

Guidance book to support the development of a Controlled Drugs* Standard Operating Procedure for Dental Practices in Primary Care

This document provides guidance on the areas that should be included in a dental practice SOP for handling controlled drugs and should be used to support the workbook on development of a Controlled Drugs* Standard Operating Procedure for Dental Practices in Primary Care

*This guidance applies to all schedules of controlled drugs

Background

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation in October 2009. Amendments were made to these regulations in July 2015. These Regulations require that appropriate arrangements are in place to ensure the safe management and use of controlled drugs in general practice e.g. dental or medical practice. A robust system and audit trail should therefore be in place for all stages in the handling of Controlled Drugs (CDs) in dental practices.

The Regulations specify that standard operating procedures must be in place and this document provides guidance to dental practices on the content they should include when developing and reviewing their standard operating procedure (SOP).

One SOP should be developed for each practice/organisation. All practice staff should be trained on this SOP and sign to confirm they understand the content.

The CD SOP should be a 'working document' within the practice. It is recommended that the SOP should be reviewed and updated at least every two years.

Objectives

To ensure implementation of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (as amended) and provide guidance on safe and secure handling and storage of controlled drugs within dental practices.

Scope

This document provides guidance on the areas that should be included in a dental practice SOP for handling controlled drugs. It covers all aspects of obtaining and prescribing controlled drug stock, handling responsibilities, storage, access, disposal, stock checks and record keeping.

The Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended) provide a legal framework for the management of controlled drugs. In the Regulations drugs are divided into five schedules with differing requirements governing import, export, production, supply, possession, prescribing, storage, reconciliation and disposal. Examples of Schedule 2, 3 and 4 controlled drugs can be found in Appendix 1. The BNF Dental Formulary sets out the range of medicines that are applicable in most circumstances within general dental practice. It should be noted that limited Schedule 3 and Schedule 4 controlled drugs are listed. Only those controlled drugs from Schedules 3 and 4 listed in the formulary may be used where appropriate for Health Service purposes. Controlled drugs from Schedules 2, 3, 4 and 5 may be prescribed privately where appropriate and within a dentist's scope of practice.

[https://standards.gdc-uk.org/Assets/pdf/Guidance%20on%20prescribing%20medicines%20\(Sept%202013\).pdf](https://standards.gdc-uk.org/Assets/pdf/Guidance%20on%20prescribing%20medicines%20(Sept%202013).pdf)

Procedures

Section 1 Ordering CD Stock

1.1 Ordering from Community Pharmacy - In line with legislation, any private Schedule 2 or 3 CD stock that is ordered from a community pharmacy must be made using the CDRF1 requisition form (Appendix 2). Orders must be made in accordance with the legal requirements for controlled drugs (Appendix 3).

The CDRF1 form should be downloaded each time a form is required and is available at: <http://www.medicinesgovernance.hscni.net/primary-care/controlled-drugs/private-cds/>

Notes on how to complete CDRF1 can be found on the reverse of the form. CDRF1 forms should be treated with care and **should not** be downloaded and stored for use at a later date. Orders should be for complete packs of medicines and community pharmacists can advise on these quantities.

1.2 Ordering from Wholesaler - A record of date, full details of what is ordered and name of the dentist writing the requisition should also be kept as part of the audit trail.

Section 2 Receipt of CDs ordered from a community pharmacy

When ordered from a community pharmacy, GDPs should order and collect their own CDs in person. Practice staff should not be involved in accepting stock into the practice and verifying the order.

2.1 Use of a messenger - In exceptional cases a messenger can be used to collect CDs on behalf of a GDP. Under these circumstances, the messenger must produce to the pharmacist a statement in writing signed by the GDP indicating that he/she is empowered to receive the drugs. The messenger must deliver the CDs directly to the GDP who has placed the order.

2.2 Delivery by pharmacy - If it is necessary for CDs to be delivered by the pharmacy, the CDs should be delivered directly to the GDP making the requisition or, if not possible, to a member of staff authorised by the GDP. The drugs received should be verified against the order. The GDP should inform the pharmacist of the name of this person in advance. A pharmacy delivery note should be signed by the GDP/authorised person to confirm the delivery. This should be retained by the pharmacy.

The GDP making the requisition is responsible for the CDs while they are in their care or the care of their delegate.

Section 3 Entering stock CDs into Dental Practice Stock

Schedule 2 controlled drugs must be recorded in a CD register. Although it is not a requirement to record midazolam ampoules in the Controlled Drug register, it is good practice to record details of stock ordered.

Each GDP is personally accountable for the CDs they order/receive.

If a principal procures midazolam for his use in practice and provides midazolam to another dentist for their use in practice an audit trail must be maintained to ensure accountability for all the CDs.

Section 4 Storage of CDs

Midazolam (Schedule 3) is exempt from the safe storage requirements outlined in The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973, however, when being kept as part of an emergency kit, it is recommended that it is stored away from public areas that may be accessed by patients. The same recommendation applies to diazepam (Schedule 4).

