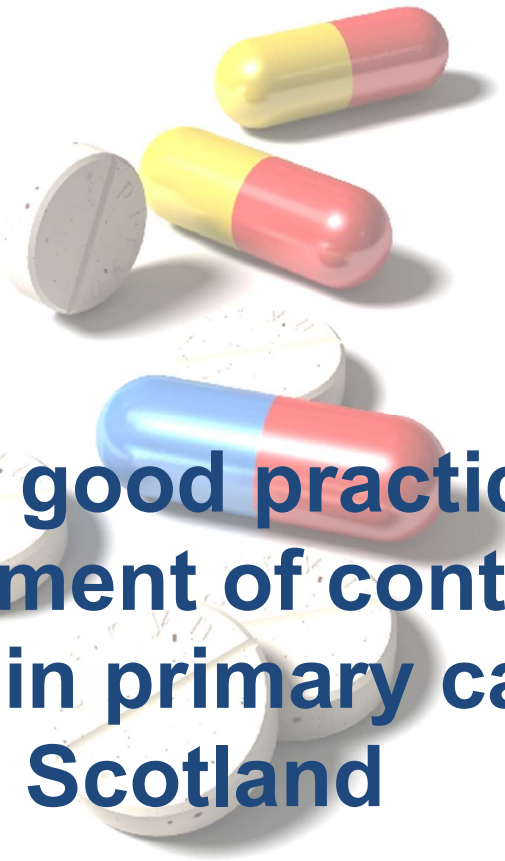
Controlled Drugs Accountable Officers' Network • Scotland

NHS SCOTLAND



A guide to good practice in the management of controlled drugs in primary care - Scotland

Version 3.0
April 2023

Safer Management of Controlled Drugs

A guide to good practice in the management of controlled drugs in primary care – Scotland (Version 3)

Foreword

This is the 3rd version of the Scottish guide to good practice in the management of controlled drugs (CDs) in primary care.

Several legislative changes have occurred since publication of the 1st edition in 2012 including the revised Controlled drugs (Supervision of management and use) Regulations April 2013 and the expansion of non-medical prescribing in relation to CDs. Since the publication of the second edition we have seen the publication of the Gosport Report plus further changes to the drugs that are covered by controlled drugs regulations. This publication has been updated to reflect these changes.

This publication is intended to provide legal and best practice information to continue to support the ongoing safe management and use of CDs.

I commend this document to all practitioners working within primary care. I believe that this will provide an invaluable reference source and make a contribution to improving governance and patient safety

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Chair Controlled Drugs Accountable Officers' Network Scotland

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Section 1: Introduction

Background

This is the third publication of the Scottish guide to good practice in the management of controlled drugs in primary care. This guide takes into account legislative changes introduced by the UK Government to strengthen the governance arrangements for controlled drugs (CDs) including the Controlled Drugs (Supervision of management and use) Regulations 2013. This guide was originally based on the National Prescribing Centre Guidance – *'A guide to good practice in the management of controlled drugs in primary care (England), third edition (V3.1), October 2010* and has been reviewed and updated by the Controlled Drugs Accountable Officers' Network Scotland.

Areas where the main alterations have occurred are listed below including reference to updated standards. Editorial rewording and alterations have been made throughout document as appropriate in relation to legislative changes e.g. change of gabapentinoids to schedule 3 Controlled Drug.

Section 2 - Legislation –Class B penalty for possession now includes cannabis and cannabis products. On 1st November 2018 access to cannabis-based products for medicinal use (CBPM) in humans in England, Scotland and Wales widened in legislation, moving cannabis products from Schedule 1 to Schedule 2.
Section 3 - Governance, Inspections and Monitoring – Role of Health Improvement Scotland (HIS)
Section 4 - Possession of Controlled Drugs – in relation to nurse & pharmacist independent prescribers, compounding
Section 5?
Section 6 - Administration of Controlled Drugs –In relation to nurse & pharmacist independent prescribers, clarification of prescribing by paramedics to include midazolam (oromucosal and by injection), lorazepam (injection) and oral codeine phosphate, Scottish Government good practice statement on injection preparation in near patient areas, Nursing and Midwifery council and RPS guidance on Administration of medicines in healthcare settings. Good practice points for supervised consumption updated
Section 7 - Editorial changes to Prescribing of Controlled Drugs – in relation licensing arrangements for prescribing (diamorphine, dipipanone & cocaine) and advice on instalment prescribing and Home Office wording advice.
Section 8 -Dispensing of Controlled Drugs –Reference to potential for changes during a pandemic, good practice advice updated regarding second check and prescriptions awaiting collection. Clarification that PC70 applies to both Schedule 2& 3 CDs
Section 9 – Recording of Controlled Drugs –Updated advice regarding recordkeeping for Sativex, computerised records and running balances.
Section 12 – Storage of Controlled Drugs – Removal of reference to NMC standards and inclusion of pharmacy and nursing joint standards. Removal of reference to National Care Standards in relation to Care Homes
Section 13 – Transportation of Controlled Drugs - Removal of reference to NMC standards and inclusion of pharmacy and nursing joint standards
Section 14 – Nurses and Midwifes working in the Community Removal of reference to NMC standards and inclusion of pharmacy and nursing joint standards -

Section 15 – Palliative Care - Updated links to Scottish Palliative Care Guideline, Scottish Partnership for Palliative Care, rewording of Good practice advice for JIC medicines
Section 16 – Care Home Services –Updated with reference to responsibilities of HIS and Care Inspectorate. National Care Standards replaced with Health and Social Care standards. Good practice points for administration of medicines and dealing with discrepancies updated.
Section 17 - Ambulance Services- Updated information for paramedics regarding possession
Section 18 – Educational Establishments-Reference to new guidance Supporting children and young people in schools
Section 19 – Overseas Travel and Patient from Overseas Requiring Controlled Drugs - Editorial rewording of advice to travellers and patients from overseas
Section 20 – Out of Hours Services – Removal of reference to NPSA
Section 21 – Patient Information - Rewording to include reference to NHS Inform, NHS 24 and how patients can access medicine information
Section 22 –Controlled Drugs in Prisons –updated re requirement for Home Office licence, national Guidance on the Safe Management of Controlled Drugs in the Scottish Prison Service Standard Operating Procedure" as a minimum standard consolidated by local SOPs. Pharmacy services including medicine supply and clinical input by external contractors

Also alterations have been made throughout document as appropriate in relation to legislative changes e.g. change of gabapentinoids to schedule 3 Controlled Drug.

Purpose of the Guide

Although this guide is aimed at developing good practice for the management, governance and use of CDs in primary care, it encompasses issues raised at the interface between primary, secondary and social care, and therefore will be relevant to the management of CDs across all NHS and non-NHS settings.

The Scottish Government issued specific guidance on the management of CDs in secondary care (CEL 7 (2008)) in February 2008.

The implementation of the recommendations contained within this guide will require healthcare professionals to adopt a systematic approach to improvement in the management, control and use of CDs. This will strengthen patient and public safety whilst at the same time ensuring that healthcare professionals are not overburdened with additional bureaucracy resulting in reluctance to prescribe CDs. Therefore this guide focuses on the roles and responsibilities of healthcare professionals working within primary care and who are commonly involved in the management and use of CDs.

Organisations holding stocks of CDs are legally required to develop and use standard operating procedures (SOPs) as a means of ensuring good practice becomes part of everyday health care activities. SOPs should be kept up to date and cover the prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed CDs. Controlled Drugs Accountable Officers (CDAOs) can assist in advising on the development and any local requirements for such SOPs.

Key Audiences

This guide should be of value in a wide range of settings where CDs are used including:

- GP and dental practices
- Pharmacies
- Midwifery services
- Out-of-hours services
- Patients' own homes
- Care homes
- Day care services
- Care at home services
- Community nursing services
- Community palliative care services
- Substance misuse services
- Hospices
- Prison services
- Ambulance services and paramedics
- Immediate care services
- Police custody services
- Residential care services (e.g. school care accommodation)
- Armed Forces

How to Use this Guide

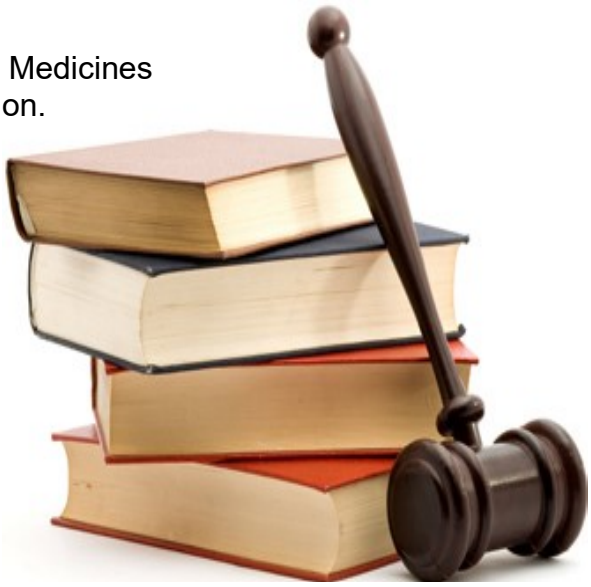
Each main section of this guide is divided - where appropriate - into 2 sections. The first identifies and clarifies the current key legal and regulatory frameworks and the second provides good practice recommendations within these frameworks.

Whilst every care has been taken to ensure the accuracy of this guide liability cannot be accepted for any errors or omissions. The contents of the guide will be updated over time to reflect legislative and regulatory changes. Individuals looking for guidance and support should ensure that they refer to the most recent edition of this guide plus any other national guidance, legislation and directions that may have been published. Local Controlled Drugs Accountable Officers (CDAOs)/Controlled Drugs teams should be contacted for further advice and support regarding the management and use of controlled drugs.

The Controlled Drugs Accountable Officers' (CDAO) Network has web pages hosted on the Knowledge Hub (Welcome - Knowledge Hub (khub.net)). These contain a wide range of documents, guidance and information relating to the management of CDs and should be referred to as an additional useful resource.

Section 2: Legislation

Misuse of Drugs Legislation



The overall legislative framework which applies to all Medicines is the Medicines Act 1968 and its associated legislation. The Human Medicines Regulations 2012 are a result of the MHRA's consolidation and review of UK legislation. They replace nearly all UK medicines legislation – most of the Medicines Act 1968 and over 200 statutory instruments.

Controlled Drugs (CDs) are additionally defined and governed by the Misuse of Drugs Act (MDA) 1971 and associated Regulations – principally the Misuse of Drugs Regulations (MDR) 2001 which fall within the remit of the Home Office.

The Health and Social Care Act was implemented in April 2012. This resulted in a review of the associated regulations and the introduction of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 which came into force in April 2013. This updates previous information from the Department of Health.

Medicines Act 1968/The Human Medicines Regulations 2012

The Medicines Act 1968 and associated Human Medicines Regulations 2012 set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import distribution, sale and supply of those products; for the labelling and advertising; and for pharmacovigilance. They also allow certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, allow midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine.

A number of healthcare professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups - but not all - are permitted to possess, supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation (see section 7).

Misuse of Drugs Act (MDA) 1971

The Misuse of Drugs Act 1971 and its Regulations control the availability of drugs that are considered sufficiently *'dangerous or otherwise harmful'* with the potential for diversion and misuse. The drugs which are subject to the control of the MDA 1971 are listed in Schedule 2 of the Act and are termed Controlled Drugs (CDs).

The MDA controls the export, import, supply and possession of dangerous or otherwise harmful drugs and largely renders unlawful all activities involving drugs controlled under the Act - except where provided for under the Regulations. Drugs controlled under the Misuse of Drugs Act 1971 are divided into three classes - Classes A, B and C for the purpose of establishing the maximum penalties which can be imposed in criminal law on persons convicted of any of the offences under the Act. The class of a drug reflects its relative harm to the individual and to society when misused, in a descending order of severity, from A to C.

The maximum penalties for offences of possession and supply of the main CDs within each class are summarised in the table below.

Drug Class Penalties for Possession

DRUG CLASSES - Examples PENALTIES		PENALTIES FOR POSSESSION	PENALTIES FOR SUPPLY/ PRODUCTION
Class A	diamorphine (heroin) cocaine MDMA (ecstasy) NBOMe lysergic acid diethylamide (LSD) methamphetamine (crystal meth) more potent opioid analgesics, e.g. methadone	Up to 7 years in prison or an unlimited fine or both	Up to life in prison or an unlimited fine or both
Class B	amphetamine barbiturates benzofuran cannabis and cannabis products synthetic cannabinoids ketamine lisdexamfetamine methylphenidate less potent opioid analgesics, e.g. codeine	Up to 5 years in prison or an unlimited fine or both	Up to 14 years in prison or an unlimited fine or both
Class C	buprenorphine, benzodiazepines (and zolpidem) anabolic steroids gamma hydroxybutyrate (GHB) tramadol	Up to 2 years in prison or an unlimited fine or both	Up to 14 years in prison or an unlimited fine or both
***Temporary class**		None – however police can remove suspected temporary class product	Up to 14 years in prison or an unlimited fine or both

NB: Any Class B drug in injectable form is treated as Class A. Some Class C drugs are legal to possess, for example, anabolic steroids are Schedule 4 Part II and may be possessed in medicinal form without a prescription

Note: Cannabis, cannabis resin, cannabinol and its derivatives were reclassified from Class C to Class B on 26 January 2009.

*The government can ban new drugs for 1 year under a 'temporary banning order' while they decide how the drugs should be classified.

Provided by the Home Office, Drug penalties

Misuse of Drugs Regulations (MDRs) 2001 and Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (MDRs) 2012

The use of CDs in medicines is permitted by the Misuse of Drugs Regulations (MDRs). The MDRs and amendments can be found at the Office for Public Sector Information website which should be checked on a regular basis. The OPSI website link can be found here: Legislation

Details of more recent amendments issued in the form of Home Office Circulars are available.

Drugs Schedules

The MDRs 2001 divide CDs into five Schedules. Each Schedule dictates the degree to which the use of a CD under that Schedule is regulated. The Schedule within which a CD is placed depends upon its medicinal or therapeutic benefit balanced against its harm when misused. Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control.

A comprehensive list of drugs included within the Schedules is available from the Home Office:

A summary of legal requirements that apply to CDs is included in Appendix 1 and provided in more detail in the table below.

Drug Schedule

Schedule 1 (Controlled Drugs – licence) - Virtually all drugs listed in Schedule 1 have no recognised medicinal use. Other Schedule 1 drugs include hallucinogenic drugs such as lysergide and mescaline and products advertised as 'legal highs' e.g. benzofuran and NBOMe
The production, possession and supply of Schedule 1 CDs are limited to research or other special purposes considered of public interest. Only certain persons can be licensed by the Home Office (HO) to possess them for these purposes. Practitioners and pharmacists may not lawfully possess Schedule 1 CDs except under license from the Home Office. On 1st November 2018 access to cannabis-based products for medicinal use (CBPM) in humans in England, Scotland and Wales widened in legislation, moving cannabis products from Schedule 1 to Schedule 2. More recently, these products have now moved in to Schedule 4.

Schedule 2 (Controlled drugs) - includes more than 100 drugs such as the opiates, ketamine, the major stimulants, secobarbital and amphetamine and lisdexamfetamine. Ketamine was rescheduled to become a Schedule 2 Controlled Drug (CD) on 30th November 2015.

***Supply*:**	This is restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess CDs. Practitioners can supply to persons authorised to possess CD's and to their patients. Hospitals may supply patients, wards and practitioners. Pharmacies may supply on receipt of a valid prescription or signed order. Additional prescription writing requirements exist.
***Record*:**	A record of all Schedule 2 CDs obtained and supplied must be kept in a register, the form of which must comply with the relevant Regulations (see section 9).
Storage:	Schedule 2 CDs (except quinalbarbitone) are subject to safe custody requirements (The Misuse of Drugs [Safe Custody] Regulations 1973, amended 2007). They must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD, or a person authorised by them.
Destruction:	The destruction of Schedule 2 stock CDs must only take place in the presence of an appropriately authorised person known as an authorised witness (AW) (see section 11). Destruction of patient returns does not currently have to be witnessed by an AW. However, good practice would deem that another person witnesses this and a written record is kept. Schedule 2 CDs must be denatured before being placed into waste containers.

Schedule 3 (Controlled drugs - no register) contains a number of substances that are perceived as being open to abuse, but less likely to be so than Schedule 2 CDs. It contains a number of synthetic opioids together with other substances including temazepam. Gabapentin and pregabalin were rescheduled as Schedule 3 CDs from 1 April 2019.

Supply:	The Regulations concerning supply (and additional prescription writing requirements) are similar to Schedule 2 CDs. Midazolam is the only Schedule 3 CD that in certain circumstances can be included in a PGD.
Record:	There is no statutory requirement to record the supply of Schedule 3 CDs.
Storage:	The majority of Schedule 3 CDs are exempt from safe custody requirements except temazepam, flunitrazepam, buprenorphine and diethylpropion. These must be stored in a locked receptacle such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by them.
Destruction:	The requirements relating to the need for an AW for destruction do not apply to Schedule 3 CDs (unless the CDs are manufactured by the individual). Schedule 3 CDs should be denatured before being placed into pharmaceutical waste containers.

Schedule 4 (Controlled drugs- benzodiazepines and anabolic steroids) is split into 2 parts.

Part 1 (CDs- Benzodiazepines) contains most of the benzodiazepines (with the exception of flunitrazepam, midazolam and temazepam which are Schedule 3), plus eight other substances including zolpidem and from 10th June 2014 zopiclone.

Part 2 (CD Anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoceptor stimulant) and growth hormones (5 polypeptide hormones).

