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How to Prescribe, Store, Order and Dispose of Controlled Drugs

Abstract: The Shipman Inquiry has led to a number of changes in the regulations that govern controlled drugs. Some of these changes, in particular the change in schedule of midazolam from Schedule 4 to Schedule 3 and the introduction of private controlled drug prescriptions, which are now mandatory for all private prescribers, have implications for dentists. This paper aims to outline the current regulations governing controlled drugs that are relevant to dentists and covers how to obtain, prescribe, store and dispose of them.

Clinical Relevance: Controlled drugs are the most highly regulated medicines and recent changes in the regulations governing them have implications for dentists in both private and NHS practice.

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Following the fourth report of the Shipman Inquiry *Safer Management of Controlled Drugs*, the UK Government amended the *Misuse of Drugs Regulations 2001* in a number of ways to improve controls on prescribing, dispensing and storage of controlled drugs. In April 2006, the Department of Health issued guidance on *Safer Management of Controlled Drugs (CDs): Private CD Prescriptions and other Changes to the Prescribing and Dispensing of CDs* which was given statutory backing by the *Misuse of Drugs (Amendment No. 2) Regulations* in July 2006. The guidance introduces a new private controlled drug prescription form (FP10PCD) for use by all private (non NHS) prescribers of controlled drugs, including dentists.

In January 2008, the legal classification of midazolam changed from Schedule 4 to Schedule 3. This affects all dentists who are required to stock midazolam in their practice for the emergency management of status epilepticus. Dentists trained in sedation techniques also use midazolam for conscious sedation.

Ongoing changes to ensure safer management of controlled drugs have

implications for dentists in both private and NHS practice.

How are controlled drugs regulated?

The *Misuse of Drugs Act 1971* controls the unlawful production, supply, possession and exportation of specified medicines considered to be dangerous or harmful (Controlled Drugs). The Act places the medicines in one of three Classes (A, B or C) used solely for determining penalties for offences under the Act. The Act does not control the legitimate use of controlled drugs by healthcare professionals, this is addressed by the *Misuse of Drugs Regulations 2001*.

The *Misuse of Drugs Regulations 2001* provides a legal framework for the management of controlled drugs. It defines the classes of people who are authorized to supply and possess controlled drugs while acting in their professional capacity (eg as a health professional) and lays down the conditions under which these activities may be carried out. In the regulations drugs are divided into five schedules each specifying the requirements governing import, export, production, supply, possession, prescribing, storage, reconciliation and disposal:

- **Schedule 1** includes drugs, such as cannabis, which are not used medicinally. Possession and supply are prohibited except

in accordance with Home Office authority.

- **Schedule 2** includes drugs such as diamorphine (heroin), morphine, remifentanyl, pethidine, secobarbital, glutethimide, amphetamine, and cocaine and are subject to full controlled drug requirements relating to prescription writing, safe custody and the need to keep registers, etc.

- **Schedule 3** includes the barbiturates (except secobarbital, now Schedule 2), buprenorphine, diethylpropion, meprobamate, midazolam, pentazocine, phentermine and temazepam. They are subject to prescription writing requirements (except temazepam) but not to safe custody requirements (except buprenorphine, diethylpropion and temazepam) nor to the need to keep registers (although there is a requirement for the retention of invoices for two years).

- **Schedule 4** includes, in Part I, benzodiazepines (except temazepam and midazolam, which are in Schedule 3) and zolpidem, which are subject to minimal control. Part II includes androgenic and anabolic steroids. Controlled drug prescription writing requirements and safe custody requirements do not apply.

- **Schedule 5** includes those preparations which, because of their strength, are exempt from virtually all controlled drug requirements other than retention of invoices for two years.

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Which controlled drugs can dentists prescribe?

Dentists prescribing on an **NHS prescription form** can prescribe the following:*

- **Schedule 3:** temazepam tablets, temazepam oral solution;
 - **Schedule 4:** diazepam tablets, diazepam 2 mg/5 ml oral solution, nitrazepam tablets;
 - **Schedule 5:** dihydrocodeine 30 mg tablets.
- *No Schedule 2 CDs are allowed on NHS prescription. In March 2009, pethidine tablets BP were removed from the Secretaries of State list of medicines prescribable by dentists on an NHS prescription (*The Dental Practitioners' Formulary*, DPF).

