman Inquiry recommended that controlled drugs registers should maintain a running balance which should be regularly reconciled against stock level. From July 2006, the 2001 Regulations will make clear the legal requirements of the CDR are a minimum and a pharmacy or GP practice may choose to include additional information. Pharmacists and other healthcare professionals who supply CDs should maintain a running balance of stock in their CDRs as a matter of good practice. Once computerised registers are in common use, subject to Parliamentary approval at the time, the Government intends to make the inclusion of a running balance in the register a mandatory requirement.

12 The Royal Pharmaceutical Society of Great Britain issued professional guidance in May 2005 on the maintenance of a running balance in the controlled drugs register, available at www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf

Physical reconciliation with stock levels

13 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 in line with any 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 should form part of Standard Operating Procedures (SOPs).

14 Accountability for maintaining the running balance of CD stock and dealing with any discrepancies lies with the health professional in charge and not with the person to whom they may delegate day-to-day responsibility under locally defined standard operating procedures.

Preservation of records

15 Registers, requisitions and orders for controlled drugs must be preserved for two years. The 2001 Regulations have been amended to allow the information contained in these records to be preserved in the original paper form, or in computerised form.

16 As with computerised CDRs, where records are preserved on computer, safeguards should be in place to ensure the data cannot be altered at a later date, that all data can be recalled for audit purposes, that adequate backups are made and that systems are in place to minimise the risk of unauthorised access to the data.

17 Once electronic CDRs are in common use, the Government intends to require pharmacists and dispensing practices to keep secure copies for up to 11 years.

ADDITIONAL INFORMATION THAT MAY BE RECORDED: JULY 2006

Prescriber and dispenser details

18 As part of further enhancements to the audit trail for controlled drugs, the register and record-keeping requirements of the 2001 Regulations have now been amended to make explicit that they are minimum requirements and that additional related information can be included. CDRs are therefore **allowed (but not required)** to include:

- the prescriber identification number (i.e. the 6 digit private prescriber code or the NHS prescriber code) and/or professional registration number of the prescriber where known and

- the name and professional registration number of the pharmacist or dispensing doctor.

19 The Home Office is working towards a thorough review of the format of the CDR specified in Schedule 6 of the 2001 Regulations – this guidance will be reviewed in due course to take account of any further regulatory changes that may result. In addition, subject to further

consultation and Parliamentary approval, it intends to mandate the requirements in paragraph 18 when electronic systems which automatically capture the data are in common use.

20 As the dispensing of a prescription can involve several pharmacists, it should be the pharmacist who makes the supply of the controlled drugs to a patient or his/her representative whose name and professional registration number are entered in the CDR.

Where to go for more information

A guide to good practice in the management of controlled drugs in primary care (England) Chapter Five of the National Prescribing Centre guide provides useful good practice guidance on record-keeping.

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

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