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anabolic steroids) drug when it is in the form of a medicinal product. However, possession of a drug from Schedule 4 Part 1 (CD - benzodiazepines) is an offence without the authority of a prescription in the required form.

Drugs in Part 1 (CD -benzodiazepines) are subject to full import and export control and a Home Office licence is also required for the importation and exportation of substances in Part 2 (CD Anabolic steroids) unless the substance is in the form of a medicinal product and is for personal use/administration.

Supply:	Supply is restricted to supplies against practitioner's prescriptions or in accordance with PGDs. There are no additional requirements as to the form of prescriptions other than those that apply to all Prescription Only Medicines (POMs).
Record:	There is no statutory requirement to record the supply of Schedule 4 CDs.
Storage:	Schedule 4 CDs are exempt from safe custody requirements.
Destruction:	The requirements relating to the need for an AW for destruction do not apply to Schedule 4 CDs (unless the CDs are manufactured by the individual). Schedule 4 Part 1 CDs should be denatured before being placed into waste container.

Schedule 5 (Controlled drugs – Invoice) - Schedule 5 contains preparations of certain CDs, e.g. codeine, dihydrocodeine, pholcodine, morphine, which are exempt from full control when present in medicinal products of low strengths.

Supply:	Certain CDs in Schedule 5 are available for over the counter sale in registered pharmacies. It is for the pharmacist to use their professional judgement to determine the appropriateness of any supply and be alert to potential misuse. The Schedule 5 CD POMs can only be supplied in accordance with a valid prescription or patient group direction.
Record:	There is no statutory requirement to record the supply of Schedule 5 CDs.
Storage:	Schedule 5 CDs are exempt from safe custody requirements.
Destruction:	The requirement to have an AW for the destruction or denaturing does not apply to Schedule 5 CDs.

Misuse of Drugs (Safe Custody) Regulations 1973

The Misuse of Drugs (Safe Custody) Regulations 1973 (the Safe Custody Regulations) imposes controls on the storage of CDs. The degree of control depends on the premises within which the drugs are being stored.
The 1973 Regulations specifically apply to any premises occupied by a retail dealer for the purpose of his business and to a care home (as defined Public Services Reform (Scotland) Act 2010 see Section 16)

All Schedule 2 and some Schedule 3 CDs (buprenorphine, diethylpropion, flunitrazepam and temazepam) must be stored securely in accordance with the Safe Custody Regulations. These CDs must be stored in a cabinet which is locked with a key.

The cabinet should be made of metal with suitable hinges and fixed to a wall, or, to the floor with rag bolts which are not accessible from outside the cabinet.

The Regulations also require that in other settings the CDs to which the provisions apply should be kept in a locked container that can only be accessed by the person authorised to possess them (or a person authorised by that person to access them) e.g. a doctor's bag. The boot of a car does not constitute a locked container under these Regulations.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

These Regulations amend the Misuse of Drugs Regulations 2001 and (Safe Custody) Regulations and:

- give authority to Controlled Drugs Accountable Officers (CDAOs) within their organisation to nominate persons or groups of persons to witness the destruction of CDs
- allow operation department practitioners (ODPs) to order, possess and supply CDs within their hospital
- remove the requirement to maintain a CDR in a prescribed format
- change the record keeping requirement for CDs
- reschedule midazolam from Schedule 4 to Schedule 3 of the MDRs 2001
- require all care homes, whether providing nursing or personal care, to store CDs in a CD cupboard.

Misuse of Drugs (Supply to Addicts) Regulations 1997

An amendment to the Misuse of Drugs (Supply to Addicts) Regulations 1997 was introduced in June 2007 meaning doctors no longer need individual Home Office licences to prescribe diamorphine, cocaine, dipipanone for the treatment of addiction, or suspected addiction. Previously doctors were prohibited from prescribing, administering or supply these CDs for these indications except under Home Office licence. Further details can be found in the Home Office website

A general licence has been issued to cover those doctors who have been approved by the Department of Health.

CEL 35, 2012 Licensing arrangements for prescribing, supplying, and administering diamorphine, cocaine and dipipanone for the treatment of drug misuse and addiction was also published. This represents a transfer of power from the Home Office to the Scottish Government in relation to granting licenses in these circumstances. This does not reflect a change in the policy for the treatment of drug misuse. Doctors who are considering prescribing these drugs for addicts must contact their CDAO or CD team for advice regarding authorisation and licensing. A licence is not required for such drugs for the treatment of organic disease or injury.

Health Act 2006

The Health Act 2006 is primary legislation and applies to the whole of the UK and provided Regulations to be laid down relating to strengthened governance and monitoring arrangements for CDs.

Controlled Drugs (Supervision Of Management And Use) Regulations 2013

The 2006 Regulations came into force on 1 March 2007 in Scotland and followed the UK Government's response to the Shipman Inquiries Fourth Report published in 2004. The 2006 Regulations strengthened and improved governance arrangements for CDs and a key component was the creation of Controlled Drugs Accountable Officers (CDAOs). Under the terms of the 2006 regulations all designated bodies in England and Scotland were required to appoint a CDAO who would be required to develop and implement systems for routinely monitoring the management and use of controlled drugs and ensuring they are alerted to any risks, concerns and/or incidents.

As a consequence of the passing of the Health and Social Care Act 2012 in England, the 2006 Regulations needed to be revised mainly to reflect the new architecture of the NHS in England. The opportunity was taken to simplify and modify the Regulations. The 2013 Regulations, came into force on 1 April 2013, contain several amendments which are specific to Scotland as follows:

The role of Health Improvement Scotland (HIS) has been extended so that they:

- become the keeper of a list of all Scottish CDAOs and publish the list;
- make a determination on whether or not smaller independent hospitals require to appoint a CDAO - but only where such hospitals make an application seeking exemption; and
- are able to seek self declarations from designated bodies about their management and use of controlled drugs.

Scottish care homes have been brought within the remit of the amended regulations. The Care Inspectorate (CI) has been designated as a "responsible body" under the terms of the Regulations and has also been given powers to ask for self declarations about how care homes manage and use controlled drugs at their care home premises. The CI has also been added to the list of bodies that a CDAO could ask to undertake inspections.

The Scottish Government response and information regarding implications for Scotland can be found on the Scottish Government web pages

A copy of the Regulations can be found on the Government Legislation Website

General information and a Q&A can be found on the Department of Health web pages

Section 3: Governance, Inspections and Monitoring

Overview

Arrangements have been established to encourage good practice in the management of CDs. These will also help to detect unusual or poor clinical practice systems, criminal activity, or risk to patients at the earliest opportunity. The arrangements follow two guiding principles:

- They should not interfere with the appropriate use of CDs and good clinical care
- The safer governance principles should apply to all health and social care settings, and individual practices, where CDs are prescribed, stored, administered, or transported

There is also a requirement for collaboration and information sharing between all healthcare and social care providers, and relevant regulators and agencies.

Appointment of a Controlled Drugs Accountable Officer (CDAO)

The Controlled Drugs (Supervision of Management of Use) Regulations 2013 specify who may be appointed as a Controlled Drugs Accountable Officer (CDAO). The Regulations state that the CDAO must be a "fit, proper and suitably experienced person" who does not routinely supply, administer, or dispose of CDs as part of their duties.

A designated body can nominate or appoint a CDAO who has an occasional, exceptional role in the use of CDs (for example, in emergencies). However, their use of CDs should be open to the scrutiny of another person to whom they are answerable. The CDAO should have credibility with all healthcare and social care professionals and be of sufficient seniority as to be able to take action regardless of how a concern is raised.

The intention is to reduce burdens on independent sector micro or start-up businesses with fewer than 10 workers by exempting them from the requirements to appoint a CDAO. Healthcare Improvement Scotland (HIS) is responsible for applying criteria for determining whether a Scottish business, e.g. an independent hospital/hospice, can be exempt.

Health Improvement Scotland (HIS) will compile, maintain and publish lists of registered CDAOs via their website.

Designated bodies must inform HIS in writing of the appointment of a CDAO and of any subsequent changes.

Overview of responsibilities of Controlled Drugs Accountable Officers

- Ensure the safe and effective use and management of CDs within their own organisation and by any body or person providing services to their organisation.
- Establish and ensure appropriate arrangements to comply with The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2020.
- Ensure adequate and up-to-date SOPs are in place in relation to the management and use of CDs.
- CDAOs must have oversight of best practice in relation to the management of CDs and must:
  - ensure adequate destruction and disposal arrangements for CDs
  - ensure monitoring and auditing of the management and use of CDs
  - ensure relevant individuals receive appropriate training
  - assess and investigate concerns
  - maintain a record of concerns regarding relevant individuals
  - take appropriate action to address well founded concerns
  - establish arrangements for sharing information
- CDAOs in special health boards, independent hospitals and hospices to produce and submit quarterly CD occurrence reports to the CDAO leading the Local Intelligence Network (LIN) of which their organisation is a member. The occurrence report must describe the details of any concerns the organisation has had regarding the management of CDs or confirm that there have not been any concerns in the required timeframe.

Additional Responsibilities of NHS Board Controlled Drugs Accountable Officers

- Establish a Local Intelligence Network (LIN)
- Analyse NHS and private prescribing of CDs using appropriate data source/s e.g. PRISMs/PIS
- Establish mechanisms to share information quickly between members of their LIN
- Convene incident panels of relevant agencies or individuals to consider specific serious concerns
- Request a periodic declaration and a self-assessment from a general medical practitioner on the NHS board's medical performers list regarding their CD management and use
- Ensure their organisation has arrangements for the periodic inspection of premises used in conjunction with the management or use of CDs and which are not subject to inspection by the General Pharmaceutical Council (GPhC) inspectors or used for private practice
- The CDAO leading the LIN must take steps to protect patients and the public if there are concerns about inappropriate or unsafe use of CDs

Standing Operating Procedures (SOPs)

Regulations require each healthcare organisation holding stocks of CDs to have standing operating procedures (SOPs) for the use and management of CDs. The Regulations require CDAOs to ensure that their organisation has - and that those organisations providing services to their organisation have - adequate and up to date SOPs in relation to the use of CDs.

CDAOs in Scotland require that, where appropriate, SOPs cover the following:

- who has access to CDs
- where the CDs are stored
- prescribing of CDs
- clinical monitoring of patients prescribed CDs
- security in relation to storage and transportation of CDs as required by *The Misuse of Drugs Regulations*
- disposal and destruction of CDs
- who is to be alerted if complications arise
- record keeping including:
  - maintaining relevant controlled drug registers under *The Misuse of Drugs Regulations*
  - maintaining a record of Schedule 2 CDs that have been returned by patients

Good Practice (SOPs)

• SOPs should cover all aspects of risk management and include audit trails for ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction of CDs appropriate to the setting and the team.	• SOPs should highlight the accountabilities and roles of all members of the relevant healthcare teams.	• The Controlled Drug Accountable Officers' Network has published guidance and SOP templates for dispensing, non-dispensing medical and dental practitioners and medical/dental practices available at: Welcome - Knowledge Hub (khub.net)

Monitoring and Auditing the Management and Use of Controlled Drugs

❖ Legal Framework

The Regulations specify that arrangements for monitoring and auditing the management and use of CDs must provide for the following:

- Monitoring and analysing health service and private prescribing of CDs through the use of PRISMS (Prescribing Information System for Scotland) data and analysis tools available from Public Health Scotland : Data and Intelligence (formerly known as information Service Division (ISD) Scotland)
- Ensuring systems are in place to alert the CDAO of any complaints or concerns involving the management and use of CDs
- Ensuring an incident reporting system is in place

- Ensuring appropriate arrangements are in place for analysing and responding to incidents

Good Practice (monitoring and auditing the management and use of CDs)

Assessing CD Practice
Good practice would suggest that a systematic audit of the processes for managing CDs in primary care is carried out. Results from local audits should be analysed to identify any areas where systems could be improved and better co-coordinated. All audit results should be kept, preferably, electronically for up to 11 years

Using Quality Indicators
This list is not comprehensive but gives a series of indicators that will help Health Boards, Special Health Boards, GP practices and pharmacies identify and demonstrate they have systems in place to minimise risk when managing CDs.

1. All staff and practitioners should be trained to ensure they have the relevant knowledge and skills to undertake the tasks required of them to manage CDs safely.
2. Practitioners and staff who work with CDs should demonstrate reflective learning in their continuous professional development portfolio or personal development plan.
3. Risk Management systems should be used to help minimise risks in the management of CDs. Such systems should be written and readily accessible to all relevant practitioners and staff and include the following:
   - Assessment of risks arising from managing CDs
   - Procedures for training new members of staff or locums in management of CDs
   - Identification of tasks requiring to be undertaken in the presence of a witness
   - Handling of all records relating to CDs including requisitions/invoices/ private and NHS prescriptions/transport and delivery notes and CD registers
   - Audit trails for CD prescriptions
   - Procedures for reporting loss or suspected theft of CDs
   - Procedures for reporting suspected cases of NHS fraud
   - Procedures for the storage and distribution of prescription forms.
   - Procedures for monitoring and recording stock reconciliation (in CD cupboards, doctors' bags) including action to be taken if a problem is identified
   - Procedures for checking expiry dates of CDs and what to do with CDs that have expired
   - Recording of critical incidents, errors and near misses with CDs through local systems
   - Complaint procedures for NHS employees and employers as appropriate
   - Copies of the organisation's policy and processes for raising concerns
   - Systems for recording and destroying CDs returned from practitioners, patients or their representative
   - Procedures for missing, stolen, lost prescription forms
4. Managers, staff and healthcare professionals should have contact details of the NHS board staff they should contact regarding concerns about the performance or practice of healthcare professionals or their staff involving CDs.

Routine monitoring

Controlled Drugs Accountable Officers (CDAOs) should ensure that the use of CDs is monitored through routine processes such as data analysis, audit and clinical governance and incorporated into the organisation's normal governance arrangements. Below is a summary of how prescribing data can be used to monitor and audit the management and use of CDs.

Prescribing data

Prescription data collected by NHS National Services Scotland (NSS) can be used to monitor and examine the prescribing and dispensing of NHS and private prescriptions for CDs in primary care. Prescriptions prescribed and dispensed in secondary care are not collected by NSS.

Data is collected and held centrally by a web-based application called PRISMS (Prescribing Information System for Scotland). PRISMS allows users' access to prescribing data relevant to their organisation. It provides a series of prescribing indicators using predefined reports and graphs which allows NHS boards to compare their prescribing performance with a number of suitable comparators.

Users can access data at NHS board, community health partnership (CHP), practice and individual prescriber level. The data does not contain patient information, diagnosis or dosage information. PRISMS also allows access to prescribing data for NHS Board prescription (HBP) prescribing by cost centre (clinic or department) - but not by individual prescriber.

Users have access to prescribing information for all prescriptions dispensed in the community for the past five years and can analyse and report on prescribing based on BNF legacy structure, from total prescribing to individual drugs and formulations. Further information on PRISMS can be found in Appendix 2 and at Public Health Scotland.

Sharing Information

A CDAO must establish and operate, or ensure their designated body establishes and operates appropriate arrangements for ensuring the proper sharing of information regarding the management of CDs. The requirements below must be followed when sharing information on concerns about relevant individuals.

- When sharing information organisations must comply with GDPR in the *Data Protection Act 2018* and the codes of practice on confidentiality, in particular the *Eight Caldicott principles*.
- When sharing information local intelligence networks may wish to agree a code of practice or information sharing agreement.
- NHS organisations, organisations contracted to provide NHS services and the independent sector may find the following documents helpful:
  - *Disclosing patients personal information a framework-GMC*
  - *In practice: Guidance on confidentiality-GPhC*
  - *General Medical Services (GMS), Section 17C Agreements and Health Board Primary Medical Services (HBPMS) Code of Practice*

- *NHS Code of Practice on Protecting Patient Confidentiality;* and
- *A Good Practice Guide to Consent for Health Professionals in NHS Scotland*
- CQC Code of practice on Confidential Personal Information

Confidential information about patients should be anonymised where possible. If it is not possible to remove patient identifiable information, then the patient's consent should be sought wherever practicable.

When information is provided to NHS Scotland Counter Fraud Services patient consent should not be sought. There is an exemption from requirements of the *Data Protection Act 2018* relating to the investigation of a suspected crime, as covered in *Part 3: Law Enforcement Processing.*

Local Intelligence Network (LIN)

The NHS board CDAO is responsible for establishing their local intelligence network.

A LIN may span more than one NHS board area if this is thought to be beneficial. Local intelligence networks allow agencies to share concerns about the activities of any healthcare professional with other local agencies who may be affected, or who may have complementary information.

The agencies that can be included in a local intelligence network are listed in the *Controlled Drugs (Supervision of Management and Use) Regulations 2013*. This list is not exhaustive and it is for the LIN to consider which bodies should be involved.

Local intelligence networks should include - as defined by the Regulations - (although it need not be limited to) the following types of bodies as appropriate:

- NHS health board
- Healthcare Improvement Scotland
- The Care Inspectorate
- NHS Scotland Counter Fraud Services
- representatives from regulatory bodies
- representatives from local authorities
- Police Scotland representative

Self-assessment and Controlled Drugs Declaration Statement

All healthcare organisations providing clinical services and relevant social care organisations are requested to complete a periodic self-assessment (expected to be at least every two years). The purpose of the self-assessment is to determine if an organisation keeps stocks of CDs and if there are any special circumstances which may explain any seemingly unusual patterns of prescribing or supply.

The declaration and self-assessment questionnaire will be sent to organisations by the relevant agency and may be included in other assessments or planning tools. The relevant agency can determine the frequency of self-assessment. Organisations should return their declaration and self-assessment to the agency responsible for monitoring their use of CDs.