NB Midazolam is a Schedule 3 controlled drug but is not in the list above as it is not for use by patients outside the dental surgery.

Dentists prescribing for **private patients** may prescribe any controlled drug as long as it has been prescribed to meet the dental needs of the patient. Pharmacists are advised to challenge dental prescriptions for controlled drugs in Schedule 2 or 3 for which there is no recognized dental use.

Which prescription forms should be used to prescribe controlled drugs?

Dentists prescribing a controlled drug for an **NHS patient** should use the NHS FP10D prescription form.

Dentists prescribing controlled drugs in Schedule 2 or 3 for a **private patient** must use the new private controlled drug prescription form (FP10PCD). Community pharmacists can no longer dispense private controlled drug prescriptions if they are not written on an FP10PCD form.

Private prescriptions for Schedule 4 and 5 controlled drugs should be written in the same way as private prescriptions for non-controlled drug medicines.

Where are private controlled drug (FP10PCD) prescription forms available from?

Dentists who need to write a private prescription for a controlled drug should contact the dental advisor, the pharmaceutical/medicines management team or the Accountable Officer in the Primary Care Trust (PCT) in which their practice is based, even if the dentist has no NHS contract

with the PCT. The PCT will arrange for the prescription forms to be printed and issued. The cost of the forms will be invoiced by the PCT to the dentist/practice.

The Prescription Pricing Division of the NHS Business Services Authority (NHSBSA PPD) issues each PCT with a unique identification number for private dental prescriptions. This number appears on each FP10PCD form (NB This is not the same as the General Dental Council registration number). After the community pharmacist dispenses the FP10PCD form he/she submits it to the NHSBSA PPD. PCTs are responsible for monitoring private CD prescribing within their boundary; data to enable this are made available by the NHSBSA PPD.

What information needs to be included on a prescription for a controlled drug?

Prescriptions for controlled drugs on both **NHS and private prescription forms** must:

- Be written (or printed) in indelible ink;
- Be signed by the prescriber;
- Be dated;
- Specify the prescriber's address and profession;
- Include the name and address of the patient;
- Include the age and date of birth for children under 12 years.

Information that must be included on both **NHS and private prescription forms** for controlled drugs in Schedules 2 and 3 (except temazepam) is:

- The name of the controlled drug in full as written in the BNF;
- The form, and where appropriate, the strength of the preparation;
- The total quantity (in both words and figures) of the preparation;
OR the number (in both words and figures) of dosage units to be supplied;
OR the total quantity (in both words and figures) of the Controlled Drug to be supplied;
- The dose;
- The words 'for dental treatment only' if issued by a dentist.

Although not yet mandatory, the Department of Health recommends that the patient's NHS number is included on the prescription form.

Prescribers are strongly advised

to limit the duration of treatment with Schedule 2, 3, and 4 controlled drugs to 30 days.

There is no legal requirement for the prescriber's name to appear on the prescription form other than in the form of a signature. However, it is good practice for the name to appear legibly to enable an accurate entry to be made in the controlled drug register by the pharmacist dispensing the prescription.

Before dispensing a controlled drug from Schedule 2 or 3, pharmacists have a legal obligation to take sufficient steps to make reasonably sure that the prescription is not a forgery. They must be acquainted with the signature of the prescriber and have no reason to suppose that it is not genuine, or take reasonable steps to satisfy themselves that it is genuine. This process may include contacting and speaking to the dentist and/or contacting the General Dental Council to ensure that the dentist is registered in the UK. NB Not all community pharmacies are registered to dispense private controlled drug prescriptions.

How long are controlled drug prescriptions valid for?

NHS and private prescriptions for Schedule 2, 3 and 4 controlled drugs are valid for 28 days from the date of the prescription. Prescriptions for Schedule 5 controlled drugs and non-controlled drugs are valid for six months.

