

## STORAGE AND DISPOSAL OF CONTROLLED DRUGS

The HTM 0701 The Safe Management of Healthcare Waste Memorandum provides guidance on the legal compliant management of clinical waste.

The Hazardous Waste Regulations and The Hazardous Waste (Northern Ireland) Regulations 2005 replaced The Special Waste Regulations in England, Wales and Northern Ireland. The Special Waste (Amendment) Regulations 2004 had previously amended the Special Waste 1996 Regulations in Scotland.

Out of date medicines are classed as non-hazardous waste which can be disposed of in a pharmaceutical waste container which will require disposal by incineration. This will prevent anyone retrieving the medicines and then misusing them. Controlled drugs such as midazolam must be handled and disposed of in the correct manner and never be disposed of via the sewage system (i.e down the sink)

All Schedule 2, 3, and 4 (part 1) controlled drugs, including midazolam, must be denatured or rendered irretrievable before they are disposed of. (Midazolam is a Schedule 3 controlled drug however it is not for use by patients outside the dental practice so does not need to be kept in a controlled drug cabinet or its use recorded on an official controlled drug register but IT SHOULD be kept in a locked cabinet and a local record of its use kept.

When disposing out of date midazolam it will need to be treated with a controlled drugs denaturing kit. The local pharmacy can treat this medication with a denaturing kit and it should also be available for dental practices from their waste contractor, DenKit is a popular brand (See Fig.1). This kit involves physically mixing the medicines with a binding matrix to make the material physically irretrievable. The material is classified, described and disposed of as a waste medicine. The person carrying out this this process will need to have a witness present, 'competent person'.

Placing partly used midazolam ampoules into the sharps container or pharmaceutical container is not acceptable. They also need to be treated with the denaturing kit or the remaining solution can be placed on a cotton wool roll and then disposed of in the pharmaceutical waste container if a denaturing kit is not available.

All staff in dental practices undertaking sedation should understand the importance of the correct management of controlled drugs in accordance with the Misuse of Drugs Act 2001 and staff training needs to be updated on a regular basis.



Fig.1 DenKit denaturing kit for midazolam disposal

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

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Before using this Q&A, read the disclaimer at [www.sps.nhs.uk/articles/about-ukmi-medicines-qas/](http://www.sps.nhs.uk/articles/about-ukmi-medicines-qas/)  
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### Summary

#### Prescribing to NHS patients

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 (Schedule 3), diazepam (Schedule 4) and dihydrocodeine (Schedule 5).

#### Prescribing to private patients

Dentists must use the private prescription form FP10PCD<sup>†</sup> when prescribing Schedule 2 and 3 controlled drugs. A dentist can prescribe privately any Schedule 2 or 3 controlled drug on an FP10PCD<sup>†</sup> 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<sup>†</sup> forms should be obtained from NHS Area Teams, even if the dentist has no NHS contract with the Area Team.

- ◆ The Department of Health recommends that the patient's NHS number is included on all NHS and private 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.

#### Ordering/requisitioning controlled drugs

From 30<sup>th</sup> November 2015 it is mandatory for all Schedule 2 and 3 controlled drugs to be ordered using the official requisition form FP10CDF<sup>‡</sup>. These forms should be obtained from NHS Area Teams, even if the dentist has no NHS contract with the Area Team.

#### 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 an official 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 an official controlled drug register is required.
- ◆ Controlled drugs invoices for midazolam are legally required to be kept for two years but for HM Revenue and Customs are required to be kept for six 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 Area Team Accountable Officer is required by law to ensure that these SOPs are adequate and up to date.
- ◆ The Care Quality Commission (CQC) may check compliance with controlled drug regulations as part of their inspection process. Practice compliance can be checked using the [CQC Primary Care Self-Assessment Tool for Controlled Drugs Governance](#).

### Background

Following the fourth report of the Shipman Inquiry *The Regulation of Controlled Drugs in the Community* and the government's response *Safer Management of Controlled Drugs* in 2004, a number of improvements to controls on prescribing, dispensing and storage of controlled drugs have been made. Since 2006 amendments to the *Misuse of Drugs Regulations 2001* and the *Controlled Drugs Regulations* have impacted on dentists as prescribers and on ordering, storage and disposal of controlled drugs in NHS and private dental practice.

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

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

‡ England = FP10CDF, Wales = WP10CDF, Scotland = CDRF (private), GP10A (NHS)

Changes have included:

- April 2006 – introduction of the private controlled drug prescription form (FP10PCD<sup>†</sup>) for use by all private (non NHS) prescribers of controlled drugs including dentists.
- January 2008 – change in the legal classification of midazolam 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.
- November 2015 – introduction of a mandatory controlled drug requisition form.