Where midazolam is being kept for conscious sedation it is recommended that as good practice it is stored in the CD cabinet.

Access to CD cabinets must be limited to designated practitioners. A full audit trail of who has access to the CDs kept in a CD cabinet must be maintained and any keys should be kept under the personal supervision of a named practitioner.

Stocks of CDs should be kept to a minimum and regularly reviewed to ensure appropriate stock management (see Section 5).

CDs must be kept in the container issued by the supplying pharmacy or wholesaler (to allow identification of batch number and expiry date).

Section 5 Checks of CD stock

5.1 Stock Checks - The dentist or delegated staff member should undertake a monthly stock check of CDs in practice emergency drug kits. Where the dental practice provides intravenous sedation, additional weekly balance checks should be carried out. Any unresolved discrepancies must be reported immediately (see below).

Balance checks should be completed in the presence of, and countersigned by, another appropriately trained member of staff.

Balance checks should include checking the expiry date of stock.

5.2 Discrepancies - If there are discrepancies identified during stock checks which cannot be readily resolved, these should be reported to the practice governance lead. If the discrepancy remains unresolved it should be reported to the Accountable Officer. This can be done at GDS.Correspondence@hscni.net

Section 6 Destruction of CDs

6.1 Part-used portions e.g. ampoules – All Schedule 3, 4 (part I) and 5 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. This may be done by placing the CD liquid on absorbent material (e.g. paper towels on to which a little soap has been added). After the drug has been rendered irretrievable this should then be placed in the relevant pharmaceutical waste bin to be disposed of by incineration via the current waste disposal method for medicines.

6.2 Out-of-date / Obsolete GDP stock- All out-of-date or obsolete CD stock must be returned to a community pharmacy for destruction. During the time between expiring and destruction, expired CDs should be segregated in a safe place within the surgery and be clearly marked

as “date expired” to prevent use in error. It is a legal requirement for a record to be kept of all Schedule 2 CDs returned to the pharmacy for destruction. For other schedules of CDs it would be good practice to keep a record of all stock returned to the pharmacy for destruction.

Section 7 Security

All CD related stationery such as prescription pads and CD record books must be kept locked away when not in immediate use and treated in line with the practice’s normal prescription security policy

http://www.hscbusiness.hscni.net/pdf/Prescription_Security_Guidance_Dental_October_17.pdf

Section 8 Prescribing of Controlled Drugs

8.1 Health Service Prescriptions- Dentists may only prescribe CDs from the Health Service Dental Practitioners Formulary list (temazepam, diazepam, dihydrocodeine) on HS21D.

All prescriptions should be written in accordance with the requirements set out in the Misuse of Drugs Regulations (NI) 2002 and HMRs.

Dosages and frequencies for all controlled drugs must be written in full by the prescriber to aid correct administration.

Prescriptions for controlled drugs should not exceed 30 days’ supply except in justifiable, exceptional circumstances.

Practitioners should not prescribe CDs or any other drugs for themselves, their family or friends except in an emergency.

8.2 Private prescriptions - Schedule 2 and 3 CDs (including temazepam) must be written on a standard private prescription form i.e. PCD1.

In order for a prescriber to obtain a supply of PCD1 forms they need to complete the PCD1 Application Form available at <http://www.hscbusiness.hscni.net/services/2272.htm>

9. Administration of Controlled Drugs

Administration must be under the instruction of a dentist who is suitably trained and qualified in the use of and management of Controlled Drugs.

If a GDP administers a CD within their practice, it is important that records are maintained to ensure that accountability for all the CDs can be demonstrated. If administering CDs from dental practice central stock, a clear process must be in place for all dentists who are using this stock; a record must be made to maintain an audit trail, including the date, name of the patient, drug/dose/quantity/route. Regular audits should be carried out to ensure appropriate management of this stock.

The record should be signed by the practitioner administering the CD and whenever possible a witness, who should be a practice employee.

The information must also be recorded in the patient's record and specify the date, time, strength, presentation and form of administration, dose administered as well as name and occupation of the person administering it.

A record of batch numbers and expiry dates is also recommended.

Practitioners should only administer CDs if they have received appropriate training and in accordance with recommended good practice.

The practice should have a procedure for emergency treatment of any potential drug overdose by a suitably trained dentist using the appropriate reversal agent.

10. Staff Training

All members of the dental practice who are involved with the prescribing or handling of CDs must be trained to do so, be aware of the contents of the CD SOP and sign and abide by it.