Are there any changes for the patient?

The back of the new FP10PCD private prescription form contains a section for the patient, or his/her representative, to sign on receipt of a Schedule 2 or 3 controlled drug from the pharmacy. In addition, for Schedule 2 controlled drugs, the pharmacist will ask the patient, or his/her representative, for proof of identity. This requirement has also been introduced for NHS controlled drug prescriptions and will be necessary once FP10D forms are issued with the appropriate section on the reverse.

How do dentists obtain controlled drugs to hold in stock?

All dentists are advised to

hold midazolam in stock for the emergency management of status epilepticus. There are two routes for obtaining midazolam or other Schedule 2 and 3 controlled drugs.

From a dental wholesaler

A dental wholesaler who supplies pharmaceutical preparations can also supply controlled drugs. Controlled drugs, including midazolam, should be ordered from a dental wholesaler in the same way as ordering pharmaceuticals (eg local anaesthetic cartridges).

From a community pharmacist

Dentists must provide the community pharmacist with a requisition for the controlled drug. Dedicated requisition forms (FP10CDF) were introduced in January 2008 and should now be used. Dentists should obtain controlled drug requisition forms (FP10CDF) from their local PCT. The requisition may be computer generated or handwritten. In exceptional circumstances, if an official requisition form cannot be obtained from the PCT, a requisition may be handwritten on a non standard form and must legally include the following information:

- The recipient's (dentist's) name, address and profession or occupation;
- The name, form and strength of the drug;
- The total quantity of the drug;
- The purpose for which the drug is required;
- The signature of the dentist (this must be handwritten).

Instructions on how to complete the FP10CDF form are included with it. The code required in Part C will be supplied by the PCT.

NB Not all community pharmacists are registered to issue controlled drugs via a requisition.

Do dentists need a controlled drugs cabinet to store controlled drugs?

All controlled drugs in Schedule 2 (and temazepam, buprenorphine and diethylpropion from Schedule 3) are subject to safe custody requirements and must be kept in a locked controlled drug cabinet. Controlled drugs in other schedules do not require storage in a controlled drug cabinet. Midazolam does not need to be kept in a controlled drug cabinet.

NB If a dental practice holds temazepam for administration prior to a procedure or for issue to patients (private patients only), it must be stored in a controlled drug cabinet.

The cabinet must comply with the requirements of the *Misuse of Drugs (Safe Custody) Regulations 1973*. For further information on the specifications for allowable controlled drug cabinets, dentists should contact the PCT Accountable Officer.

Do dentists need to keep a controlled drugs register?

No, not unless dentists hold supplies of Schedule 2 controlled drugs, eg morphine. No Schedule 3 controlled drugs, including temazepam and midazolam, need to be recorded in a controlled drug register.

What is the legal requirement for controlled drug invoices?

It is a legal requirement to keep invoices for all controlled drugs in Schedules 2 to 5 for a minimum of two years.

Are there any regulations surrounding the disposal of controlled drugs?

Yes. Controlled drugs that need disposal, eg part used ampoules left over after a clinical procedure or stock that is out of date, unwanted or for some other reason unusable, must be destroyed and disposed of safely.

Schedule 2 controlled drugs require witnessed destruction by an individual authorized under the *Misuse of Drugs Regulations*. Dentists are unlikely to need to destroy Schedule 2 controlled drugs unless they hold, for example, morphine for use in the practice. Dentists should seek advice from their local PCT Accountable Officer if they require Schedule 2 controlled drug destruction to be witnessed.

Before disposal, Schedules 2, 3 and 4 (part 1) controlled drugs, eg midazolam, must be denatured, dissipated, or rendered irretrievable. All drugs, once disposed of, should be unrecognizable as such. It is not acceptable to put partly used midazolam ampoules straight into the pharmaceutical waste and sharps container.

Wherever practicable, controlled drug denaturing kits should be used. These should be available from the dental practice's

contract waste management company. Where use of controlled drug denaturing kits is not possible or practicable, absorbing a liquid preparation on to cat litter or similar product (eg cotton wool roll) is acceptable.