## 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 management of controlled drugs. They define the classes of people authorised to supply and possess controlled drugs while acting in their professional capacity (e.g. as a health professional) and lay down conditions under which these activities may be carried out. In the regulations drugs are divided into five schedules each specifying 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, remifentanyl, pethidine, secobarbital, amphetamine, and cocaine, which 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 but not to safe custody requirements (except buprenorphine, diethylpropion, and **temazepam**) nor to the need to keep registers. Invoices must be retained 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:

Schedule 3: temazepam tablets, temazepam oral solution  
Schedule 4: diazepam tablets, diazepam 2mg/5ml oral solution  
Schedule 5: dihydrocodeine 30mg tablets

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<sup>†</sup> 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 from any Schedule for an **NHS patient** should use the NHS FP10D\* prescription form.

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<sup>†</sup> England = FP10PCD, Wales = WP10PCD, Scotland = PPCD

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

Dentists prescribing controlled drugs in Schedule 2 or 3 for a **private patient** must use a **private controlled drug prescription form (FP10PCD<sup>†</sup>)**. Community pharmacists cannot dispense private controlled drug prescriptions unless written on an FP10PCD<sup>†</sup> 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<sup>†</sup>) prescription forms available from?**

Dentists who need to write a private prescription for a Schedule 2 or 3 controlled drug should obtain form FP10PCD<sup>†</sup> from their 'designated' Area Team (or equivalent), usually the Area Team 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 Area Team. The Area Team will arrange for the prescription forms to be printed and issued. The cost of the forms will be invoiced by the Area Team to the dentist/practice.

The Prescription Pricing Division of the NHS Business Services Authority (NHSBSA PPD) issues a generic 'Private controlled drug dentist code' to the Area Team to be used by all dentists prescribing controlled drugs private within their area. This code appears on each FP10PCD<sup>†</sup> form (N.B. this is not the same as the General Dental Council registration number). After the community pharmacist dispenses the FP10PCD<sup>†</sup> form they submit it to the NHSBSA PPD. Area Teams are responsible for monitoring private controlled drug prescribing within their boundary; data to enable this are made available to the Area Team by the NHSBSA PPD.

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

All prescriptions, including 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 professional qualification e.g. BDS & GDC number
- 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** (including temazepam – see below) is:

- 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.
- the name of the controlled drug in full as written in the BNF/Summary of Product Characteristics (necessary but not a legal requirement)

Although not yet mandatory the Department of Health recommends that the patient's NHS number is included on all NHS and private controlled drug prescription forms.

Prescribers are strongly advised to limit 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.

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<sup>†</sup> *England = FP10PCD, Wales = WP10PCD, Scotland = PPCD*

## How should prescriptions for temazepam be written?

The *Misuse of Drugs Regulations 2001* were amended in 2015 and from June 2015 all prescriptions for temazepam must comply with prescription writing requirements for Schedule 2 and 3 controlled drugs (see above). Private prescriptions for temazepam must be written on the private controlled drug prescription form FP10PCD<sup>†</sup>. NHS prescriptions for temazepam should be written on the usual NHS prescription form FP10D<sup>\*</sup>.

## 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 after the appropriate date on the prescription. The appropriate date is either the date the prescription was written and signed or any other date indicated on the prescription (by the prescriber) as a date before which the drugs should not be supplied – whichever is later. Prescriptions for Schedule 5 controlled drugs and non-controlled drugs are valid for six months.

## Controlled drug prescriptions – what are the implications for the patient?

The backs of FP10D<sup>\*</sup> and FP10PCD<sup>†</sup> prescription forms contain 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.

**Note:** Not all community pharmacies are registered to dispense private controlled drug prescriptions.

## How do dentists obtain controlled drugs to hold in stock (requisitions)?

All Schedule 2 or 3 controlled drugs **must** be ordered using an official requisition form - FP10CDF<sup>‡</sup>. Use of this form is **mandatory from 30<sup>th</sup> November 2015**. The official controlled drug requisition form must be used in both NHS and private practice. The FP10CDF<sup>‡</sup> forms should be downloaded via the [NHSBSA website](#). Dentists requisitioning controlled drugs must have a 'private controlled drug dentist code' which they should apply for via their designated Area Team. This is the same number required to write private controlled drug prescriptions (see above). The requisition may be completed online or downloaded locally prior to being completed, printed and signed manually in ink.

All dentists are advised to hold midazolam in stock for emergency management of status epilepticus. There are two routes for obtaining (requisitioning) Schedule 2 and 3 controlled drugs – via a community pharmacy or via a dental wholesaler.

- **From a dental wholesaler**

A dental wholesaler who supplies pharmaceutical preparations can also supply controlled drugs. Even if orders are submitted electronically, an official controlled drug requisition form (FP10CDF<sup>‡</sup>), signed by the dentist, must be provided to the wholesaler. This is a legal requirement. (In practice the requisition may be handed to the delivery driver.)

- **From a community pharmacist**

Only licensed medicines can be requisitioned from a community pharmacist e.g. Buccolam<sup>®</sup> but not Epistatus<sup>®</sup>. Only manufacturer's original packs can be supplied.