The education and training standards for all members of the dental team providing conscious sedation is outlined in “Conscious Sedation in the Provision of Dental Care.” <https://rqia.org.uk/RQIA/files/bc/bcb0650d-8660-4d5f-940f-ea3b60ecf5f6.pdf> This report states that all team members must have received appropriate supervised theoretical, practical and clinical training in the sedation technique being used before undertaking independent practice. This is to include theoretical knowledge of the topics outlined in the report, practical skills related to drugs, equipment and management of complications and clinical training which can be provided in a variety of settings. It should include documented, supervised cases, competently completed according to contemporary recommendations. All education and training must be regularly reviewed and updated to take account of accepted standards.

Staff working under the SOP should read and sign the practitioner authorisation sheet see Appendix 4 for sample sheet.

11. Self-assessment and CD Declaration Statement

Each Dental Practice is required to complete a Controlled Drugs Self Assurance declaration when requested by HSCB, usually annually.

Appendix 1 Examples of Schedules 2 – 4 Controlled Drugs

Schedule 2 CD	Schedule 3 CD	Schedule 4 part 1 CD
Alfentanil	Buprenorphine	Alprazolam
Amphetamine	Gabapentin	Chlordiazepoxide
Diamorphine	Meprobamate	Clobazam
Dipipanone	Midazolam	Clonazepam
Dronabinol	Pentazocine	Diazepam
Fentanyl	Pregabalin	Flurazepam
Hydromorphone	Temazepam	Loprazolam
Ketamine	Tramadol	Lorazepam
Lisdexamphetamine		Lormetazepam
Methadone		Nitrazepam
Methylphenidate		Oxazepam
Morphine		Sativex
Nabilone		Zaleplon
Oxycodone		Zolpidem
Pethidine		Zopiclone
Remifentanil		
Sufentanil		
Tapentadol		

Appendix 2

Northern Ireland Controlled Drug Stock Requisition Form (Schedules 2 & 3) CDRF1

Northern Ireland Controlled Drug Stock Requisition Form (Schedules 2 & 3)
The guidance notes on the reverse should be read before completion. All sections must be completed legibly using indelible ink.

Part One - Details of Purchaser

Name of Authorised Person (capitals)			
Occupation (capitals)			
Professional Registration Number e.g. GMC/GDC (If applicable)			
Details of organisation(s) where drugs may be used			
Name Address			
Contact Telephone Number			
Signature of Authorised Person		Date	
Counter Signature (if required – see guidance notes)		Date	

Part Two - Details of Controlled Drugs Requested

Drug Name (in capitals)	Full Details of Strength	Form	Quantity

Purpose for which drugs are to be used (tick in box provided ✓)

1	<input type="checkbox"/>	For use in medical practice	2	<input type="checkbox"/>	For use in dental practice
3	<input type="checkbox"/>	For use in independent hospital/clinic	4	<input type="checkbox"/>	For paramedic use
5	<input type="checkbox"/>	For use in veterinary practice	6	<input type="checkbox"/>	Other (please state reason briefly below)*
* _____					

Part Three - Details of Supplier and Person Collecting Controlled Drugs

Name & Address of Supplier (Legible Stamp acceptable)			
I confirm that I am authorised to supply controlled drugs in this way and have checked that the recipient is authorised to possess the controlled drugs ordered above. <input type="checkbox"/>			
Name & Role of Person Supplying (capitals)			
Signature of Person Supplying		Date	
To be completed at the point of collection/delivery			
Signature of Person Collecting/Receiving CDs		Date	
If CDs are not collected/received by the authorised person, he/she must provide a written statement confirming the recipient is empowered to collect/receive the CDs on their behalf. <input type="checkbox"/>			
For record-keeping purposes, provide the person collecting/receiving CDs with a copy of the completed form.			

REFERENCE NUMBER
(optional)

Appendix 3 Summary of Legal requirements for prescribing Controlled Drugs

	Schedule ₁	2	3	4 I	4 II	5
Designation	CD	CD No Reg	CD Benz	CD Anab	CD Inv	
Obtained only on prescription (see emergency supply)	Yes	Yes	Yes	Yes	No	
Must be stored locked away and secure	Yes ₂	No ₃	No	No	No	
Prescription requirements ₄	Yes	Yes	No	No	No	
Emergency supplies to patients are permitted	No	No ₅	Yes ₆	Yes ₆	Yes ₆	
Repeatable prescriptions permitted	No	No	Yes	Yes	Yes	
Prescription valid for:	28 days ₇	28 days ₇	28 days ₇	28 days ₇	6 months ₇	
Prescription supply limited to 30 days as good practice	Yes	Yes	Yes	Yes	No	
Private CD prescriptions to be written on standardised form (PCD1)	Yes	Yes	No	No	No	
Private CD prescription form to be sent to BSO	Yes	Yes	N/A	N/A	N/A	
Can be prescribed by nurse/pharmacist independent prescriber	Yes ₈	Yes ₈	Yes ₈	Yes ₈	Yes ₈	
CD register for stocks and supplies to be maintained	Yes	No	No ₉	No	No	
Destruction only under authorised witness	Yes	No	No	No	No	