The following bodies may request an appropriate periodic declaration and an appropriate self-assessment from the organisations listed.

NHS Board CD Accountable Officer	General medical practitioner on medical practitioners list
The Care Inspectorate	Registered care homes
Healthcare Improvement Scotland	Designated bodies
General Pharmaceutical Council	Registered pharmacy premises

It is important that duplication of self-assessment requests and visits are avoided wherever possible. The Chair of the Controlled Drugs Accountable Officers' Network and officials from HIS and CI will continue to monitor implementation of the 2013 Regulations via the Controlled Drugs Accountable Officers' Executive Group.

Routine Inspections

❖ Legal Framework

- The Regulations contain the provision for a power of entry and inspection for certain designated persons to facilitate the inspection of CDs. Inspection provides a useful tool to:
  - check the physical arrangements for CD storage
  - check record keeping and management of CDs
  - support individual and organisational development
  - identify and investigate concerns
- Inspections will comply with the ten principles of inspection set out in the Government's policy on inspection of public services which states that public service inspections should:
  - pursue the purpose of improvement
  - focus on outcomes
  - take a user perspective
  - be proportionate to risk

- encourage self-assessment by managers
- use impartial evidence wherever possible
- disclose the criteria used for judgements
- be open about the processes involved
- have regard to value for money including that of the inspecting body
- continually learn from experience

Reporting Concerns

In addition to concerns arising from routine monitoring and inspection concerns may be raised by individuals. *The Public Interest Disclosure Act 1998* was introduced to protect employees who are worried about wrongdoing in their place of work and want to raise concerns has been withdrawn in April 2021. Whistleblowing is when a worker or employee suspects wrongdoing at work. Officially this is called 'making a disclosure in the public interest'. All NHS Scotland Boards are required to have a local Whistleblowing policy in place. As a whistleblower you are protected by law if you are a worker for example, all NHS employees and includes all self-employed NHS professional, i.e. doctors, dentists, opticians, optometrists, and pharmacists. For this purpose, the employer of a self-employed NHS professional is deemed to be the relevant NHS board or special health board.

Investigating Concerns

The CDAO will need to ensure that robust systems are in place to:

- enable concerns to be raised about CDs, individuals or processes
- ensure that the concerns raised are logged
- ensure that, if appropriate, the relevant CDAO is alerted of these concerns
- allow an investigation to be initiated.

Education and Training

The Regulations state that CDAOs are expected to ensure that the relevant individuals receive appropriate training in relation to the management of CDs. CDAOs must ensure that individuals:

- receive appropriate training to carry out their responsibilities relating to the prescribing, supplying, administering or disposing of CDs; and
- receive information and when appropriate, training on local SOPs for CDs when they first become involved in prescribing, supplying, administering or disposing of CDs.

Good Practice (education and training)

- The initial education, continuing education and continuous professional development (CPD) for healthcare professionals should include appropriate material on the following:
  - safe storage of CDs
  - possession of CDs
  - return of all medicines
  - legal status of CDs
- All individuals working in NHS and non-NHS settings who are involved in the following activities should ensure that they have appropriate, timely and up-to-date knowledge of all processes involved in managing CDs.
  - CD supply
  - CD administration
  - CD storage
  - CD prescribing
  - CD dispensing
  - CD destruction
- The UK Government in its response to the Fourth Report of the Shipman Inquiry recommends that all healthcare professionals who prescribe, dispense or administer CDs must demonstrate (in meeting their CPD requirements) that they keep up-to-date on all aspects of CD management.
- These healthcare professionals must demonstrate the following:
  - safe custody
  - safe storage
  - record keeping
  - supply
  - disposal of CDs
  - legal requirements of CDs
- All individuals should have at least an annual appraisal in discussion with their employer to identify gaps in their knowledge and skills. This should result in an agreed personal development plan and access to development mechanisms that will meet the agreed needs of the individual.
- For those professions that have formal revalidation processes this appraisal should form an integral part of revalidation.
- The Controlled Drugs Accountable Officers, Scotland have published 'An Information Booklet for Admin/Clerical Staff in General Practice on the Management and Use of Controlled Drugs (CDs) and Prescription Stationary in NHS Scotland'. This is a useful resource to assist in training of General Practice staff.
- It is the legal responsibility of the provider of a care service to ensure that their employees have the qualifications, skills and experience necessary for the work that the person is to perform. This would include where appropriate the effective management of all medicines including CDs.
- Good practice in the management of medicines in secondary care, including CDs, is set out in the Safe and Secure Handling of Medicines (SSHM 2019)
- All care staff involved in the prescribing, supply or administration of medicines should be familiar with the contents of the report.
- National authorities should consider including more details relating to the prescribing, administering, supplying, destruction and recording of CDs in their undergraduate and pre-registration courses for healthcare professionals.
- The Government's response to the Fourth Report of the Shipman Inquiry sets out those areas that the undergraduate education for healthcare professionals who prescribe, dispense or administer CDs needs to cover.

Section 4: Possession of Controlled Drugs

The Misuse of Drugs (Amendment no.2) (England, Wales and Scotland) Regulations 2012 state that a person may not legally have a CD in their possession unless the regulations allow them to do so. Unlawful possession of any CD in Schedules 1 to 4 (Part I) is a criminal offence. Persons who can legally possess CDs are listed below.

❖ Legal Framework

- Medical practitioners - including doctors, dentists and veterinary surgeons
- Pharmacists or a person lawfully conducting a retail pharmacy business
- Supplementary prescribers where CDs form part of an agreed clinical management plan
- Nurse and pharmacist independent prescribers (any Schedule 2-5 CD that they prescribe)
- Persons administering CDs under the direction of a doctor or dentist
- Persons acting under the direction of a nurse or pharmacist independent* prescriber may administer any Schedule 2-5 CD that the independent nurse or pharmacist* can prescribe.
- Midwives acting in their capacity as such can administer only those CDs in accordance with *The Medicines Act 1968* and *The Medicines for Human Use (Miscellaneous Amendments) Order 2010*
- Paramedics acting in their capacity as such (only those CDs which are the subject of the group authority issued by the Secretary of State under the 2001 Regulations)
- Healthcare professionals supplying or administering certain categories of CDs under a PGD
- Individuals and bodies corporate licensed by the Home Office Drugs Branch
- Persons in charge of a hospital or care home – see section 5.
- The owner of a ship, the master of a ship which does not carry a doctor on board and the installation manager of an offshore installation
- Someone who has legally been prescribed a CD
- Police officers when acting the course of their duty as such
- Persons engaging in the business of a carrier when acting in the course of the business
- Persons engaging in the business of postal operator when acting in the course of that business
- Customs and excise officers when acting in the course of their duty as such

- Persons engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of their duty as a person so engaged
- Someone who has found a CD and is immediately taking it to a person who may lawfully possess it e.g. a pharmacist for a medicinal product, a police officer for illicit drugs
- Someone who has removed a CD from someone else to stop them offending and is immediately taking it to a person who may lawfully possess it

Compounding

Practitioners – doctors, dentists, veterinary surgeons and veterinary practitioners – and pharmacists have authority to possess, supply and 'compound' any drugs in schedules 2-5 to the 2001 Regulations. Nurse and pharmacist independent prescribers and supplementary prescribers are also authorised to ‘compound’ any drugs listed in schedules 2-5 prior to administration as part of a clinical management plan for a patient.

Home Office Circular 009/2012: nurse and provisions pharmacist independent prescribing for schedule 4 part II drugs regularises the compounding of medicines that include controlled drugs by any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber or a supplementary prescriber when acting under and in accordance with the terms of a clinical management plan prior to administration to a patient as part of a clinical management plan.

In practice 'compounding' relates to the 'mixing' of two or more drugs, which include a controlled drug(s), for instance for use in palliative care. The authority given by the Home Office *Circular 009/2012* complements the authority provided under the POM Order which enables the 'mixing' of medicines in clinical practice by healthcare professionals and persons acting on accordance with their written directions.

Preparing Unlicensed Medicines

Pharmacists who choose to manufacture/compound an unlicensed controlled drug preparation (e.g. prepare methadone 1mg/ml mixture) must ensure that they act in accordance with General Pharmaceutical Council guidance for registered pharmacies preparing unlicensed medicines (revised August 2018).

They must also ensure that such activities are adequately covered by professional indemnity insurance. Refer also to section 6

Section 5: Purchasing and Supply of Controlled Drugs

It is important to distinguish between supplies of CDs prescribed for individual patients on a prescription and those obtained by practitioners for stock or bags for home visits. Medicines prescribed for an individual patient must be supplied to, and used by that patient only. The prescribing of CDs is covered in detail in section 7.

Practitioners must NOT use patient-specific CD prescriptions to replace or 'top-up' their bags for home visits or practice stock, even if the stock was used for that patient initially.

Wholesale supply of stock medicines on a commercial basis by a community pharmacy requires a Wholesale Dealers Licence. If supplies include CDs in Schedules 2-5 then it is likely that a corresponding Home Office CD licence is also needed by the pharmacy to legalise this supply. The MHRA has also provided guidance on supplies of small quantities of medicines considered essential for the provision of healthcare service.

Requisitions

❖ Legal Framework

- The following individuals can obtain supplies of Schedule 2 or 3 CDs for use in their practice, business or profession:
  - A practitioner (this includes doctors, dentists, independent nurse and pharmacist prescribers and veterinary surgeons)
  - A person in charge of a laboratory is restricted to obtaining a specified range of CDs for specific medical conditions if the laboratory carries out scientific research or is used for educational purposes, and is attached to a university, university college hospital or approved institution.
  - The owner of a ship, the master of a ship which does not carry a doctor on board or the installation manager of an offshore installation (such as an oil-rig).
    Note that a requisition from the master of a foreign ship must contain a statement signed by the appropriate authority indicating that the quantity of the drug is necessary for the equipment of the ship (port health authority officer in England and Wales, or Health Board competent person in terms of the Public Health (Scotland) Act 2008 in Scotland).
  - Schedule 2 drugs may be possessed by the person or acting person in charge of a hospital or care home which is wholly or mainly maintained by a public authority out of public funds, by a charity or by voluntary subscriptions. In other such circumstances a licence is required. With Schedule 3 and 4 drugs the basis of the funding makes no difference at all, and the person in charge may supply and possess under the authority of the Regulations. Such requisitions must be countersigned by a doctor or dentist who works there.

Good Practice (purchasing and supply of CDs)		
• Any person who, or organisation that holds stocks of CDs should keep stock levels to a minimum - but enough to meet clinical need.	• CD usage over the last two years should be reviewed when assessing current stock requirements. The level of stock held should then be reviewed on an appropriate or annual basis.	• Requisitions and invoices for CDs 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 the evidence would have been destroyed.

Purchasing by practitioners from wholesalers or pharmacies for practice use or stock purposes

❖ Legal Framework

- Schedule 2 and 3 Controlled Drugs: practitioners (doctors and dentist) may obtain CDs from pharmacies or wholesalers for practice use or stock upon the production of a written requisition/order – only whole packs must be ordered and supplied
- Schedule 4 and 5 Controlled Drugs: A requisition is not required before supplying or obtaining Schedule 4 or 5 CDs

Requisition requirements

In Scotland GPs in non-dispensing medical practices use a GP10A (stock order) form to order stock (including CDs) for the immediate treatment of patients in their NHS practice. It is good practice to use a separate GP10A for each Schedule 2 and 3 CD preparations.

Standardised private controlled drugs requisition forms (CDRFs) have been produced for use in Scotland. Although there is no legal requirement to use these forms they should be used as a matter of good practice wherever possible. GPs and dentists can obtain a supply of CDRFs for private use by applying to their local NHS board.

Requisitions and orders must:

- be signed by the prescriber
- state the prescriber's name and address
- state the prescriber's profession or occupation
- specify the total quantity in whole packs of the drug (words and figures are not required)
- specify the purpose for which it is required such as 'for practice use'.

Good Practice (Audit trail for requisitions)

A comprehensive recording and audit trail should commence at the point at which a practitioner orders CDs and should include a means of identifying when orders were received. The practitioner who orders the CDs should retain a copy of the original GP10A stock order form within the practice.

A wholesaler or pharmacy supplying CDs to a prescriber must be reasonably satisfied that the requisition is genuine. This means that it should be the signed original document. Faxed or other electronically transmitted requisitions are not permitted. The supplier must be reasonably satisfied that the signature on the requisition is that of the person claiming to have signed the requisition and that they are engaged in the occupation stated on the requisition. The name and address of the supplier must be recorded indelibly (i.e. using permanent ink that cannot be removed).

Pharmacists are required to submit the original requisitions (not the copy) to NHS NSS for processing. The pharmacist must retain a duplicate (photocopy) for their own records.

Good Practice (Community Pharmacy Requisitions)

When one pharmacy orders a CD privately from another pharmacy the pharmacy supplying the CDs should submit a written CDRF (CP) to practitioner services for processing. CDRF(CP) forms are available from practitioner services or can be downloaded from the web link below:
Order prescription stationery | National Services Scotland (nhs.scot)

Retention of requisitions

Suppliers must keep copies of all requisitions and orders for a minimum of two years. The Misuse of Drugs 2001 Regulations have been amended to allow the information contained in orders, requisitions and private prescriptions to be preserved as a copy on computer. Safeguards must be in place to ensure the following:

- data cannot be altered at a later date.
- all entries are attributed to an individual making the entry.
- all data can be recalled for audit purposes.
- adequate backups are made.
- that systems are in place to minimise the risk of unauthorised access to the data.

Urgent Supplies to Practitioners

A practitioner who requires a Schedule 2 or 3 CD urgently in an emergency situation, but who is unable to supply a signed order is permitted to request the CD on condition that they give an undertaking to supply a written, signed requisition or order **within 24 hours**. Failure to do this is a criminal offence on the part of the practitioner.

Good Practice (requisitions) ✓		
• The prescriber's identification number (i.e. professional registration number) should be included on the requisition. • Suppliers of CDs should provide a delivery note for the purchaser to sign.	• The person signing the delivery note should be authorised to receive CDs by the prescriber. • A copy of the signed delivery note should be retained by the supplier.	• If a messenger is sent to collect the CD they must carry a bearer's note signed and dated by the prescriber. The note should state that they are authorised to collect the CD. Any bearer's note should be retained by the pharmacy for a minimum of two years.

Purchasing by Pharmacists and Doctors from Wholesalers

Pharmacists do not need to issue a signed order when purchasing Schedule 2 or 3 CDs from a pharmaceutical wholesaler.

❖ Legal Framework

- Pharmacists or doctors can electronically purchase CDs from wholesalers for their dispensary.
- Doctors and dentists must provide the wholesaler with a signed requisition as described previously on receipt of the CDs. This requisition is distinct from the delivery note which the doctor must sign and give to the courier at the time of delivery.
- When the pharmacist, doctor or dentist receives a supply of CDs from any source they are responsible for ensuring that the correct item is delivered and that all appropriate entries are made in the CDR on the day of supply, or on the day following the day of supply. The task of completing the CDR can be delegated, but the pharmacist or doctor retains full accountability for this process.

Good Practice (purchasing by pharmacists, doctors and dentists from wholesaler		
• Any tamper-evident seals on packs of CDs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks as sealed containers can be assumed to contain the full amount as stated on the pack. • A seal should only be broken when the pack is required for dispensing or administration.	• If the tamper-evident seal is broken and the contents do not match the expected amount stated on the manufacturer's pack the following action should be taken: - Where practical, the pack and contents should be kept as evidence to present to the manufacturer - CDs should be dispensed to the patient from an alternative pack. If this is not possible, for instance, because it would compromise patient care, the professional should assure themselves that the contents are suitable for dispensing and then appropriately repackage them for the patient. - the original packaging should be kept as evidence - appropriate records should be made in the CDR and all necessary action should be taken to resolve the discrepancy.	• The pharmacist or doctor should authorise the person receiving the CDs from the wholesaler in advance, and in writing. • The person receiving the CDs should sign the supplier's delivery note on receipt of the CDs. • To ensure good clinical governance a prescriber should not both purchase and prescribe a CD wherever possible.

Acquisition of Controlled Drugs by other Healthcare Professionals

The following applies when other healthcare professionals acquire CDs.

Midwives

❖ Legal Framework

- A registered midwife who has notified the Local Supervising Authority (LSA) of their intention to practice is authorised to possess and administer specific CDs provided it is in the course of their professional practice.
- The MDR 2001 covers the possession and administration of CDs by midwives.
- Registered midwives are authorised to possess and administer certain medicines including diamorphine, morphine, pentazocine and pethidine in the course of their practice.

Community Midwifery practice

- **Community practice midwife's supply order**

A Midwife Supply Order (MSO) can only be issued to a community midwife. MSOs are not issued to midwives operating in the hospital setting. Midwives may obtain specified CDs from a hospital pharmacy or community pharmacy by a MSO, signed by their Supervisor of Midwives. Midwives must make all relevant entries in their own CDRs. The midwife supply order must state the following:

- the name and occupation of the midwife
- the purpose for which the CD is required
- the total quantity of CDs required
- the drug required and dose

Local Supervising Authorities (LSAs) determine systems for providing midwives with supply orders in their area. LSAs or CDAO/CD team should be contacted for further advice.

- **Individual patient prescription**

Alternatively, a prescription can be written by a doctor, e.g., GP, consultant obstetrician or other appropriate prescriber, if the patient is under their care. The patient obtains the prescribed CD from a pharmacy and keeps it in their home until it is required for administration by the midwife.

Good Practice (individual patient prescription)

- A CD that has been prescribed for a patient but is no longer required for the purpose for which it was prescribed should normally be returned to the pharmacy for safe destruction and disposal by the patient or their representative. For instance, a CD prescribed for a patient for a homebirth, but which is not used.
- Midwives should recommend patients to return any unused CDs to their community pharmacy.

