How should dentists prescribe, store, order and dispose of controlled drugs?

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Date prepared: June 2011

Summary

♦ Private prescriptions

Dentists must use the private prescription form FP10PCD* when prescribing Schedule 2 and 3 controlled drugs. A dentist can prescribe privately any Schedule 2 or 3 controlled drug on an FP10PCD form, as long as it meets the dental needs of the patient. Pharmacists may challenge private controlled drug prescriptions if they feel that the controlled drug has no recognised dental use. FP10PCD forms should be obtained from Primary Care Trusts (PCTs), even if the dentist has no NHS contract with the PCT.

♦ NHS prescriptions

The standard FP10D** prescription form should be used to prescribe controlled drugs. Dentists can only prescribe controlled drugs included in the DPF list (e.g. temazepam, diazepam, dihydrocodeine).

♦ The Department of Health recommends that the patient’s NHS number is included on all controlled drug prescriptions. This is not yet mandatory but may be in the future.

♦ NHS and private controlled drug (Schedule 2, 3 or 4) prescriptions are valid for 28 days.

♦ Patients, or their representatives, collecting Schedule 2 and 3 controlled drugs must sign for them when collecting from the pharmacy.

♦ Storage and disposal of controlled drugs

♦ Midazolam (Schedule 3) does not need to be kept in a controlled drug cabinet and records do not have to be kept in a controlled drug register. If temazepam (Schedule 3) is held in a dental practice it must be stored in a controlled drug cabinet but no record in the controlled drug register is required.

♦ It is a legal requirement that invoices for Schedule 2 to 5 controlled drugs are kept for a minimum of two years.

♦ All Schedule 2, 3, and 4 (part 1) controlled drugs, including midazolam, must be denatured or rendered irretrievable before they are disposed of.

♦ All practices holding controlled drugs e.g. midazolam, are legally required to have Standard Operating Procedures (SOPs) to ensure they are safely managed. The PCT Accountable Officer is required by law to ensure that these SOPs are adequate and up to date.

♦ The Care Quality Commission (CQC) will check compliance with CD regulations as part of Outcome 9 – Management of Medicines.

Background

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 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.

* England = FP10PCD, Wales = WP10PCD, Scotland = PPCD

From the NHS Evidence website www.evidence.nhs.uk
Answer

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 provide a legal framework for the management of controlled drugs. They define the classes of people who are authorised to supply and possess controlled drugs while acting in their professional capacity (e.g. as a health professional) and lay 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 ecstasy and LSD, 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, remifentanil, pethidine, seccobarbital, 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 seccobarbital, 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 (e.g. dihydrocodeine).

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 2mg/5ml oral solution, nitrazepam tablets
- Schedule 5: dihydrocodeine 30mg 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).

N.B. 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 i.e. an FP10D prescription is not required.

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 recognised dental use.

Which prescription forms should be used to prescribe controlled drugs?
Dentists prescribing an allowable 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.

** England = FP10D, Wales = WP10D, Scotland = GP14

From the NHS Evidence website www.evidence.nhs.uk
Where are private controlled drug (FP10PCD) prescription forms available from?
Dentists who need to write a private prescription for a Schedule 2 or 3 controlled drug should obtain form FP10PCD from their ‘designated’ Primary Care Trust (PCT) (or equivalent), usually the PCT in which their practice is based. Contact the Accountable Officer, dental advisor or pharmaceutical/medicines management team. This applies 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 (N.B. this is not the same as the General Dental Council registration number). After the community pharmacist dispenses the FP10PCD form they submit it to the NHSBSA PPD. PCTs are responsible for monitoring private controlled drug prescribing within their boundary; data to enable this are made available to the PCT 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 prescriptions 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 reasonably ensure 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.

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 their 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 their representative, for proof of their
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.

N.B. Not all community pharmacies are registered to dispense private controlled drug prescriptions.

**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 (e.g. local anaesthetic cartridges).

- **From a community pharmacist**
  Dentists must provide the community pharmacist with a requisition for the controlled drug using dedicated requisition forms (FP10CDF\(^1\)) which were introduced in January 2008. Dentists ordering controlled drugs must have a unique prescriber ID which they should apply for via their designated PCT. This is the same number required to write private controlled drug prescriptions (see above). Dentists should obtain controlled drug requisition (FP10CDF) forms from their designated PCT. The requisition may be completed by a computer 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.

