

THE NEW YEAR, NEW CHANGES – CONTROLLED DRUG REQUIREMENTS IN PHARMACY '08

As a direct response to the January 2000 conviction of Harold Shipman and the government's inquiry in 2004/05, changes to the controls on procurement, storage and supply were recommended. The 2006 Health Act enacted the changes to the regulations and most of these came into effect in March 2007. However, there are still a few significant regulations coming in this year.

Requisitions

1st January 2008 saw the regulations for requisitions change, requiring the name and address of the supplier to be recorded on all requisitions for schedule 1, 2 and 3 controlled drugs issued in the community.

The requisition can either be computer generated or hand written and must contain the following information*:

- 1) The name, address and profession or occupation of the recipient
- 2) The purpose for which the drug is supplied and the total quantity to be supplied
- 3) Is signed by the recipient in their own handwriting

****A standard form is being developed by the NHSBSA, PPD department but it will not be mandatory to use it. Your local PCT will be able to inform you how to obtain it.***

The supplier must complete the following:

- 1) Record their name and address on the requisition and this can be done by using the pharmacy stamp
- 2) Endorse the supplier of the medicine
- 3) Add their CD prescription F code (this must be obtained from the PPD and is different from your contracting code, PPD tel-0845 610 1171)

The regulations will also require the original requisitions for all schedule 1, 2 and 3 controlled drugs to be submitted to the NHSBSA Prescription Pricing Division. This data will provide PCTs and Accountable officers with a more complete picture of the use of Controlled Drugs in the Community.

Controlled Drugs Register

From 1st February 2008 the regulations for the form of the controlled drugs register (CDR) will be changed and replaced with a requirement for specific headings/fields in the CDR. The new headings that must be followed are:

When a controlled drug is received

- 1) Date supply obtained
- 2) Name and address from whom received
- 3) Quantity received

When a controlled drug is supplied

- 1) Date supplied
- 2) Name and address of person or firm supplied
- 3) Details of authority to possess-prescriber or license holder details
- 4) Person collecting schedule 2 controlled drug (patients/patients representative/healthcare professional) and if healthcare professional name and address.
- 5) Was proof of identity requested of patient/patients representative? (Yes/No) – If person is not known to staff ID must be requested
- 6) Was proof of identity of person collecting provided? (Yes/No)- NB. If proof is not presented the pharmacist can still supply even though the person may not be known to them
- 7) Quantity supplied

Pharmacy contractors are required under their terms of service to have SOPs for dispensing and repeat dispensing and regulations now also require SOPs relating to the management and use of controlled drugs. The PCT accountable officers have the responsibility of ensuring that pharmacies have their SOPs up to date. Further information on the CD SOPs can be obtained from the RPSGB and template SOPs are available from the NPA.

In brief, the SOPs should include:

- who has access to the controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs
- disposal and destruction of controlled drugs;
- Patient Returns – internal procedures
- Out of Date Stocks – control, storage and notification arrangements
- Frequency of Audit
- who is to be alerted if complications arise record keeping, including registers and records of patient returns

Additional information that may be recorded

Currently the following information MAY (not must) be recorded in the CD register:

Running balances; Prescriber identification number.

These will become mandatory at a later date, but are now considered good practice.

MONITORING OF CD MANAGEMENT.

The monitoring of the Controlled Drug controls will fall to the Society Inspectors who during routine visits will be looking at issues relating to:

- Personnel – adequately trained
- Accountability & SOPs (specific to CDs)
- Security & Safe Custody
- CD Stock & assembled medicines
- Records – running balances?
- Supplies – advice given to patients
- Destructions – procedures and records
- Concerns about prescribing & OTC sales
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Further information

Full document available on DH website: www.dh.gov.uk/publications

Regulations required for computerised CDRs: www.opsi.gov.uk/si/si2005/20052864.htm

Safer management of Controlled Drugs: a guide to good practice in secondary care (England).

www.dh.gov.uk or www.rpsgb.org.uk

A guide to good practice in managing CD's in Primary Care- www.npc.co.uk/background_for_cd.htm

The Accountable Officer for Devon PCT has now changed to Joy Davey, 01392 207818

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