- **Hospital Midwives**

Midwife Supply Orders are only issued to community midwives, and not midwives operating in the hospital setting. The administration of CDs by midwives working in a hospital or institution should be in accordance with locally agreed policies and procedures.

Paramedics

Registered paramedics serving or employed at any approved ambulance station are authorised to possess diazepam and/or morphine sulphate (to a maximum strength of 20mg), and/or morphine sulphate oral for the purpose of administration for the immediate necessary treatment of sick or injured persons. The Advisory Council on the Misuse of Drugs (ACMD) is supportive of the prescribing and administration of morphine, diazepam, lorazepam, midazolam and codeine by paramedics, although not yet implemented.

Registered paramedics may also supply or offer to supply these drugs to other such registered paramedics under the same restrictions.

The person in charge, or acting person in charge of the Scottish Ambulance Service is authorised to supply, or offer to supply, diazepam and/or morphine sulphate (to a maximum strength of 20mg), and/or morphine sulphate oral, to any registered paramedic serving with or employed by the Scottish Ambulance Service. The group authority does not cover the employing organisation of private paramedics. This means that private paramedics must personally source their own stocks of CDs. Paramedics can obtain stocks of CDs by wholesale from a registered pharmacy.

Hospices and independent hospitals

Where a hospice or private hospital does not employ a pharmacist, the person in charge or acting person in charge, may obtain CDs via a requisition signed by a doctor (or dentist) who is employed or engaged there. This requisition may be presented to a wholesaler, community pharmacy or the pharmacy department of an NHS board with whom a service level agreement (SLA) is in place.
Establishments with employed pharmacists can obtain CD stocks via a requisition which complies with the Regulations described earlier.

Out of hours (OOHs) premises

Guidance from the Home Office indicates that the ability of the practitioner to operate will not require licensing where practitioners are involved in the management and/or handling of CDs for out of hours premises or bodies corporate

- if they provide a public, voluntary or charity funded service to the general public
- if their non-clinicians have no involvement in CD ordering, receipt or supply of CDs
- they are regulated by the CDAO in the NHS board in which they are situated. See section 20 for more details.

Ships and Offshore Installations

The owner of a ship, the master of a ship which does not carry a doctor on board, the master of a foreign ship or the installation manager of an offshore installation can order CDs for medical stores directly from a pharmacy or pharmaceutical wholesaler by a requisition, as long this conforms to the Misuse of Drugs Regulations.

In the case of the master of a foreign ship presenting a requisition for supply of schedule 2 or 3 CDs in Scotland, this must contain a statement signed by the Health Board competent person designated in terms of the Public Health (Scotland) Act 2008 by the Health Board within whose jurisdiction this ship is 'that the quantity of the drug to be supplied is the quantity necessary for the equipment of the ship'.

Community pharmacists dealing with such requests must:

- Ensure requisition meets legal requirements before dispensing. Ensure that requisitions from foreign ships are appropriately authorised.
- For UK registered vessels, confirm (with the MCA if necessary) that the requested drugs are appropriate for the category of the ship.

  Contact information: The Maritime and Coastguard Agency

  Tel: 02380 329249 (UK Registered Vessels only)
- The Master's Certificate of Competency may be requested for proof of identity and status as master of a ship prior to supply.
- Dispense appropriately and make relevant entries in CD register.
- Mark the requisition with the date of supply and name and address of supplier before forwarding to NHS NSS with regular prescription submission

Pharmacists should follow Medicines & Healthcare products Regulatory Agency (MHRA), Home Office and ethical guidance when undertaking wholesale transactions.

Section 6: Administration of Controlled Drugs

❖ Legal Framework

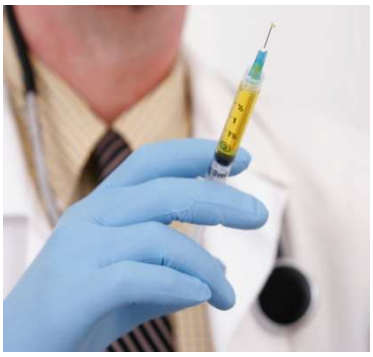
- Any person may legally administer a Schedule 5 CD to any other person.
- When administration of a Schedule 5 CD is defined in a PGD only those healthcare professionals specified in the PGD can supply or administer. The healthcare professionals specified in the PGD cannot delegate these functions in this instance.
- Some professional groups, but not all, are permitted to supply or administer CDs in accordance with a PGD (see section 7).
- A doctor or a dentist may administer to a patient any drug specified in Schedule 2, 3 or 4.
- Any person other than a doctor or dentist may administer to a patient, in accordance with the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4.
- Nurse independent prescribers (NIP) or any person acting in accordance with their directions can administer any schedule 2, 3, 4 or 5 CD the NIP can prescribe
- Pharmacist independent prescribers (PIP) or any person acting in accordance with their directions can administer any schedule 2, 3, 4 or 5 CD the PIP can prescribe
- A carer or relative can, with consent, administer a CD that has been individually prescribed for a third party.
- As CDs are included within the legal category of POMs, local authority employed home carers who are competent to administer medicines should also be competent to administer CDs – this normally relates to the administration of oral and topical preparations e.g. capsules, tablets and patches.
- Midwives may possess those CDs which they may lawfully administer under the Medicines Act (i.e. diamorphine, morphine, pethidine and pentazocine).
- Registered ambulance paramedics are able to administer diazepam and/or morphine sulphate injection (to a maximum of 20mg) for immediate necessary treatment of sick or injured persons

The Advisory Council on the Misuse of Drugs recommended in October 2019 that legislation should change to allow competent paramedic independent prescribers to prescribe and administer Midazolam (oromucosal and by injection) , lorazepam (by injection) and codeine phosphate (oral)

Good Practice (administration of CDs)

- Unless in exceptional circumstances the person who is prescribing the CD should not personally undertake all of the following tasks: preparation of the CD; dispensing of the CD and transportation and administration of the CD.
- For safety reasons it is good practice to ensure that, wherever possible, another appropriate competent individual is involved in the preparation and administration of CDs so that they can provide some assurance on the accuracy of the processes.
- There will be occasions such as the initial treatment of acute myocardial infarction or, in single handed practices, where this separation of tasks is not possible. In these instances it is important that accurate records are kept.
- Depending on the environment of care that the patient is in, a record of each administration should be kept in the relevant patient clinical notes. The date, time, strength, presentation and form of dose administered, and the name and occupation of the person administering the CD should be specified.
- Safeguards must be in place when any prescribed medicine is given to residents of a care service by care workers. A procedure for giving CDs to residents should be in place to minimise the potential for a drug error and the diversion of CDs. This should normally include a witness to the administration of CDs.
- CDs given by care workers (employed by a care at home service) in a person's own home should be treated in the same way as other prescribed medicines. No additional records or witnessed administration are required.
- CDs must not be pre-measured e.g. drawing up liquid into a syringe or into a measure for administration by care service staff at a later time

Preparation and Administration of Injections



Serious medication errors have been reported as a result of process errors during the preparation and administration of injections, including CDs.

Healthcare organisations should publish policies and procedures that define safe medication practice for the preparation and administration of injections including CDs. Any such procedures should include references to information on the following:

- aseptic preparation
- manufacture

- mixing two or more medicines in a syringe – drug compatibility
- expiry dating and labelling of prepared medicines
- safe administration of bolus doses
- programming and safe use of syringe-driver pumps
- single-checking versus double-checking with another practitioner or carer
- the dangers of confusing different strengths and types of CDs during preparation and administration.

Further information on safe medication practice for the preparation and administration of injections can be found in the following publications:

The Scottish Government has published the Good Practice Statement for the Preparation of Injections in near-patient areas including clinical and home environments: https://www.webarchive.org.uk/wayback/archive/3000/https://www.gov.scot/resource/doc/46932/0013922.pdf

NHS England » The NHS Patient Safety Strategy developed by the Department of Health and the Safer culture, safer systems, safer patients guidance produced in July 2019.

The Nursing and Midwifery Council and Royal Pharmaceutical Society have produced guidance on The administration of medicines in healthcare settings in January 2019

Extemporaneous Preparation of Methadone

Where a licensed product is available this should be supplied preferentially. The General Pharmaceutical Council has published guidance on specific requirements for those community pharmacies opting to prepare methadone extemporaneously. This is normally only acceptable where limited space precludes the safe storage of appropriate quantities of the licensed product. In these circumstances the prescriber and patient should be informed each time an unlicensed preparation is supplied

The General Pharmaceutical Council Guidance for registered pharmacies preparing unlicensed medicines was reviewed in 2018 and highlighted the need for communication with patients and prescribers

This guidance applies to the preparation of methadone either for immediate supply in accordance with the prescription, or initially as stock to be supplied against a prescription at a later time.

Pharmacies who prepare methadone extemporaneously must carry out a risk assessment of the entire process. Robust systems and SOPs must be in place to demonstrate that the pharmacy

- is a safe place in which to prepare unlicensed medicines for patients, and
- can produce safe, effective medicines which are of a suitable quality.

Regular audits should be carried out and these should form part of the evidence which provides assurance of the safety and accuracy of the process.

Detailed records of the preparation of the unlicensed medicine are necessary to safeguard patients. This is necessary to ensure the appropriate action in the event of a recall, or an incident affecting a patient's safety.

Supervised Consumption

In some health boards a new approach to supervision has been implemented to ensure that patients receive appropriate care. Where difficulties arise, the appropriate support can be provided either by the pharmacy staff or other care workers. In these cases, the strict adherence to accepted standards is a vital part of caring for patients.

Good Practice (Supervised Consumption)

- The dispensing process should be separated from the supervised consumption process.
- When supervising daily instalments the patient's identity must be confirmed. The pharmacist should check the patient's name, address, and date of birth and dose before offering to the patient for consumption.
- Where available, fingerprint recognition software can help to validate patient identity, but should not replace the questions above.
- The medicine should be dispensed in an appropriately labelled container
- Patients should be invited to check the label on the container prior to consuming their dose
- The container should be used once, retained and disposed of appropriately
- The label should be disposed of in confidential waste.
- Where more than one days supply is dispensed at once, each daily dose should be supplied in a separate, labeled child resistant container
- Safe storage instructions should be confirmed with the patient

Section 7: Prescribing Controlled Drugs

❖ Legal Framework

- **Medical practitioners**
  - Doctors and dentists may prescribe all Schedule 2 to 5 CDs for organic disease.
  - Doctors in England and Wales no longer need individual Home Office licenses to prescribe diamorphine, dipipanone and cocaine to substance misusers for the treatment of addiction. A general license has been issued to cover those doctors who have been approved by the Department of Health in England and Wales.
  - Under the Misuse of Drugs (Supply to Addicts) Regulations 1997, the Scottish Ministers have the power to grant licences to allow registered medical practitioners to prescribe, supply and administer (or authorise the supply and administration) of cocaine, diamorphine and dipipanone for the treatment of drug misuse. The application form and guidance were revised in June 2019. The new application form must be used for all applications for this license. The guidance note explains the specific requirements for any application being submitted to Scottish Government, as well as setting out the conditions of the license.
  - Doctors considering prescribing diamorphine, dipipanone or cocaine for the treatment of addiction must contact their CDAO/CD team for information regarding approval and licensing.

- **Non-medical prescribers**
  - **Community Practitioner Nurse Prescribers** may only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for Community Practitioners. No CDs are included in this formulary.
  - **Nurse independent prescribers** and **Pharmacist independent prescribers** can prescribe any CD listed in schedules 2-5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction (nurse and pharmacist independent prescribers are able to prescribe other controlled drugs for the treatment of addiction).
  - **Supplementary prescribers** can prescribe CDs only if they are acting in accordance with a patient specific clinical management plan. The MDRs 2001, General Medical Service and Personal Medical Service Regulations were amended in 2005 to include supplementary prescribers to the list of people authorised to prescribe CDs. Supplementary prescribers working to agreed patient specific management plans are able to prescribe for substance misuse. However, they cannot prescribe dipipanone, diamorphine and cocaine for addicts as licences are restricted to doctors.

Registered nurses, midwives, pharmacists, chiropodist, podiatrists, physiotherapists, radiographers and optometrist supplementary prescribers may now prescribe any CD for organic disease as long as it is within the clinical management plan specific to that patient and is agreed between the independent prescriber (doctor or dentist), supplementary prescriber and the patient.

- **Midwives**

  Midwives can train as non-medical prescribers. Midwives who are not trained as non-medical prescribers may administer CDs under Exemption Orders of the Regulations. (See section 5)

Patient Group Directions (PGDs)

From April 2012 the supply and administration of the following CDs is allowed under PGDs:

- Nurses and pharmacists working under a PGD are now authorised to supply, or offer to supply, diamorphine and morphine where administration of such drugs is required for the immediate and necessary treatment of sick or injured persons (excluding the treatment of addiction). This removes the restrictions whereby a nurse could only supply diamorphine under a PGD for the treatment of cardiac pain in patients admitted to a coronary care unit or an accident and emergency department of a hospital.
- All drugs listed in Schedule 4 of the Regulations plus midazolam (Schedule 3), except the anabolic steroids in part 2 of Schedule 4 and injectable formulations for the purpose of treating a person who is addicted to a drug.
- All drugs listed in Schedule 5 of the Regulations.
- Midazolam is the only Schedule 3 CD that can be included in a PGD.

Midwives do not require a PGD to administer specified CDs included under exemption orders of the Regulations. The Regulations will be amended to ensure that those acting in accordance with PGDs have authority to possess certain CDs for those purposes. The regulations will also be amended so that patients possessing CDs, who have failed to disclose a previous supply of such a drug under a PGD, will be committing an offence.

Independent healthcare providers

Patient group directions (PGDs) do not normally extend to authorising administration of CDs by staff employed by an independent or public sector care home, or, to those independent sector schools that provide healthcare entirely outside the NHS.

In Scotland only independent hospitals and hospices are currently registered under the Public Services Reform (Scotland) Act 2010. Until the Scottish legislation which governs the regulation of care services is extended to include independent clinics and medical agencies (which will encompass private GPs and dentists) PGDs can only be set up for use in independent hospitals and hospices. Furthermore, a PGD signed by a provider of an independent healthcare service registered in England and Wales, cannot be used to authorise the supply or administration of medicines by its own staff in Scotland. However, a provider registered in England and Wales, can enter into an arrangement with a

pharmacist based in a Scottish community pharmacy, to operate under a PGD. The same applies to the use of PGDs in England and in Wales by a provider registered in Scotland.

Prescription Requirements

- **Legal Framework**
  - Amendments to the MDRs 2001 removed the requirement for prescriptions for Schedule 2 and 3 CDs to be written in the prescriber's own handwriting. Only the signature has to be in the prescriber's own handwriting.
  - Alterations should be avoided as much as possible but if any are made, they should be clear and unambiguous, and be initialled and dated by the prescriber. If an error is made best practice would be to cancel and destroy the prescription and issue a new prescription. This is especially important with the electronic transfer of prescriptions.
  - It is a legal requirement under the Medicines Act 1968 that all prescriptions for POMs contain 'Such particulars as indicate whether the appropriate practitioner is a doctor, dentist, supplementary prescriber, etc.' (Regulation 15 of The Prescription Only Medicines (Human Use) Order 1997.

Good Practice (prescription requirements*)*

All 'other details' (except the signature on the prescription) can be 'written in any form' – this allows for computer printing of prescriptions. If these other details on the prescription are handwritten, good practice would indicate that they are hand written by the prescriber.

If these 'other details' are not hand written by the prescriber then an appropriate healthcare professional should handwrite these details on the prescription.

Schedule 2 and 3 controlled drugs

A prescription for Schedule 2 and 3 CDs must contain the following details, written so as to be indelible (e.g. written in ink, typed or computer-generated):

- The patient's full name, address and where appropriate, age. An email address or PO Box is not acceptable. 'No fixed abode' is acceptable as an address for homeless people
- The name and form of the drug, even if only one form exists, and/or it is implicit within the proprietary name
- The strength of the preparation, where appropriate (if more than one strength exists)
- The dose must be clearly defined (i.e. "take one as directed" constitutes a dose, but "take as directed" does not)
- The total quantity of the preparation, or the number of dose units to be supplied written in both words and figures. For liquid preparations it is recommended that the total volume should be expressed in millilitres
- If issued by a dentist, the words *'for dental treatment only'*
- The date of signing

- The date the prescriber wishes the prescribing to start if this differs from the date signed
- The address of the prescriber which must be within the UK. *(NB: the UK does NOT include the Channel Islands or the Isle of Man)*
- The prescriber's usual signature in their own handwriting

NB: A faxed/scanned/mailed prescription does not fall within the definition of a legally valid prescription because it has not been signed in ink by an appropriate prescriber.

See sections on private prescribing and instalment prescribing for additional information.

Schedule 4 and 5 controlled drugs

Prescriptions for Schedule 4 and 5 CDs are exempt from the specific prescription requirements of the Misuse of Drugs Regulations 2001. However, they must still comply with the general prescription requirements as specified under the Medicines Act.

Validity of prescriptions

In order to reduce the likelihood of CDs being dispensed beyond their clinical need and stored or diverted inappropriately, the maximum validity of a prescription for Schedule 1, 2, 3 and 4 CDs is 28 days. The prescription must not be dispensed more than 28 days from the date it was signed and dated by the prescriber. If the prescription has a later start date it must not be dispensed more than 28 days from this date.

In the case of a prescription containing a Schedule 2 or 3 CD to be supplied in instalments, the first instalment must be supplied no later than 28 days after the 'appropriate date'. Best practice is to include a start date for the first instalment although this is not a mandatory requirement.
If the full quantity of the prescription cannot be supplied when first presented any balance must be collected within this 28 day period.