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

\(^1\) England = FP10CDF, Wales = WP10CDF, Scotland = CDFR

**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.

N.B. 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. Dentists should contact the PCT Accountable Officer for further information on the specifications for allowable controlled drug cabinets.

**Do dentists need to keep a controlled drugs register?**
No, not unless dentists hold supplies of Scheduled 2 controlled drugs e.g. 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. Requisitions and invoices for controlled drugs should ideally be kept for longer than the mandatory two years, as cases often come to court at a much later date, by which time any evidence would have been destroyed.

**Are there any regulations surrounding the disposal of controlled drugs?**
Yes. Controlled drugs that need disposal e.g. 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 authorised 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. Destruction of Schedule 3, 4 and 5 controlled drugs does not need to be witnessed.

Before disposal Schedule 2, 3 and 4 (part 1) controlled drugs e.g. midazolam, must be denatured, dissipated, or rendered irretrievable. All drugs, once disposed of, should be unrecognisable 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, adsorbing a liquid preparation onto cat litter or similar product (e.g. 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 onto 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”. For destruction of large volumes e.g. a whole box of expired stock, a controlled drug denaturing kit or cat litter should be used.

**Standard Operating Procedures (SOPs) for controlled drugs**

Regulations made under the Health Act 2006 (The Controlled Drugs (Supervision of management and Use) Regulations 2006) require each healthcare organisation to have SOPs for the use and management of controlled drugs. SOPs should be readily accessible, must cover all aspects of risk management and highlight the accountabilities and roles of all members of the dental team when managing controlled drugs. All staff and practitioners, including new members of staff, should be trained to ensure they have the relevant knowledge and skills to undertake the tasks required of them for managing controlled drugs safely.

The Accountable Officer in the designated/contracting PCT has responsibility for ensuring that these controlled drug SOPs are adequate and up to date.

SOPs must cover:

- Who has access to controlled drugs.
- Where controlled drugs are stored.
- Security in relation to storage and transportation of controlled drugs as required by Misuse of Drugs legislation.
- Monitoring and recording stock reconciliation (emergency drug box, controlled drug cupboards), including action to be taken if a problem is identified.
- Checking expiry dates of controlled drugs and disposal/destruction of controlled drugs that have expired.
- Reporting loss or suspected theft of controlled drugs including who is to be alerted if complications arise. This would normally be the Accountable Officer.
- Handling of all records relating to controlled drugs, including requisitions, invoices, private and NHS prescriptions, transport and delivery notes, and record keeping including:
  - Maintaining relevant controlled drug registers under Misuse of Drugs legislation (uncommon in primary dental care unless e.g. temazepam or morphine are held within the practice).
  - Recording critical incidents, errors and near misses with controlled drugs through local systems and the confidential National Reporting and Learning System.

Managers, staff and healthcare professionals should know which member of staff at the PCT to contact if they have a concern regarding the performance or practice of healthcare professionals, or their staff, involving controlled drugs.

More detailed advice on controlled drug SOP requirements can be found in the Department of Health guidance *Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs.*

**The role of the Care Quality Commission (CQC)**

All dental practices have been required to register with the Care Quality Commission (CQC) from April 2011. Management of medicines, including controlled drugs, is included in Regulation 13 of the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*.
The registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

The CQC has assigned each regulation an associated outcome and is responsible for checking providers' compliance - providers must have evidence that they meet the specified outcomes. The CQC translates Regulation 13 to Outcome 9:

People will have their medicines when they need them, and in a safe way. People will be given information about their medicines whenever possible.

When assessing how well an organisation is managing its controlled drugs, the CQC consider all of the related legislation and will follow up and investigate when necessary.

Limitations
This Q&A reflects the law in England. The implications of, and differences in the regulations as applicable to Scotland, Wales and Northern Ireland have not been fully addressed.

Bibliography
- NHS Business Services Authority Prescription Services Division. Safer Management of Controlled Drugs - Requisitions for schedule 1, 2 and 3 controlled drugs. Via http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer_Management_of_Controlled_Drugs_requisitions.doc on 2/06/11.

From the NHS Evidence website www.evidence.nhs.uk
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Date Prepared
April 2009
Updated: June 2011

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Date of check
April 2009
June 2011