Partly used ampoules or opened out-of-date ampoules should have as much of the content as possible emptied into the controlled drug denaturing kit or on to cat litter or cotton wool roll(s). The cat litter or cotton wool roll(s) and empty ampoule should be disposed of in the sharps bin labelled 'contains mixed pharmaceutical waste and sharps – for incineration'.

Do dentists need Standard Operating Procedures (SOPs) for controlled drugs?

Yes. The *Health Act 2006* introduced new monitoring and inspection arrangements for controlled drugs, including a requirement for standard operating procedures (SOPs) for the use and management of controlled drugs by all health care providers.

SOPs should cover every aspect of the controlled drugs journey – from procurement, administration or dispensing to disposal.

SOPs must cover the following:

- Ordering and receipt of CDs;
- Assigning responsibilities;
- Where the controlled drugs are stored;
- Security and who has access to the controlled drugs;
- Record keeping;
- Who should be alerted if complications arise.

These requirements apply to dental practices. The inspection of controlled drug arrangements and SOPs is the responsibility of the Accountable Officer at the PCT. Further details can be found in *Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs*.

Further Reading

1. Department Of Health. *Safer Management of Controlled Drugs (CDs): Private CD Prescriptions and other Changes to the Prescribing and Dispensing of Controlled Drugs (CDs)*. June 2006 (Final Guidance) Gateway Reference: 6820. Accessed via <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/>

2. Royal Pharmaceutical Society of Great Britain. Legal and Ethical Advisory Service, Fact Sheet: One: *Controlled Drugs and Community Pharmacy*. September 2007. Accessed via <http://www.rpsgb.org.uk/pdfs/factsheet1.pdf> on 16/10/08.
3. Department Of Health. *Private Controlled Drugs Prescriptions and Dental Prescribing*. 31st May 2006. Accessed via http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4135432.pdf on 16/10/08.
4. NHS Business Services Authority Prescription Services Division. *Safer Management of Controlled Drugs*. Accessed via http://www.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer_Management_of_Controlled_Drugs_prescribing.doc on 16/10/08.
5. British Dental Association. Advice Sheet B9: *Prescribing in General Practice*. September 2006. Accessed via <http://www.bda.org/> on 16/10/08.
6. Joint Formulary Committee. *Guidance on Prescribing*. British National Formulary 57th edn. London: British Medical Association and Royal Pharmaceutical Society of Great Britain, 2009. Accessed via www.bnf.org on 1/04/09.
7. National Prescribing Centre. *A Guide to Good Practice in the Management of Controlled Drugs in Primary Care* (England). 2nd Ed Feb 2007. Accessed via http://www.npc.co.uk/policy/resources/cdguide_second_edition_feb_2007.pdf on 20/04/09.
8. NHS Business Services Authority Prescription Services Division. *Safer Management of Controlled Drugs – Requisitions for Schedules 1, 2 and 3 Controlled Drugs*. Via http://www.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer_Management_of_Controlled_drugs_requisitions.doc on 20/04/09.
9. Department Of Health. *Safer Management of Controlled Drugs (CDs): Changes to Requirements for Requisitions for Supply of Schedules 1, 2 and 3 Controlled Drugs*. Accessed via http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079571 on 20/04/09.
10. Royal Pharmaceutical Society of Great Britain. *Guidance for Pharmacists on the Safe Destruction of Controlled Drugs England, Scotland and Wales*. September 2007. Accessed via <http://www.rpsgb.org/pdfs/cdsafedestructionguid.pdf> on 14/01/09.
11. Department of Health. *Safer Management of Controlled Drugs: Guidance on the Destruction and Disposal of Controlled Drugs*. October 2006 (Interim Guidance). Gateway Reference: 7186. Accessed via www.dh.gov.uk/controlleddrugs on 14/01/09.
12. Department of Health. *Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs*. January 2007 Gateway Reference: 7585. Accessed via http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064828.pdf on 22/2/10.