Medicines that are not controlled drugs should not be prescribed on the same form as schedule 2 or 3 controlled drugs.

Further information can be found here

Technical errors on a prescription

Where a prescription for a Schedule 2 or 3 CD contains minor technical errors but the prescriber's intentions are clear, pharmacists can make amendments and proceed with the supply. The only errors that pharmacists may amend are:

- minor typographical errors or spelling mistakes
- where the total quantity of the preparation of the CD or the number of dosage units is specified in either words or figures but not both (they may add the words or the figures to the CD prescription if they have been omitted)

The pharmacist needs to have exercised due diligence, and be satisfied that the prescription is genuine and that the supply is in accordance with the intention of the prescriber.

The prescription must also be marked to show that the amendments are attributable to the pharmacist (e.g. name, date, signature and GPhC registration number).

Pharmacists cannot correct other amendments or omissions (e.g. missing date, incorrect dose, form or strength). These should be corrected by the original prescriber or, in an emergency, another prescriber authorised to prescribe CDs. Amendments cannot be made by covering letter from the prescriber.

Good Practice (Prescriptions)

• All prescriptions for Schedule 2 and 3 CDs should include the patients CHI number • The prescriber's full name, address and telephone number where they can usually be contacted should be included on the prescription • Dosages and frequencies for all CDs should be detailed in full to aid administration. Particular care should be taken to ensure clarity of dosage instructions, where systems such as syringe drivers are being used	• Any space on the prescription form that has not been written on should be blanked off to reduce the opportunity for fraud, e.g. by drawing a line through it	• CDs have the potential to be diverted to the illicit market. When a patient presents a CD prescription for an acute condition more than two or three weeks after the prescriptions was issued, it would be prudent to check with the patient and/or the prescriber that the supply of the CD is still warranted before dispensing

Good Practice (patients receiving treatment for substance misuse)		
• Opiate Replacement Therapy -when patients present more than three days after either the date the prescription was written or the start date, the pharmacist should check with the prescriber before dispensing. The patient's tolerance to the opioid may have reduced and the same dose taken after three days break in treatment could result in overdose. Pharmacists should inform the prescriber or key worker and agree the most appropriate course of action	• The quantity of drug prescribed on each prescription should be appropriate for the patient's clinical need. Careful consideration should be given to the quantities prescribed – both to anticipate requirements, e.g. over a weekend, and to reduce the amount of CDs stored in the patient's home	• Although not a legal requirement there is a strong recommendation that prescriptions for Schedule 2, 3 and 4 CDs should not exceed 30 days supply unless there is a clinical need

Prescribing more than 30 days supply

In exceptional circumstances where the prescriber believes a supply of more than 30 days' medication is clinically indicated and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons for this in the patient's notes and be ready to justify their decision if required.

Dispensing more than 30 days supply

- It is not illegal for a pharmacist to dispense a prescription for more than 30 days' supply, but they must satisfy themselves as to the clinical appropriateness of the prescription before doing so
- A pharmacist does not need to contact the prescriber each time they receive a prescription requesting a supply in excess of 30 days for a Schedule 2 to 4 CD. Pharmacists should exercise their professional judgement and assess both the prescription and the situation to check the suitability for the patient
- Where there is concern that the prescription is not appropriate the prescriber should be contacted
- CDAO monitoring checks are likely to pick up large prescribing amounts
- The CDAO/CD team can also be contacted where prescribing concerns are identified for advice and follow up

Prescribing in Instalments

In Scotland, Schedule 2 and 3 CDs can be dispensed to patients in instalments if specific information is included on the prescription.

Details to be specified

If a CD prescription is to be dispensed in instalments, e.g. daily, the prescription must specify the following:

- the dose to be taken
- the quantity to be supplied in each instalment
- the intervals to be observed between instalments
- the total quantity of CD to be provided.

It is a legal requirement that the dose and instalment amount are specified separately on the prescription. It is not a legal requirement to specify the starting date but this is recommended as good practice.

Collection of instalments

The prescription must be dispensed on the date on which it is due.

If the person does not collect a single day's instalment when it is due, that supply is no longer valid, and the person cannot collect that supply the following day.

If a prescriber has ordered several days' instalments to be collected on one day and the person does not come in on the specified day, then the person loses the complete instalment - in other words, the client cannot have the remainder of the instalment.

Pharmacists should endorse the prescription '*not dispensed*' for that instalment and if possible notify the prescriber.

However, guidance from the Home Office has indicated that the use of specific wording will enable those supplying CDs to issue the remainder of an installment prescription when the person has failed to collect the instalment on the specified day.

The wording below can be used by those prescribing CDs by instalment in accordance with the Misuse of Drugs Regulations 2001. If a prescription does not contain such wording the Regulations only permit the supply to be made in accordance with the prescriber's instalment direction.

Home Office Approved Wording

1. Please dispense instalments due on pharmacy closed days on a prior suitable day
2. If an instalment's collection day has been missed, please still dispense the amount due for any remaining day(s) of that instalment
3. Consult the prescriber if three or more consecutive days of a prescription have been missed
4. Supervise consumption on collection days
5. Dispense daily doses in separate containers

Supervised consumption:
'Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied.'

Unsupervised consumption:
'Instalment prescriptions covering more than one day should be collected on the specified day. If this collection is missed the remainder of the instalment (i.e. the instalment less the amount prescribed for the day(s) missed) may be supplied.'

Good Practice (prescribing instalment prescription requirements)

- The individual should collect the CD in person. If they are unable to collect prescriptions they may arrange for a representative to collect it. The representative should bring a suitable note on each occasion to ensure they have authority to collect the CD. The pharmacist should be convinced, beyond reasonable doubt, that the note is valid. The note should be retained by the pharmacy for a period of time to allow comparison of signatures.
- The requirement to see identification on collection of CDs only applies to the first dispensing of an instalment prescription
- Where more than one days supply is dispensed at once, each daily dose should be supplied in a separate labelled container

Repeat Prescribing

It is clear under the current legislation that repeat* prescribing of CDs in Schedule 2 and 3 is not permitted on a private prescription. However, practice management systems e.g. Vision, Emis which allow the patient to receive a prescription (hand signed by a practitioner) without a consultation are not subject to legislation. For example, patients receiving ongoing supplies on medicines on GP10 prescription from their 'repeat' list of medicines on their medical record. These are considered to be a clinical decision made on a case-by-case basis. It is good practice that patients should be reviewed before prescribing Schedule 2 and 3 CDs and at regular intervals during the prescription period.

**The repeat method is where a private prescription is written for a specified quantity of drugs and the prescriber endorses the prescription with the number of times the prescription should be repeated. The pharmacist is then able to make the specified number of dispensing transactions from that prescription.*

NHS Serial Dispensing Scheme under Medicines Care and Review (MCR)

The Medicines Care and Review (MCR) is a Scottish Government initiative which aims to improve the care of patients with long term conditions. Patients register for the service with a community pharmacy of their choice and for those on stable medication regimens; their GP may issue a serial prescription covering 24 or up to 56 weeks treatment and specifies how many instalments and the frequency of the instalments. Controlled drugs in Schedule 1,2,3 and 4 are excluded from serial prescribing but Schedule 5 controlled drugs may be supplied.

Emergency Supplies

Emergency supplies (as defined in the Medicines Act) of Schedule 2 and 3 CDs for a specific patient are not permitted at the request of the patient or a practitioner. The only exception to this rule is the supply of phenobarbital for the treatment of epilepsy. In national emergency situations, e.g. a pandemic, additional time limited special legislation may be introduced at the discretion of the Home Office to allow emergency supply of CDs in specific circumstances. For further information regarding urgent supplies to practitioners please refer to section 5

Prescribing for Self and Family

Good Practice (prescribing for self and family)

• Other than in emergencies no prescriber should prescribe any drug for themselves or anyone with whom they have a close personal or emotional relationship. • If necessary the relationship with the individual should be documented on the prescription. • There is a risk that those who self-treat may ignore or deny serious health problems.	• There is also a risk that self-prescribing could lead to drug misuse or dependence. • In an emergency situation where no other person with the legal right to prescribe is available to assess the patient's clinical condition and take the appropriate action. In these circumstances it can be acceptable to prescribe for family, friends or self if it is immediately necessary to save life, avoid a significant deterioration in the patients health or alleviate uncontrollable pain.	• The following professional bodies advise healthcare professionals against prescribing for themselves, for their family, friends or for colleagues. British Medical Association (BMA) General Medical Council (GMC) General Dental Council (GDC) General Pharmaceutical Council (GPhC) Royal Pharmaceutical Society (RPS)

Private Prescribing

The term 'private prescriber' is used to describe the situation when a private prescription is written either by NHS or non-NHS practitioners in either NHS or non-NHS settings.

In addition to reviewing the current legal framework for the management of CDs this document helps to establish good practice for the management of CDs. Although this is presented in the form of guidance for the NHS this good practice is equally applicable to professionals providing healthcare in non-NHS settings. The law relating to prescribing applies to all NHS and non-NHS settings and good governance is equally applicable to non-NHS organisations.

Prescription of requirements

❖ Legal Framework

- Prescribers must comply with all legal requirements when writing private prescriptions including appropriate record keeping when ordering, prescribing, dispensing, administering and destroying CDs.
- Private prescribing can take place in a number of settings including independent hospitals, independent clinics and medical agencies. An independent medical agency may provide medical practitioner services to hotels. Independent clinics include services provided by doctors, non-medical independent prescribers and dentists such as:
  - Health screening services
  - Occupational health services
  - Weight management treatments
  - Cosmetic surgery and treatment
  - Private dental services
  - Private consultations
  - Surgical dentistry
  - Orthodontic work
  - Ophthalmic surgery
  - Fertility management clinics
  - Travel advice, travel vaccinations and other immunisation clinics
  - Armed forces
  - Specialist medical consultations and investigations including x-rays, blood tests, endoscopic treatments, treatments where lasers are used (e.g. eyesight improvement, birthmarks, tattoo or excess hair removal)

Standardised private prescription form

All private prescriptions for human use of Schedule 2 and 3 CDs that are presented for dispensing in the community (not in hospitals) must be written on the standard PPCD(1) prescription form.

A prescriber can obtain a PPCD(1) pad by applying to their NHS board. Private prescribers will be allocated an identification number by NHS National Services Scotland. In Scotland a valid, NHS prescriber code is used where available or a new one issued where necessary. Prescribers working in private practice in a hospital should inform patients that private prescriptions not written on the standard PPCD form can only be dispensed in that hospital pharmacy.

Submission of private prescriptions

The original of each private prescription for a Schedule 2 or 3 CD must be submitted after dispensing (community pharmacists or dispensing doctors) to NHS National Services Scotland along with a dispensary submission form (CD34).

Good Practice (private prescriptions)		
• Private prescribers should produce their own procedures for use in their services with respect to treatment, prescribing and review policies, clinical governance systems and training and continuing professional development.	• Private prescribers should, in most circumstances, and with the patient's agreement, contact the patient's private or NHS GP before initiating treatment and during the course of treatment. They should also liaise as appropriate with other health care professionals involved in the care of the patient. This should include the pharmacist or dispensing doctor.	• Private prescribers should indicate on the prescription when prescribing for a non-UK resident. Several of the points here are included in Regulation under the Health and Social Care (Community Health & Standards) Act (2003).

In this context, the term ‘dispense’ means to assemble and to supply a medicine. The term ‘dispense’ is not defined in legislation.

❖ Legal Framework

- Details of supplies of Schedule 2 CDs must be entered into the CD register (CDR) as soon as possible and at the latest the next day following the day of supply.
- The date entered in the CDR should be the date of supply (i.e. the date on which the CD is handed to the patient, carer, representative) and not the date when it is assembled.
- The pharmacist or dispensing doctor must endorse prescriptions for Schedule 2 and 3 CDs with the date of supply to the patient.
- As with all dispensed medicinal products (except unlicensed medicines), it is a legal requirement to provide a manufacturer’s patient information leaflet.

During a pandemic the Home Office may introduce temporary legislation around the supply of CDs to allow for contingency and flexibility in some key areas.

Good Practice

• It is good practice (not a legal requirement) for people collecting Schedule 2 or 3 CDs to sign the back of the NHS and private prescriptions.	• It is considered good practice and strongly recommended for a second person to check the quantity, volume and strength of the CD being dispensed. However, it is accepted that this may not be practical in all situations • In cases where the CD prescription is assembled and stored in a CD cabinet awaiting collection it may be useful to note the final valid day of collection of the supply to safeguard against supply outside the 28 day validity	• As with all prescribed medicines, CDs should normally be dispensed in child-resistant containers or with child-resistant closures. • Advice should be provided on safe and secure storage at home, especially being out of sight and reach of children and safe disposal by returning any unused CDs to a pharmacy.

Dispensing against Instalment Prescriptions

Prescription requirements

❖ Legal Framework

- For instalment prescriptions of Schedule 2 CDs, each supply must be entered on the day of supply into the relevant section of the CDR. This task must not be left until the end of the prescription period or carried out in advance
- Instalments must only be supplied on the day that they are due as specified on the prescription

Validity

Prescriptions are valid for 28 days. The 28 day period starts on the applicable date entered on the prescription form. This date will be the date of signing the prescription form, or a start date specified on the prescription form by the prescriber. The first instalment must be dispensed within the 28 day limit. The remainder instalments should be dispensed in accordance with instructions.

Authorised wording to allow the supply in advance of the patient's first dose has been approved by the Pharmacy Regulators from the General Pharmaceutical Council:

"Commence dispensing on dd/mm for patient to consume from dd+x/mm".

This will ensure the pharmacy addiction team and patient get the service they expect on the correct date with no issues.

A PC70 form must be completed for each instalment controlled drug prescription as the pharmacist is legally obliged to sign and date the prescription form each time a Schedule 2 or 3 CD is dispensed. The PC70 is linked and is counted as an extension to the original form and in order to ensure correct payments, the pharmacist must endorse the prescription form with the details of the instalment dispensing. The completed and signed PC70 should be submitted with the original prescription to practitioner services.

Good Practice (dispensing methadone prescriptions)

- Where appropriate, shared care arrangements for the prescribing and dispensing of CDs for substance misusers should be developed.
- When an instalment prescription for a CD is presented, it should be stamped with the pharmacy or dispensing practice address at the first dispensing. This is done to prevent the possibility of future misdirection of the prescription.
- In practice, methadone prescriptions are often made up in advance to ensure substance misusers can be dealt with in a proactive and timely manner. The pre-assembled methadone must be stored in a cabinet which meets the legal requirements, or be under the direct personal supervision of the pharmacist or doctor. If the patient does not collect the instalment it can be returned to stock provided it is labelled appropriately, e.g. with batch number and expiry date.

/cont.

- Where CDs are assembled in advance for instalment dispensing and not collected, the patient medication record should be amended and the prescription annotated to reflect the fact that the supply was not collected.
- Patients receiving some drugs, e.g. methadone, may require supervision of consumption by a pharmacist. This should ideally be carried out in a quiet area of the pharmacy. This area should not normally be the dispensary, or involve taking the patient through the dispensary.
- Pharmacists dispensing CDs to substance misusers should liaise with the prescriber regarding non-collection of the CDs.
- The requirement for signing the prescription and identification on collection only applies to the first dispensing of instalment prescriptions. As with all CD prescriptions, the pharmacist has discretion to dispense without identification being presented.
- Patients should collect the CD in person. If the patient cannot collect the CD in person, they may arrange for a representative to collect it. In such circumstances, pharmacists require a letter on each occasion from the patient stating that a named person is authorised to collect the medicines on their behalf. The pharmacist will keep the letter.
- A written authorisation is also recommended, for example, when a patient is in custody to authorise a named police officer to collect an instalment from the pharmacy.
- Authorisation letters are necessary to allow people to carry CDs when they are not the person for whom the CD was intended – otherwise they are in unlawful possession. It may also prevent misunderstandings or deceit. The person collecting may be asked to sign a record book. It is at the pharmacist's discretion whether to supply to another person. Refer to section 4 regarding the possession of CDs by other authorised individuals.
- If a patient regularly sends a third party to collect the supply, it may be necessary for the pharmacist to notify either the clinic where the substance misuser is being treated, or the prescriber.

'Owing' Prescriptions for Controlled Drugs

Prescription requirements

❖ Legal Framework

- If the pharmacist or dispensing doctor is unable to supply the total quantity of the drug requested the entry made in the CDR must only be for the quantity of drug actually supplied. A further entry must be made when the balance is supplied. If the patient no longer requires the balance of the prescription, the prescription should be endorsed with the amount dispensed. It is good practice to record the reason why the remainder was not dispensed for instance if the patient has died
- Dispensed items or owings for Schedule 2, 3 or 4 CDs cannot be supplied more than 28 days after the appropriate date on the prescription

- Where the prescriber has written on the prescription that it must be supplied on a specific date, as in the case for instalment prescriptions, those instructions must be complied with. When a prescription requires a specific quantity of CDs to be dispensed on a specific date, the dispenser may not dispense a part of this quantity and then dispense the remainder at a later date. Doing this would deviate from the prescribers instructions. The stock initially held in the dispensary, plus the balance remaining, can be dispensed to the patient, as long as it is done during the same calendar day

Proof of identity – prescriptions for schedule 2 controlled drugs

❖ Legal Framework

- ❖ Patients or their representatives may require evidence of identity when collecting CD medication.
- ❖ Persons asked to supply schedule 2 CDs on prescription must seek to establish whether the person collecting the drug is the patient, the patient's representative or a health care professional acting in his professional capacity on behalf of the patient.

