

Safer Management of Controlled Drugs: a guide to good practice in secondary care (England) October 2007





The Department of Health and Royal Pharmaceutical Society of Great Britain guidance document “Safer Management of Controlled Drugs; a guide to good practice in secondary care (England)” has recently been released. This PHS Guide is intended to summarise the key points related to the disposal of CDs and highlight areas where your waste disposal contractor may be able to offer additional support and guidance.

Relevant Legislation

The Guidance is in addition to and in support of existing legislation such as the Misuse of Drugs Regulations 2001, Controlled Drugs (Supervision of Management and Use) Regulations 2006 (England) and the Health Act (2006).

For further information on the relevant regional Regulations please visit www.opsi.gov.uk

Scope of Guidance

The “Safer Management of Controlled Drugs” is aimed at any secondary care practitioner, either hospital or community based, who processes or administers controlled drugs.



The guidance was issued following the fourth report of the Shipman inquiry and is aimed at strengthening the current controlled drugs management systems and thereby minimise the risk to patients, the environment and the wider general public. It sets out how controlled drugs should be bought, stored, transported, prescribed, administered and safely disposed of.

The Guidance is intended to be of particular use to:

- Pharmacies
- Hospital wards
- Operating theatres
- Midwifery units
- Mental Health units
- Other health and social care bodies including hospices, ambulance trusts and nursing homes

To support the guidance, each Trust is required to appoint an Accountable Officer who will ultimately be responsible for the processes and procedures set in place to ensure the safe use and management of CDs.

Disposal of Controlled Drugs

The Guidance clearly states that in all situations where controlled drugs are used, CDs should be safely denatured and disposed of securely to avoid both environmental damage and misuse:

“CDs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used”

It is good practice to ensure that these drugs are disposed of as quickly and securely as possible to minimise the risk of drugs being accessible. In an acute environment, this may be done either on the wards or at the central pharmacy.



Disposal in wards and departments

For wards and departments where small quantities of drugs are used, a number of options are available. Whether it is a general ward, a midwifery unit or theatre, you should always choose the option which presents the most secure and safe disposal route for your particular workplace.

Unused stock controlled drugs

Unused or out of date controlled drugs can be returned to the pharmacy for safe disposal as witnessed by an authorised person.

Unused part doses

For part-used vials, ampoules or infusion bags, it may be more practical to issue wards with a stock of denaturing kits for use by staff. In principal, unused part-doses should "be destroyed promptly and witnessed by a registered nurse". Where denaturing kits are to be used, a risk assessment should also be performed and a Standard Operating Practice developed.

Even very small amounts of controlled drugs, e.g. a dosage surplus, should NEVER be put down the sink. When dealing with very small quantities, the Guidance does allow for disposal in an appropriately labelled sharps bin (yellow lid ONLY). However, this procedure should be checked by your waste disposal contractor as the container used may mean that the drugs are not classed as "irretrievable" or compliant for transport purposes.

Disposal in pharmacies

All pharmacies should ensure that their disposal process and records operate in line with current Royal Pharmaceutical Society of Great Britain recommendations. Again, the guiding principal should always be that controlled drugs are securely stored and then denatured prior to final disposal to ensure that they are safe, cannot be re-used and are therefore without value.



Storage

Any unwanted, expired or obsolete controlled drugs must be securely stored and segregated from other CDs in the CD cupboard. In addition, they should be clearly marked “for disposal” in order to minimise the risk of error.

Records

Any controlled drugs that are to be destroyed must also be clearly recorded in the Controlled Drugs register. The entry must contain the drug name, form, strength, quantity, date of destruction and the signatures of both the witness and the person destroying the drugs.

Authorised witnesses

The Guidance re-iterates current Best Practice by stating that:

“Any pharmacy held stock of obsolete, expired or unwanted Schedule 2 CDs...can only be destroyed in the presence of an authorised person...”

Authorised inspectors include:

- Royal Pharmaceutical Society inspectors
- Police Constables
- Pharmaceutical Advisors who report directly to a Primary Care Trust Director

A Trust’s Accountable Officer is also able to authorise groups of people to act as witnesses as long as the destruction process is carried out in line with The Misuse of Drugs Regulations 2001. Further Guidance on authorisation levels can be found at www.dh.gov.uk

Licenses

The Environment Agency has confirmed that at this time, the denaturing of controlled drugs by pharmacists using authorised methods is classed as a “low risk” activity. This means that pharmacies are not required to hold a Waste Management licence to undertake this activity.

Denaturing and Disposal

The Guidance clearly states that controlled drugs awaiting disposal should be regularly denatured using only authorised methods:

“Wherever practical, CD denaturing kits should be used to denature CD’s”

Unlike other methods, denaturing kits are approved for use for the disposal of both unwanted or out of date stock and small amounts of surplus doses. Even small amounts of drugs must NEVER be disposed of via the sewage system and out-of-date stock must NEVER be placed in either a sharps bin or pharmaceutical bin without first being denatured.

It is also practical and cost-effective to ensure that you are using the correct sized CD destruction kit for your purposes. Never over-fill such containers as this may reduce the effectiveness of the kit and mean that the drugs are not effectively rendered irretrievable.

Whichever denaturing and disposal method is selected, it is recommended that a brief risk assessment is undertaken and a Standard Operating Procedure produced. For example, when crushing pills (a requirement of any CD destruction kit to ensure efficacy) protective equipment such as gloves and a mask should be provided. Your waste disposal contractor will be able to offer advice on the risks associated with using CD destruction kits and full instructions should be provided on the label.

Further information

A full copy of the Guidance can be downloaded at
www.dh.gov.uk/controlleddrugs

Details of the Misuse of Drugs Regulations 2001 can be found at
www.homeoffice.gov.uk or ordered from www.opsi.gov.uk

The Royal Pharmaceutical Society has issued detailed guidance for pharmacists
www.rpsgb.org.uk

PHS Wastemanagement offer a range of Controlled Drugs Destruction Kits in sizes from 250ml to 20 ltr. www.phs.co.uk/wastemanagement

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