The FP10CDF<sup>‡</sup> consists of five parts (A to E); parts B and C must be completed by the dentist. The following information must legally be added to the form:

- the name, form and strength of the drug (part B)
- the total quantity of the drug (part B)
- the purpose for which the drug is required (part B) – e.g. 'for use within practice/surgery'
- the recipient's (dentist's) name, address and professional qualification/occupation (part C)
- private controlled drug dentist code, supplied by the Area Team (part C)
- the signature of the dentist (this must be handwritten) (part C)

It is desirable to include the GDC number with the professional qualification to enable the supplier to check the validity of the requisition.

Instructions on how to complete the FP10CDF<sup>‡</sup> form are included with it (part D).

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<sup>\*</sup> England = FP10D, Wales = WP10D, Scotland = GP14

<sup>‡</sup> England = FP10CDF, Wales = WP10CDF, Scotland = CDRF (private), GP10A (NHS)

**Note:** Within a dental practice, ONLY the dentist has the legal authority to sign a controlled drug requisition, this cannot be delegated to any other member of the dental team.

**Note:** 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.

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 Area Team Accountable Officer for further information on specifications for allowable controlled drug cabinets.

### **Do dentists need to keep an official controlled drug register?**

No, unless they hold supplies of Scheduled 2 controlled drugs e.g. morphine. Schedule 3 controlled drugs, including temazepam and midazolam, do not need to be recorded in an official controlled drug register. However, records to provide an audit trail for supply, administration and disposal of controlled drugs should be kept. All processes should be covered by a Standard Operating Procedure (see below).

### **What is the legal requirement for controlled drug invoices?**

It is a legal requirement to keep invoices for all controlled drugs in Schedules 3 and 5 for a minimum of two years. Invoices for all controlled drugs (Schedules 2,3,4, and 5) should be kept for longer than the mandatory two years, in order to be available for HM Revenue and Customs (six years) and Consumer Protection (eleven years) purposes.

### **Are there any regulations surrounding 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 in accordance with *Misuse of Drugs Regulations 2001*.

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 unused/partly used midazolam ampoules/syringes straight into the pharmaceutical waste or sharps container or empty them down the sink/toilet.

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 is acceptable.

Partly used ampoules or out of date ampoules should have as much of the content as possible emptied into the controlled drug denaturing kit or onto cat litter. The cat litter and empty ampoules should be disposed of in the sharps bin labelled "contains mixed pharmaceutical waste and sharps – for incineration".

Sorting and denaturing controlled drugs for disposal in dental practice must be covered by an Environment Agency exemption: *Waste exemption: T28 sort and denature controlled drugs for disposal*. Register for an exemption at <https://www.gov.uk/guidance/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal> NOTE - a separate T28 exemption is required for each part of an organisation if they are located in different postcode areas e.g. a practice based on two or more sites.

Schedule 2 controlled drugs require witnessed destruction by an individual authorised under *Misuse of Drugs Regulations 2001*. 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 Area Team 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 by an authorised individual.

Although destruction and disposal of Schedule 3 and 4 controlled drugs, including midazolam, does not require witnessing by an authorised individual all destruction and disposal carried out within the practice should be documented and witnessed internally to ensure robust stock reconciliation and audit trail.

## Standard Operating Procedures (SOPs) for controlled drugs

The *Controlled Drugs (Supervision of management and use) Regulations 2013* require each healthcare organisation to have SOPs for use and management of controlled drugs. SOPs should be readily accessible, must cover all aspects of risk management including; ordering, storing, destruction, prescribing, supply, administration and clinical monitoring of patients.

SOPs should highlight 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 relevant knowledge and skills to undertake tasks required of them for managing controlled drugs safely.

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

SOPs should 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.
- 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 Area Team to contact if they have a concern regarding the performance or practice of healthcare professionals, or their staff, involving controlled drugs.

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

Management of medicines, including controlled drugs, is included in Regulation 12 – Safe care and treatment of the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)*:

### **12(2)(g) the proper and safe management of medicines;**

- Staff responsible for the management and administration of medication must be suitably trained and competent and this should be kept under review.
- Staff must follow policies and procedures about managing medicines, including those related to infection control.
- These policies and procedures should be in line with current legislation and guidance and address:
  - Supply and ordering.
  - Storage, dispensing and preparation.
  - Administration.
  - Disposal.
  - Recording.

Under the *Health and Social Care Act 2008*, the Care Quality Commission (CQC) is responsible for making sure that health and social care providers, and other regulators, maintain a safe environment for management of controlled drugs in England.

The CQC's Controlled Drugs Regulation Team have compiled a Self-Assessment Tool intended for use by Primary Care Organisations to assess their organisation's arrangements for controlled drugs governance and identify areas requiring improvement. The tool can be downloaded from the CQC website at [Controlled drugs governance self assessment tool for primary care organisations](#)

## 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.

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Available at [www.sps.nhs.uk](http://www.sps.nhs.uk)



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### Search strategy

See bibliography for resources used