Patient or patient representative

Where the person is the patient or the patient's representative the dispenser may request evidence of that person's identity and may refuse to supply the drug if he is not satisfied as to the identity of that person.

The new requirement placed on the dispenser allows them the discretion not to ask patients or their representatives for proof of identity, if for example, they have concerns that to do so, may compromise patient confidentiality or deter patients from having their medicine dispensed.

Healthcare professional

Where the person collecting the prescription is a healthcare professional acting in his professional capacity on behalf of the patient the dispenser:

- must obtain that person's name and business address
- must, unless he is acquainted with that person, request evidence of that person's identity
- may supply the drug even if he is not satisfied as to the identity of that person

❖ Legal Framework

- It is a legal requirement to record the following information in the CDR for Schedule 2 CDs supplied on prescription:
  - Whether the person who collected the drug was the patient, the patient's representative or a health care professional acting on behalf of the patient
  - If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name and address
  - If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory)

- Whether evidence of identity was provided by the person collecting the drug

Forms of identification

The following forms of ID are considered suitable:

- Professional registration number of healthcare profession
- Driving license (including photo card section)
- Any official photo ID
- Passport
- Cheque guarantee/debit/credit card
- Birth/marriage certificate
- Bank or building society statement
- Utility bills(two different ones (excluding mobile phone statement)
- Council tax payment book
- Pension or benefits book
- Store charge card
- National savings book
- Cheque book
- Council rent book

It is good practice to record information to support the proof of identity requirements outlined. Healthcare professionals should use their professional registration number as their form of identification.

Delivery Schemes

As with any other delivery scheme, a robust audit trail should be in place so that when the driver hands over the medicine to the patient/patient's representative or carer it is documented. Wherever possible a signature should be obtained indicating safe delivery of medicines.

Dispensing Doctors

Prescription requirements

❖ Legal Framework

- It is lawful for a dispensing doctor to delegate the act of dispensing medicines for their patients to employed staff. However, accountability remains with the dispensing doctor.

Good Practice (dispensing doctors)

- The medical practice and partners carry vicarious liability for errors made or for any breach of the law.
- A dispenser or other employee would not normally be expected to dispense and issue a Schedule 2 or 3 CD without first checking the dispensed items with a doctor. The Dispensing Doctor's Association's Guidelines state that *'the doctor should check all prescriptions for CDs'*. Updated guidance on managing the use of CDs is available from the Dispensing Doctor's Association

Section 9: Recording of Controlled Drugs

Overview

This section applies to all Controlled Drugs Registers (CDRs) whether held by a doctor, a pharmacist or other healthcare professional (personally or as part of the activities of an organisation).

❖ Legal Framework

- Doctors, pharmacists or other healthcare professionals are legally required to record Schedule 2 CDs in a controlled drugs register. There is no legal requirement to record Schedule 3, 4 or 5 CDs in a controlled drugs register, although pharmacists are required to keep records of Sativex, which is a Schedule 4 Part 1 CD. The Home office recommends the use of a CD register to do so.
- All healthcare professionals who hold personal CD stock must keep their own controlled drugs register and are personally responsible for keeping this accurate and up-to-date.

  If a GP does not carry CDs in his bag, but occasionally takes stock from the surgery to a patient's home, the GP must transfer the stock from the surgery's CDR into his own CDR whilst he is carrying the CD in his bag. If the CD is not used the stock can be returned and re-entered into the main surgery CDR and out of his own CDR.
- Although it is no longer a legal requirement to maintain a CDR in a prescribed format, the Regulations require certain headings to appear in the controlled drugs register and require specific fields of information to be completed.
- A separate page must be used for each strength and form of each drug. Entries made in respect of drugs obtained and drugs supplied may be made on the same page or separate pages. For further details see *CEL 21 (2007) 'Safer management of controlled drugs: changes to record keeping requirements'*
- A record of all receipts and supplies of schedule 2 CDs must be made in the CDR at the time of the transaction or as soon as possible but no later than the following day.

Record Keeping Requirements

For CDs received into stock the following details must be recorded in the CDR:

- the date on which the CD was received
- the name and address of the supplier (e.g. wholesaler, pharmacy)
- the quantity received
- the name, form and strength of the CD.

For CDs supplied to patients (via prescriptions) or to practitioners (via requisitions) the following details must be recorded in the CDR:

- the date on which the supply was made
- the name and address of the patient or practitioner receiving the CD
- the particulars of the authority of the person who prescribed or ordered the CD
- the quantity supplied
- the name, form and strength in which the CD was supplied
- the person collecting the Schedule 2 CD (patient, patient's representative or healthcare professional). (*If the person is a healthcare professional then their name and business address should be recorded)*
  the following information must also be recorded:
  - was proof of identify requested of patient or patient's representative? (yes/no)
  - was proof of identify of person collecting provided? (yes/no)

The record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a CDR from including additional related information. It is good practice to record the following:

- running balances
- the prescriber's identification number and/or professional registration number (where known)
- the name and registration number of the healthcare professional supplying the CD.

Currently where a CDR is kept on paper the CDR must comply with the following:

- be bound (not loose-leaved)
- contain class sections for each individual drug
- have the name, class, strength and form of the drug specified at the top of each page
- have entries in chronological order and made on the day of the transaction of the next day
- have the entries made in ink or otherwise so as to be indelible
- not have cancellation, obliterations or alterations. Corrections must be made by signed and dated entry in the margin or at the bottom of the page
- be kept at the premises to which it relates and be available for inspection at any time
- a separate register must be kept for each set of premises where CDs are held (not just the main surgery)
- be kept for a minimum of two years after the date of the last entry
- not be used for any other purpose

Doctors and practitioners with personal CD stock, emergency bags or practice central CD stock can obtain a primary care CDR from their NHS board. Contact your CDAO or CD team for information.

Computerised controlled drugs registers

An electronic CDR may be used as an alternative to a bound book. A computerised CDR must be held on a computerised system which complies with specified best practice guidance. It must be attributable and capable of being audited, and must be capable of printing or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout.

Full details of the requirements for computerised CDRs are set out in S.I. 2005/2864. It is strongly recommended that the electronic CDRs comply with best practice highlighted in the current edition of the RPS Medicines, Ethics and Practice (MEP) guide.

Good Practice (computerised CDRs)

- If the CDR is held in computerised form the following should be put in place:
  - Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
  - Entries cannot be altered at a later date
  - A log of all data entered is kept and can be recalled for audit purposes.
- Any pharmacies or dispensing doctors considering computerised CDRs are advised to discuss this with their NHS board CDAO/CD team prior to implementation, to ensure the system complies with the requirements.
- Access control systems should be in place to minimise the risk of unauthorised or unnecessary access to the data. Adequate backups must be made of computerised registers. Arrangements should be made so that inspectors can examine computerised registers during a visit with minimum disruption to the dispensing process.

Good Practice (CDRs – running balances)

The aim of maintaining running balances in a CDR is to ensure irregularities are identified as quickly as possible.

- **Maintaining a running balance of stock**

  Pharmacists and other healthcare professionals who supply CDs should maintain a running balance of stock in their CDR as a matter of good practice.

  The running balance of drugs remaining should be calculated and recorded after each transaction. It is also appropriate to visually check the running balance each time a CD is dispensed (i.e. where the calculated balance in the register visually matches the quantity you can see. If it does not match, you should investigate in more detail).

  Accountability for maintaining the running balance of CD stock and dealing with any discrepancies lies with the healthcare professional in charge and not with the person to whom they may delegate day-to-day responsibility under defined SOPs.

- **Physical reconciliation with stock levels**

  The running balance recorded in the CDR should be checked against the physical amounts of stock at regular intervals.

  Guidance from professional representative bodies and the findings from local risk assessments should determine the frequency of stock checks.

  The General Pharmaceutical Council (GPhC) advises that the physical amount of CDs should be checked at least weekly in a community pharmacy. The date on which a stock check is carried out should be recorded. Checks on the expiry date of stock should also be carried out at regular intervals.

/cont.

- **Liquid CD preparation excess liquids (overage)**
  Bottles of liquid CD preparations (e.g. methadone) are likely to contain a slight overage. In order to maintain an accurate running balance when the end of a bottle is reached any excess liquid must be measured and recorded in the CDR. The stock balance must be adjusted accordingly and this entry annotated and signed by the pharmacist or dispenser.
- **Balance Checks** It is good practice for a person first taking over accountability for premises with CD stock to ensure the CD stock levels are correct. This primarily applies to GP practices holding CD stock; pharmacies; dispensing doctor practices; care services, hospices; independent healthcare establishments, hospitals and community hospitals without a pharmacy. Where changeover of responsibility occurs frequently, for instance when multiple locums are required within community pharmacies, out-of-hours providers or GP practices, it is impractical to carry out stock checks at every changeover.
- SOPs for the reconciliation of physical stock with CDR balances should define how often this takes place. As a minimum it should take place weekly. If the usage of CDs is high, e.g. in drug and alcohol units or palliative care establishments, or if there are several different professionals in charge over a short period, stock checks should be carried out more frequently and by different, suitably trained members of staff. The day-to-day responsibility for this can be delegated under SOPs, to another appropriate, suitably trained, member of staff who is routinely present at the premises.

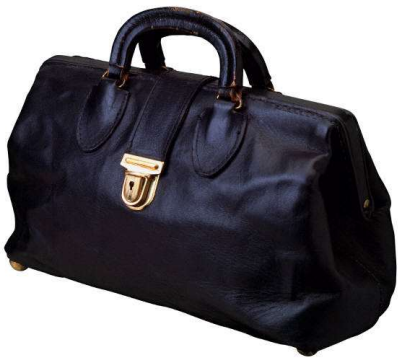
  Wherever possible two members of staff should check all stock received or removed. Both individuals should initial the entry in the CDR. Individuals should not sign against a balance unless they have physically checked and verified it.

Preservation of Records

Registers, requisitions and orders for CDs must be preserved for a minimum of two years. If a CDR contains information relating to destruction of CDs it is good practice that this should be preserved for a minimum of two years. These records may be preserved in the original paper form or in computerised form.

Doctor's Bag

Where a practitioner carries a bag containing CDs, e.g. for home visits, a separate CDR must be kept for the CD stock held within that bag.



Each doctor is responsible for the receipt and supply of CDs from their own bag.

Another member of practice staff should witness both the restocking of the bag from central practice stock and the appropriate entries into the practice's CDR.

Where a prescription is written by a doctor from a dispensing practice following the administration of a CD to a patient, the doctor should endorse the prescription form with the word 'administered' and then date it. This aims to avoid unauthorised individuals attempting to reuse such 'prescriptions' to obtain CDs illegally. Information should also be entered into the patient's record as soon as practicable.

Recording of Expired Controlled Drugs Stock

If CDs kept in a doctor's bag expire they should be returned to the central practice stock for future destruction in the presence of an authorised witness.

When CDs are transferred from the bag to central practice stock this should be witnessed and documented in both CDRs to ensure a clear audit trail.

If the practice does not hold central stock then the CDs need to be destroyed directly from the bag in the presence of an Authorised Witness and appropriate records made in the CDR.

Recording of 'patient returned' Controlled Drugs

'Patient returned' CDs are those that have been prescribed for, and dispensed to, a named patient and then returned unused, or part used, for destruction.

Pharmacies and dispensing practices will routinely deal with patient returns.

Non-dispensing doctors should encourage patients to return drugs they no longer require to the community pharmacy for appropriate destruction.

Non-dispensing practices should only accept patient returns in exceptional circumstances.

❖ Legal Framework

- It is a legal requirement for a standard operating procedure (SOP) to be in place covering the maintenance of records for Schedule 2 CDs returned by patients. A separate book should be kept to record these details which must include:
  - the date on which the CD was returned
  - the name and address of the patient (where available)
  - the role of the person returning the drugs (if not the patient)
  - the name, form, strength and quantity of the CD returned
  - the name and signature of the person receiving the CDs
- Records of these patient returns should be kept for at least 7 years.
- It is not a legal requirement to destroy patient returned CDs in the presence of an Authorised Witness. However, good practice dictates that such destruction is witnessed by another member of staff and the signature of both the person witnessing and the person destroying should be entered into the records as well as the date of the destruction.

Section 10: Discrepancies, Incidents and Concerns

Discrepancies

❖ Legal Framework

- When a CD discrepancy is discovered it must be fully investigated as soon as possible.
- Where the discrepancy cannot be resolved, the Controlled Drugs Accountable Officer CD team must be notified.
- Where criminality is suspected this must also be reported to the police.

Good Practice (discrepancies, incidents and concerns)

- Where a discrepancy has occurred the following checks may help to provide a solution.
  - Check arithmetic since the last correct balance
  - Re-check CD cupboard or bag with colleague including date expired stock, prescriptions awaiting collection and excluding patient returns
  - Check other CDR sections of same drug class for erroneous entries
  - Check all other holdings, e.g. GP bags
  - Sense-check CDR (correct pack sizes, patterns of entry for potential missing entries and unusual quantities)
  - Check all orders have been recorded, delivery notes, invoices and stock orders.
  - Check all prescriptions have been recorded correctly
  - Check with any locums or practitioners who have worked in the premises during the relevant period to verify all supplies made have been recorded.
- As each step is carried out and completed this should be recorded.
- Liquid CD preparations - bottles of liquid CD preparations e.g. methadone are likely to contain a slight overage.
- The following procedure may help to maintain an accurate running balance
  - When the end of a bottle is reached the stock level recorded in the CDR may be adjusted accordingly to reflect the actual stock level. This entry should be annotated and signed by the pharmacist or registered technician
  - Where a spillage has occurred, the pharmacist or person in charge of the clinical area, may correct the running balance. The record should be initialled by a second person, who has witnessed the spillage.

Good Practice		
• When a dispensing error has occurred the CDR entries and balances should be corrected to show what has been dispensed. • Medicines incorrectly dispensed have not been supplied in accordance with a prescription and have therefore not been legally dispensed • Medicines incorrectly dispensed should be retrieved from the patient and returned to safe storage, segregated from normal stock and destroyed in the presence of the authorised witness • Near misses could be returned to stock and used later, providing they have not left the control of the pharmacist	• Discrepancies and any methods of resolution should be notified to the contractor, owner, senior manager, and superintendent pharmacist in accordance with local policy. .	• Consideration should be given to notifying the GPhC or other regulator where professional standards are compromised.

Incidents and Concerns

The NHS Board Controlled Drugs Accountable Officer CD team must be notified of all unresolved incidents and concerns involving CDs that occur within their organisation and within the premises of any independent contractors who provide a service to their organisation. This must be done as soon as possible, within 3 working days. This allows the CDAO to identify any trends of incidents and share learning with colleagues to reduce the likelihood of a similar recurrence. This applies to all incidents involving Schedules 2, 3, 4 and 5 CDs but not to incidents involving illicit drugs, which should be reported as per local organisational policy.

❖ Legal Framework

- The Controlled Drugs (Supervision of Management and Use) Regulations 2013 requires that the CDAO/CD team be notified of any incident involving a CD as soon as possible and within three working days. These include:
  - Unexplained losses or discrepancies in CD registers against actual stock
  - Any discrepancy in CD stock which, although resolved, raises concerns
  - All significant events or near misses involving prescribing, administration, supply, dispensing or destruction of CDs
  - Complaints from patients, carers, and service users relating to CDs.
  - Any concerns raised about professional practice or behaviour of staff in relation to CDs, e.g. unusual prescribing patterns, attempts to fraudulently produce prescriptions
  - Any illegal activity relating to CDs, e.g. theft, break-in to premises, patients attempting to obtain CDs by deception.
  - Any CD register loss
  - Any loss of prescription stationery including CD order books

CD incident reports must provide details of the episode and importantly of the contributing factors and of any action taken following the incident to help prevent a recurrence The report must include details of what immediate steps were taken to prevent or reduce harm to patients; any investigations that were undertaken or planned following an incident; and what actions have been taken.

Where reports are made through electronic or other systems or, for other purposes, a copy of the existing paperwork should be supplied (Datix; significant event analysis; appraisal or company reports).

Guidance on reporting incidents and a reporting template is available on the from your local NHS board Controlled Drugs Team

Practitioner Services Division of NHS National Services Scotland has produced Guidance for NHS Scotland on Security of Prescription Forms

Contact details for CDAOs can be found on the Register of Controlled Drugs Accountable Officers (Scotland)

Section 11: Destruction of Controlled Drugs

❖ Legal Framework

- **Persons currently authorised to witness the destruction of controlled drugs**

  In Scotland, the Regulations prevent CDAOs from undertaking the role of witnessing the destruction of CDs. However they can authorise certain individuals to witness the destruction of CDs. Such persons are known as 'Authorised Witnesses (AW)'.

  An AW is directly accountable for this activity to the CDAO; they must have appropriate training and they must be subject to a professional code of ethics and/or have been the subject of enhanced Disclosure Scotland checks/Protection of Vulnerable Groups (PVG) Scheme.

  An AW must be independent of day-to-day use or management of CDs.

  Certain pharmacy multiples may have their own authorised witness (see Authorised Witnesses for Pharmacy Multiples)

  There must be an appropriate separation of roles and responsibilities. Any AW directly involved with a GP practice or community pharmacy, or any practice based pharmacy staff must not be asked to witness the destruction of CDs in that practice or pharmacy.

Authorised Witnesses for Pharmacy Multiples

The Scottish Government issued guidance on authorising witnesses for CD destruction within pharmacy multiples (CEL 21 (2007)). An AW from a pharmacy multiple must meet a specific set of criteria including being subject to a professional code of ethics.

The NHS Scotland Controlled Drugs Accountable Officers' network has developed a national process for authorising AWs for employees that are members of the Company Chemists Association. Further guidance is available from your local NHS Controlled Drugs governance team

Pharmacy multiples that are not members of the Company Chemists Association can apply to their NHS board Controlled Drugs Accountable Officer for staff to be authorised. The list of authorised witnesses is held by each NHS board CDAO.
Contact details for Controlled Drugs Accountable Officers can be found on the Healthcare Improvement Scotland Website

- **Controlled drugs held in stock**

  CD 'stock' refers to CDs that have been obtained from a wholesaler in anticipation of clinical need and not those dispensed to a patient. The possession, storage and

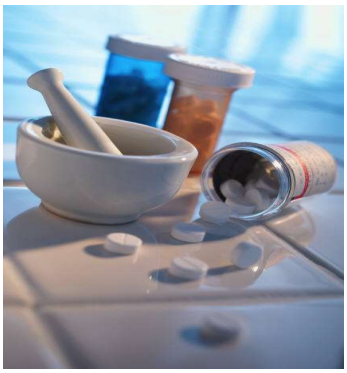
destruction of CD stocks are governed by the MDA 1971 and MDRs 2001 as amended. Healthcare professionals and service providers who are required by law to maintain a CDR are not allowed to destroy expired Schedule 2 (or 1) CDs from their stock, except in the presence of an AW.

- **Out of date CDs**
  Out of date CDs must be stored securely until they are destroyed. They must be clearly marked and segregated from in-date stock to minimise the risk of errors and inadvertent supply (see section 12).
- **Recording the destruction of Schedule 2 CDs**
  A record of all 2 CD destructions must include the following details in the CDR:
  - name
  - form
  - strength
  - quantity of the drug,
  - the date the CD was destroyed
  - name and signature of the authorised witness and the individual destroying the CD

Sufficient Witnesses

NHS board CDAOs who oversee community pharmacy and dispensing practices must ensure they have sufficient AWs to avoid a build-up of expired or unwanted CD stock. A build-up of such CD stock can become a crime prevention issue and breach waste management regulations.

Methods of Destruction



Schedules 2, 3 and 4 (part I) CDs should be rendered irretrievable prior to safe disposal. CDs should be removed from their packaging and then denatured. Wherever practical, denaturing kits should be used. Where alternative methods are used, e.g. for large volumes of liquids, these should protect the environment and workers who might be affected by this activity.

A Standard Operating Procedure (SOP) for Destruction of Schedule 2 Controlled Drugs observed by an Authorised Witness is available from your local NHS Controlled Drug Team

Specific information on denaturing kits is also available from a range of manufacturers.

Scottish Environment Protection Agency (SEPA) Regulations and Permissions on Waste

The destruction and disposal of medicines are subject to The Waste Management Licensing (Scotland) Regulations 2011.

The Scottish Environmental Protection Agency (SEPA) defines the destruction of CDs in a

pharmacy as a low risk activity and does not expect pharmacies to obtain a waste management licence. This exemption has been applied to all pharmacies via a letter from the Chief Pharmacist. SEPA may amend or revoke this position at any time and will continue enforcement in all circumstances where activity has or is likely to cause pollution or harm to health.

Section 39 of schedule 1, The Waste Management Licensing (Scotland) Regulations 2011 allows pharmacies to accept a range of waste including CDs from individuals, households and care services, (including all care homes irrespective of whether or not they employ nurses). This waste must not be stored for more than 3 months. 'Care Services' for the purposes on the above Regulations has the same meaning as in section 2 of the Public Services Reform (Scotland) Act 2010.

For further information on Waste Management Regulation visit the SEPA website

Additional information regarding NHS Board waste management responsibilities is available http://www.hfs.scot.nhs.uk Scottish Health Technical Note 3 Part B – NHS Scotland Waste Management Guidance Waste management Policy Template.

Good Practice (destruction of CDs)

- When Schedule 2 CDs plus temazepam, flunitrazepam, buprenorphine and diethylpropion pass their expiry date, they must be stored in the CD cabinet/safe until destruction. They should be segregated and clearly marked as 'date-expired' stock to prevent them being issued in error to patients.
- When signing the CDR, it is good practice for the authorised person to state their authority, e.g. Health Board Authorised Witness
- When a CD is returned to a community pharmacy from a ship/offshore installation it must be entered into the CD register. They must be stored in the CD cabinet/safe , segregated from pharmacy stock and clearly marked as 'ship return for destruction' to prevent them being issued in error to patients until destroyed in the presence of an authorised witness
- When a CD is returned to a community pharmacy after a dispensing error it must be entered into the CD register. Stored in the CD cabinet, segregated until destroyed by an authorised witness – this should be treated as a stock CD (see section 10)
- GPs with out of date stock CDs should be advised to contact their CDAO/CD team to arrange appropriate witnessed destruction and record keeping.

Patient returned controlled drugs

'Patient returned' CDs are those that have been prescribed for and dispensed to a named patient, and then returned unused or part used for destruction. Pharmacies and dispensing practices will routinely deal with patient returns. Non-dispensing doctors should only accept patient returns in exceptional circumstances . They should encourage patients to return drugs they no longer require to their community pharmacy for appropriate destruction.

❖ Legal Framework

- Patient returned controlled drugs should be destroyed by the GP, pharmacist, or delegated member of staff . There is no legal requirement for 'patient returned' Schedule 2 to be destroyed in the presence of an authorised witness.(see section 9)

Good Practice (patient returned CDs)

- It is good practice to record the date of receipt of patient returned CDs and the date of destruction.
- The destruction should be witnessed by another member of staff (preferably by a registered health care professional).
- Both the person denaturing and the person witnessing should sign that destruction has taken place.
- These records should be retained for a period of at least seven years.

Section 12: Storage of Controlled Drugs

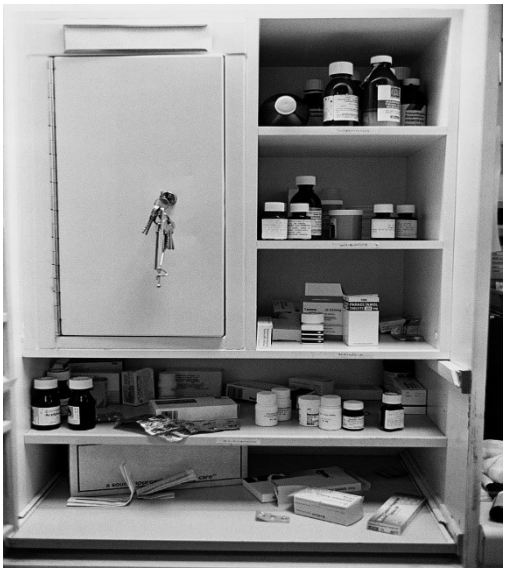
This section covers the legal and good practice issues for the storage of CDs. It does not cover any clinical or drug stability issues which should be addressed separately.

❖ Legal Framework

- The Misuse of Drugs (Safe Custody) Regulations 1973 imposes controls on the storage of Schedule 1, 2 and Schedule 3 CDs.

  The Regulations apply to all Schedule 2 CDs (except quinalbarbitone) and the Schedule 3 CDs buprenorphine, diethylpropion, flunitrazepam and temazepam.

  More recent Schedule 3 additions include tramadol, gabapentin and pregabalin. They are not subject to safe custody regulations.



- Pharmacies and care home services must comply with the requirements for safe custody. They must ensure that the relevant CDs are kept in a locked cabinet or room constructed and maintained in accordance with the Misuse of Drugs (Safe Custody) Regulations 1973. This requirement does not apply in respect of any CD which is under the direct personal supervision of a pharmacist, e.g. when dispensing a prescription.
- The specification with which cabinets and rooms must comply is given in great detail in the Regulations.
- The requirement for safe custody for CDs which must be kept in a CD cabinet until they can be denatured applies to stock CDs, patient returned CDs and out-of-date CDs
- The requirement for safe custody for CDs applies equally to CD prescriptions, including those dispensed in a compliance aid awaiting collection by the patient or their representative.
- Patient returned CDs and out of date stock must be kept segregated from in-date stock CDs and clearly marked as being out of date. This will minimise the risk of errors and inadvertent supply.

The Nursing and Midwifery council has worked closely with the Royal Pharmaceutical Society and their stakeholder partners to produce guidance for all healthcare professionals covering areas such as the storage, transportation and disposal of medicines: Professional Guidance on the Safe and Secure Handling of Medicines

Good Practice (storage of CDs)

- Nothing should be displayed on the outside of the cabinet to indicate that CDs are kept within the cabinet.
- The area where the CD cabinet is situated and the keys required for access should not be accessible to patients or service users. Responsibility and control of CD keys lies with responsible pharmacists at all times. This applies to alternate CD storage devices including robots and automatic methadone dispensing systems e.g. Methameasure®. If patients, workmen, drivers or others do have to enter the area where CDs are stored, they should be continuously supervised.
- One designated person within the premises should take overall responsibility for the keys / codes. The number of sets of keys to the cabinet, and who holds them, or who has access codes for digital key pads, must be known at all times by the designated person. The keys should always be kept separate from the cabinet and should never be accessible to unauthorised persons. The CD cabinet should only be opened by the designated person or by a person authorised by them, e.g. a locum. The designated person (responsible pharmacist) remains ultimately accountable for the management of the CDs.
- Other drugs that are liable to misuse can be locked in the CD cabinet if this is deemed appropriate by the relevant health care professional/CD team.
- Drugs in Schedules 4 and 5 can also be a target for substance misusers. Dispensary areas are required to be secure enough to prevent unauthorised access, but additional precautions, such as keeping these items out of sight of patients may be advisable.
- For CD stock held within any types of premises, the CDR should be stored safely outside the CD cabinet but near to it, however not easily visible or accessible.
- In other healthcare settings (including GP surgeries and out of hours (OOH)) the specifications of CD cabinets set out in the Safe Custody Regulations should be regarded as a minimum standard for the storage of CDs. This is a good practice requirement rather than a legal requirement.

Doctor's bag

❖ Legal Framework

- A doctor's bag is a locked bag, box or case for home visits, etc. which must be kept locked at all times except when in immediate use. The person in lawful possession of this bag or an individual authorised by them must always retain the keys.
- Legal precedent holds that such a doctor's bag is regarded, once locked, as a suitable receptacle for storing CDs.
- A locked car is not considered to be suitable for storing CDs.
- The CDs within a doctor's bag must be recorded in an associated controlled drug register – refer to section Section 9

Good Practice (storage of CDs – doctors bag)

- For a bag for home visits, etc. a digital combination lock on a case is often the most practical and convenient solution and avoids problems with keys.
- Bags containing CDs should not be left in a vehicle overnight or in a vehicle left unattended for long periods of time due to risks of theft and temperature fluctuation affecting drug stability.
- Many doctors only use the CD stock carried in their bag on rare occasions. The stock levels held in this bag should be kept to a minimum and informed by previous requirements.
- It is good practice for the doctor, or a delegated member of staff to undertake a monthly stock check of CDs held within each GP bag. This process also provides a good opportunity to check for out-of- date (or soon to expire) stock. This should be included in an SOP. Where possible such checks should be witnessed and records kept.
- To minimise the risk of confusion, error and inappropriate administration, it is normal practice that only one strength of each CD is kept in a doctor's bag
- When a doctors bag used for home visits containing CDs is in the practice it should be stored in a in a locked room away from patient areas. This location should be determined by carrying out a risk assessment.
- Oral preparations of CDs would not routinely be considered essential items to be carried in such a bag.

Care home and care services – refer also to section 16

Good Practice (storage of CDs in care homes and care services)

- If patients are self-administering medication, best practice is that they will be given their own lockable storage to keep their medicines in their room. If necessary they can also be provided with special storage elsewhere (e.g. in a fridge) that is secure and accessible to them.
- CDs are sometimes stored in care services which are not defined as 'care home services', for instance school care accommodation or after school clubs and day care.

  The Home Office has advised that in such situations the CDs need to be kept in a locked receptacle which can only be opened by authorised people.

Section 13: Transportation of Controlled Drugs

Transportation of Controlled Drugs

It is the responsibility of the patient to collect or arrange collection of their medicines from their community pharmacy or dispensing practice, see section 8.

❖ Legal Framework

- All healthcare professionals in legal possession of a CD have a professional duty to take all reasonable steps to maintain safe custody of that CD.
- Nurses, midwives, doctors, pharmacists, pharmacy staff and other healthcare professionals plus formal carers and patients' representatives are legally allowed to transport prescribed CDs to that patient. Any individual is also allowed to return CDs from the patient to the pharmacy or the dispensing practice for destruction. The person authorised to possess the CD may grant permission and this should be in writing.
- Although healthcare professionals should not routinely return CDs that are no longer required to a pharmacy on behalf of patients, there may be circumstances where this is considered appropriate, e.g. when there is a greater risk by leaving the CDs in the patient's home. It is recommended that this is documented in the patient's clinical record and preferably witnessed.

Transportation of controlled drugs by nurses and midwives

- Nurses and midwives may transport CDs in exceptional circumstances to a patient for whom the medicine has been prescribed, e.g. from a pharmacy to the patient's home. It is recommended that SOPs should also be developed locally to cover this activity. The community pharmacy will record the details of any health care professional collecting CDs on behalf of a patient in the CD register.

Good Practice (transportation of CDs)

- Healthcare professionals involved in the delivery of patient care should not routinely transport CDs to and from a patient's home. Where this is essential, part of an organised service, or where pharmacies operate collection and delivery schemes, it is good practice to keep the CDs out of view during transit.
- Prescription forms for Schedule 2 CDs should not routinely be sent to the patient's pharmacy via the postal system. A healthcare professional, a member of their staff, the patient or their representative should collect them from the surgery.
- CDs should not generally be transported via mail, taxi services or equivalent other than in urgent clinical need. Where the mail route is used, the CD should always be sent as a special delivery item to ensure the pathway is auditable. Controlled drugs must not be posted outside of the UK.

Good Practice (transportation of CDs cont.)

- If CDs or CD prescriptions need to be transported via mail, taxi services or equivalent a SOP should be developed which reflects a risk management assessment.
- If a messenger is sent to a community pharmacy to collect the CD on behalf of a practice they must carry a bearer's note signed and dated by the prescriber, stating that they are authorised to collect the CD. Any bearer's note should be retained by the pharmacy for a minimum of two years.
- Nurses and midwives should not routinely transport CDs. This should only be undertaken in circumstances where there is no other reasonable mechanism available.

Section 14: Nurses and Midwives Working in the Community

Administration

❖ Legal Framework

- Nurses may administer CDs to a patient in their care as long as they are acting in accordance:
  - with the directions of a doctor or dentist
  - with the directions of a non-medical supplementary prescriber who is acting within the terms of a patient specific clinical management plan
  - with the directions of a non-medical independent prescriber

  The exception to this is that the administration of diamorphine, dipipanone or cocaine for the treatment of addiction can only be done on the direction of a suitably licensed doctor.
- Midwives are permitted to administer the following CDs to their patients acting on their own professional judgement: diamorphine; morphine; pentazocine and pethidine
- A nurse/midwife who administers a CD must record the following in the relevant clinical notes and CD register: name of CD; dose of CD; method of administration; date of administration and the name of the person who administered the CD.
- When a community nurse administers CDs to a person who lives in or is attending a care service, details of the administration should also be recorded in the care service's personal plan.
- Many care home services, including respite services and children's care homes, take responsibility for the storage of CDs. Any CDs in the 'possession' of the care home service need to be recorded appropriately in a CD register and stored securely. This includes CDs that are stored in the care home but are administered by members of the primary care team, for example community nurses and GPs. Refer to section 16 for further information.
- Guidance on handling and administering CDs for nurses and midwives can be accessed at :

  Royal Pharmaceutical Society: Safe and secure Handling of Medicines

  RPS and RCN: Professional Standards in Administering Medicines in Healthcare Settings.

Transportation of CDs by nurses and midwives

Please refer to section 13

Good Practice (CDs no longer required)

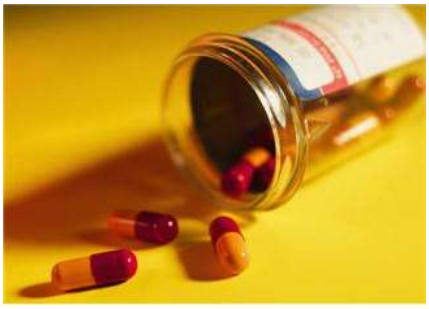
Prescribed drugs including CDs are the property of the patient and remain so even after death. It is illegal to possess CDs that have not been prescribed for you.

- In the first instance the patient and patient's relatives should be advised that all CDs no longer required should be returned to a pharmacy for safe destruction.
- The community nurse/midwife is not normally responsible for the safe disposal of unwanted CDs in the community. However, there may be occasions when it is appropriate for healthcare professionals to take CDs to a local community pharmacy for safe destruction.
  It is recommended that this is documented in the patient's notes and preferably witnessed.

Section 15: Palliative Care

Overview

Palliative care has been described as the active total care of patients whose disease is not responsive to curative treatment. Prescribing and supply of CDs can take place across a number of care settings. It is important that robust governance systems are maintained while at the same time ensuring that patients have appropriate access to medicines.



Good Practice (palliative care)

- It is good practice to only prescribe quantities of CDs that are needed by the patient for effective symptom control. This can include CDs for regular dosage, plus, a quick-acting CD at an appropriate dose for breakthrough pain. The good practice principles for managing CDs described earlier in these guidelines apply equally to the palliative care situation. Refer to section 7.
- Where prescribers are prescribing high doses of CDs or unusual/ unfamiliar CDs, it is recommended that the specialist palliative care team are contacted for advice and support wherever feasible. Any actions resulting from such a contact should be recorded in the patient's notes.
- To aid the interpretation of prescribing data the Prescribing Advisor or Controlled Drugs Accountable Officer should be notified of any patient who is prescribed high doses of CDs, particularly where prolonged use is expected.
- Palliative care patients may obtain CD prescriptions from several sources including GPs, hospices, hospitals, out-of-hours services and specialist palliative care teams. To ensure patient and public safety a professional in the locality should coordinate this to avoid an oversupply of CDs being prescribed to the patient.
- Additional sources of information include:

  Guidance for doctors, nurses and pharmacists caring for people in the last days of life: Scottish Palliative Care Guidelines

  Gold Standards Framework

  Scottish Partnership for Palliative Care

  Palliative Care Formulary (accessed via Medicines Complete)

Out-of- hours palliative care

Good Practice (out of hours palliative care)

To ensure problems are not encountered with the availability of medicines and to maintain effective symptom control during the out-of-hours period:

- Sufficient quantities of appropriate palliative care medicines, including CDs should be available in the patient's house with a completed administration chart, to anticipate deterioration in the patient's condition.
- Supply of palliative medicines should be documented in electronic care summary to ensure out of hours staff have access to this information.

Anticipatory care and the use of 'Just in Case Boxes'

'Just in case' boxes support anticipatory prescribing and access to palliative care medicines for patients at the end of life
Adequate quantities of the appropriate medicines (including CDs) are prescribed for the patient and ideally stored in an identifiable container - the 'just in case box' - in the patient's home or care home. Some areas have an orange 'Just in Case Bag' scheme or similar. This is intended to prevent unnecessary delays in symptom management especially out of hours and at weekends.

The individual needs of each patient are assessed, and the GP will issue a prescription/GP10 for the appropriate medication and a corresponding prescription chart. If symptoms develop the nurse can administer the appropriate drugs as prescribed and as clinically indicated.

National and local guidance regarding 'just in case' boxes should be followed, noting the following points:

- Generic 'Just in case' boxes are not allowed, as the medicines must be prescribed for an individual patient following assessment. They must not be retained or used for any other patient, unless following locally approved repurposing of medicines in care homes policy.
- 'Just in Case' medicines should be reviewed regularly to ensure medicine and dose are still appropriate.
- At the end of the period of care the patient's relative or care service staff must return the drugs to the community pharmacy or dispensing practice for safe disposal: Palliative Care Guidelines
- The potential needs of the patient due to deteriorating condition needs to be balanced with the safety of increased quantities of CDs left in the domiciliary or care setting. A risk assessment should be completed to ensure it is safe and appropriate to store CD's in individual patients' homes and alternatives considered to ensure medicines can be accessed timeously if this is not appropriate.

Section 16: Care Home Services

❖ Legal Framework

- In Scotland 'a care home service' is defined in the Public Services Reform (Scotland) Act 2010. There is no legal difference between residential and nursing homes.
- Two new improvement and scrutiny organisations were formed on 1st April 2011 by the Public Sector Reform (Scotland) Act 2010:
    1. Healthcare Improvement Scotland scrutinises healthcare services to provide public assurance about the quality and safety of that care.
    2. The Care Inspectorate is responsible for the scrutiny of social work and social care services.
- Although this section primarily applies to registered care homes some of the good practice can apply to other social care environments (e.g. school care accommodation). Advice can be sought from the Care Inspectorate about specific care service types.
- Scottish Statutory Instrument 210 – The Social Care and Social Work Improvement Scotland (Requirements to Care Services) Regulations 2011 requires registered providers to make proper provision for the health and welfare of service users.

The Care Inspectorate also defines which records registered care services must keep. This includes details of medication records.

- Scottish care homes have been brought within the remit of the amended regulations Controlled Drugs (Supervision of Management and Use) Regulations 2013

- In monitoring a care homes activity, the Care Inspectorate (CI) has been designated as a "responsible body" under the terms of the Regulations

  The consequences of including Scottish care homes within the 2013 Regulations are:

    - The manager or other person responsible for running the care home, and their workers who are engaged in relevant activities, are now "relevant persons" to the Health Board in whose area they are located. This means that they become people whose activities could be monitored by the Health Board CDAO as part of the Local Intelligence Network (LIN)
    - To assist Health Boards with this increased role, the CI in Scotland has been appointed as a "responsible body" (that is, a body who is entitled to participate in LIN's and other information sharing with responsible bodies)
    - The CI has also been included in the list of bodies that a CDAO could ask to undertake inspections relating to the management of CDs in the services it regulates

- The CI has powers to ask for self-declarations about how care homes manage and use controlled drugs at their care home premises
- Care Providers must notify the Care Inspectorate of any adverse events and/or concerns involving schedule 2, 3, 4 and 5 controlled drugs used in care settings, when they occur, and while the service user is receiving care in the care service
- Where appropriate the Care Inspectorate can share information with local CDAO/CD team

The Health and Social Care Standards expect care services to ensure high quality care and support based on relevant evidence, guidance and best practice.

Supply

The usual method of supply is a prescription for individual residents.

The Human Medicine Regulations 2012 permits a care home service to purchase and use stocks of prescription only medicine (POM) medicines in pursuant to an arrangement with an NHS Authority.

- In the context of the Misuse of Drugs Regulations 2001, a care home service requires a licence from the Home Office to possess stock of Schedule 2 CDs unless the care home is wholly or mainly maintained by a public authority out of public funds, by a charity or by voluntary subscriptions. This may be the case in some care homes and drug and alcohol rehabilitation units.
- A Home Office licence must be obtained for each type of Schedule 2 CD held as stock. A supply can be obtained via a requisition supplied by a person (or acting person) in charge of a care home, signed by a doctor or dentist who works there. The requisition must comply with the usual requisition requirements.

Receipt, Storage and Recording

❖ Legal Framework

- The Misuse Of Drugs And Misuse Of Drugs (Safe Custody) (Amendment) Regulations 2007 amended the MDRs 2001 to replace the term ‘nursing home’ with the term ‘care home’. This administrative change has rendered the term ‘nursing home’ obsolete.
- Since August 2007 it has been a legal requirement for all care home services in Scotland (including children’s services) to store any CDs in their possession which are subject to safe custody requirements (all schedule 2 and some schedule 3), in a cabinet which complies with the Misuse of Drugs (Safe Custody) Regulations. Temazepam is a Schedule 3 CD which requires storage in a CD cabinet. The special storage requirements also apply to these CDs when supplied in a monitored dosage system or compliance aid.

- The safe custody Regulations specify the quality, construction, method of fixing, and lock and key for the cupboard. The cupboard should be made of metal with suitable hinges and fixed to a wall or to the floor with rag bolts (expanding bolts) which are not accessible from outside the cabinet. The cabinet does not necessarily have to be a cupboard within a cupboard, or have a red light on the outside. Care home services should retain the specification details of the fitting of any cupboard as evidence that it complies with the Regulations.
- Some care home residents are responsible for storing and administering their own medication (as they would in their own home) and do not need to keep their medicines in a CD cabinet. For residents who are self-medicating, all of their medicines should be kept in their own lockable storage in their room. This also applies to any monitored dosage systems containing CDs.
- The Care Inspectorate defines which records registered care services must keep. Where a home manages medicines for a resident it is expected the home keep accurate and up-to-date records of all the medicines that have been ordered, taken or not taken, and disposed of.
- Schedule 2 controlled drugs brought into the care home by a patient/relative/carer or healthcare professional, and held by the home, should be recorded by the home in the CD record book/register. There should also be a record of transaction in the CD register where CDs are handed back over from the home to a patient/relative/carer or healthcare professional. Where an external healthcare professional like a community nurse subsequently administers that medicine to a care home resident *the home* should ensure a note of this is made on the Medicine Administration Recording chart to ensure a consistent record in the home of medicines given.

Good Practice (receipt, storage and recording)

- All care homes should keep a record of a resident's CDs in addition to the records maintained on the medicine administration and record (MAR) charts. This would normally be in a CDR (see section 9).
- The care home does not need to keep a record in the CDR when the person is wholly independent and is responsible for requesting a prescription and collecting the CDs personally from the pharmacy.
- If the person does not arrange the supply and collection of CDs but relies on the care workers to do so, the receipt from the pharmacy, the supply to the person and any subsequent disposal of unwanted CDs should be recorded in the CDR
- The CDR should be used to record the receipt, administration and disposal of CDs held in the care home.
- The CDR should contain a separate page for each drug for each resident. The name, dose and strength of the drug should be written clearly at the top of the page. A column for recording running balances should be on each page to maintain effective control and identify any discrepancies relating to the use of CDs.
- On receipt of the CD, the date, quantity and source of the CD should be entered into the CDR and initialled by the member of staff and witnessed by a second member of staff. The correct balance should be verified at each transaction.
- For residents who are self-administering each individual dose taken does not need to be recorded in the CDR.
- When transferring the drug record to a new page in the CDR, the amount remaining should be identified with *'brought forward from page x'* written clearly on the new page. Similarly, any balance brought forward from an old CDR to a new CDR should be checked by a second member of staff.
- It is good practice to keep CDRs for longer than the mandatory two years, as cases often come to court at a much later date, by which time the records would have been destroyed.
- The CDR must include details of CDs returned to the supplier or pharmacy for disposal.

Good Practice (administration of CDs)		
• In most care home services the only document signed by a GP or prescriber is the NHS prescription form. They do not sign a prescription sheet or record held by the care home. The NHS prescription serves two purposes. It authorises the pharmacist to supply the medicine and authorises the care staff to administer the medicine. • Where care home staff order and administer CDs it is recommended that they see the signed prescription if possible. They may also want to keep a copy (paper or electronic) of the prescription as evidence that, at the time of administration there was a current prescription in existence.	• The information on the medication administration and recording (MAR) sheet should be checked against the medication ordered/NHS prescription, irrespective of whether the MAR is produced by the care home or provided by the community pharmacy. • Staff administering medicines should do so in full accordance with the prescriber's instructions. • Before administering the medicine the care worker should measure and check the dose with another appropriately member of staff acting as a witness. • Only those with authorised access should hold keys to the CD cupboard. It is good practice to have the CD key separate from other keys. If non clinical staff or users of the service have to enter the area where CDs are stored, they should be continuously supervised.	• In the correct section of the CDR for the patient and CD the dose and the time of administration should be recorded. The care worker should initial, witnessed/initialled by another member of staff, the entry after verifying the balance on the CDR is correct. Once the care worker(s) have witnessed the resident taking the medication, the resident's medicine administration chart (MAR) can be updated. The administration process should be fully completed for each resident before moving on to the next resident • CDs should be administered by appropriately trained care home staff. The administration should be witnessed by another appropriate member of staff. In some situations the resident may be able to verify and record that they have been given the CD.

Disposal of Controlled Drugs in Care Homes

Good Practice (disposal of CDs in Care Homes)

- Community pharmacists in Scotland can accept waste medicines including CDs from **all** types of registered care services.
- CDs should be returned to community pharmacy or dispensing practice at the earliest appropriate opportunity for destruction. This includes CDs that are prescribed to a specific resident which have passed their expiry date; prescriptions that are no longer required or if the resident has died
- Even when still in date, CDs no longer required must not be used for other residents unless under repurposing guidance during a declared pandemic.
- Care homes should record the form and quantity of all unused returned CDs. The details of CDs for disposal should be entered into the CDR and signed by the care worker returning the drug.
- The pharmacist/dispensing doctor should sign for the returned CDs on receipt or on collection.
- Used or spoiled medicines should be returned in a way which ensures that any pharmacy or waste contractor is protected from any safety, contamination or infection control issues. This may include the use of a container for waste medicines.
- As CD patches, e.g. fentanyl patches, still contain quantities of the drug when they are removed from patients they should be folded in half following removal to render the contents irretrievable. Care homes should make arrangements with a local community pharmacy for the safe disposal of used fentanyl patches. Contact your local CDAO or CD team for advice.

Dealing with Discrepancies

Checks of CD balances in the register should be made at each transaction for that medicine (for example a fentanyl patch for a resident may be checked every three days). In addition, routine checks of *all* CDs held and their recorded running balances should be carried out by two members of staff on a regular basis (e.g. weekly, fortnightly or monthly, as appropriate to the needs of that service) and a record kept.

Where a discrepancy is found with any CD (schedule 2-5) it should be reported immediately to the manager who should investigate the discrepancy promptly. Advice can be obtained from the Care Inspectorate if needed at this point.

If the discrepancy is an error in the subtraction or addition in the calculation of the stock balance do not change the balance column or use correction fluid.
The following details should be entered under the last entry.

- the date
- the error in subtraction/addition (indicated with an asterisk)
- the correct balance
- the signature of the member of staff and the witnessing member of staff.

In care homes where a dose is given, but the administering care worker fails to complete the CDR at the time of administration, the following details should be recorded under the last entry:

- the current day's date
- the 'dose administered but not recorded at the time' followed by the resident details
- the correct balance
- the signature of the administering care worker and that of a witness

If neither of the above discrepancies can be identified, the pharmacist who supplied the medicines to the care home should be contacted to establish whether there were any unrecorded returns of CDs. If the pharmacist confirms that returned CDs have gone unrecorded, full details of these returns should be entered into the CDR. The signature of the person who returned the CDs, and that of the pharmacist who received them, should also be entered into the CDR. The correct date and the words 'entered in retrospect' should be added.

If the reason for the discrepancy cannot be found, and the CDs appear to have gone missing, then all relevant people, including the police, should be notified. The Care Inspectorate should be informed immediately through the electronic notification form for controlled drugs. The general notification form for incidents should not be used for CDs.

Section 17: Ambulance Services

❖ Legal Framework

- The Scottish Ambulance Service (SAS) is required to comply with the statutory requirements and guidance with respect to the management of Controlled Drugs (CD).
- The Controlled Drugs Accountable Officer (CDAO) for SAS is responsible for the safe procurement, storage, supply and destruction of any unused and/or expired controlled drugs. The CDAO is also responsible for ensuring effective governance arrangements are in place for the management of controlled drugs within the service.
- Paramedics may possess, supply or offer to supply diazepam and/or morphine sulfate injection (to a maximum strength of 20mg) and/or morphine sulfate oral for the purpose of administration for the immediate necessary treatment of sick or injured persons. [1]
- Registered Paramedics may also possess ketamine (limited to pre-hospital critical care paramedic role), midazolam, Schedule 4 (Part I) and Schedule 5 Controlled Drugs permitted under the Misuse of Drugs regulations and its amendments when administering or supplying medicines in accordance with a Patient Group Direction (PGD).[2]
- Privately employed paramedics are not under the jurisdiction of SAS, therefore these individuals will be responsible for sourcing and managing their own stocks of CDs and complying with legislation (see section 5).
- Registered Nurses working for SAS can also carry morphine sulfate (oral and injection), ketamine (limited to pre-hospital critical care nurse role), midazolam and Schedule 4 (Part I) and Schedule 5 Controlled Drugs permitted under the Misuse of Drugs regulations and its amendments when administering or supplying medicines in accordance with a Patient Group Direction (PGD).
- All storage and recording Regulations for CDs must be complied with (see section 9 & section 12).

[1] Group Authority issued under Regulations 8(3), 9(3) and 10(3) of the Misuse of Drugs Regulations 2001

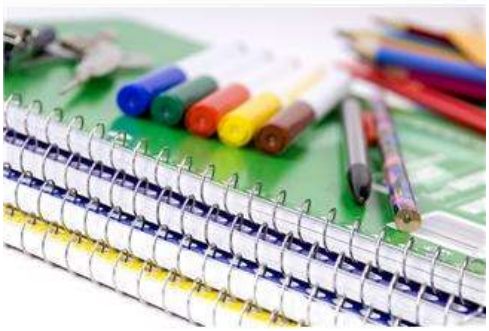
[2] Misuse of Drugs (Amendment No. 2) Regulations 2012

Section 18: Educational Establishments

The administration and safekeeping of CDs (e.g. methylphenidate) for individual pupils in educational establishments must be managed effectively.

Educational establishments should have a policy that is understood and accepted by staff, parents and pupils, to ensure the proper and safe administration of CDs.

Any policy should aim to minimise any risk of harm to staff and pupils while still allowing the pupils' medication requirements to be met.



Good Practice (educational establishments)

- All schools should have a medicines policy. It is the responsibility of the education authority to ensure that these are in place.
- The Scottish Government has produced "Supporting children and young people with healthcare needs in schools".
- Wherever possible, dosing regimens should be designed to allow medicines to be taken outside school hours. For some people, there may be valid clinical reasons for medicines being taken during school hours so arrangements need to be in place to allow this to happen.
- A CD, as with all medicines, should be returned to the parent/guardian for safe disposal when no longer required. If this is not possible the CD should be returned to a community pharmacy.
- CDs are sometimes stored in care services which are not defined as 'care home services' including:
  - school care accommodation
  - after school clubs
  - day-care.

  The Home Office has advised that these types of care services need to keep the CDs in a locked receptacle which can only be opened by authorised people.
- Records should be kept for audit and safety purposes.

Section 19: Overseas Travel and Patient from Overseas Requiring Controlled Drugs

❖ Legal Framework Controlled drugs: personal licences

- A personal licence is required by those people who carry more than three months' supply of CDs lawfully prescribed to them in their country of habitual residence and who plan to stay in the United Kingdom for three months or more. Similarly, people travelling overseas from the United Kingdom would normally have no more than three months' supply of CDs. Those who do would also need a licence
- The Home Office recommend that travellers carrying less than three months' supply of CDs obtain a letter from their prescribing doctor or drug worker confirming their name, travel itinerary, details of the prescribed medicines, dosages and total amounts of each drug being carried.
- People staying outside their resident country for a period exceeding three months are advised to register with a doctor as a temporary resident in the country they are visiting for the purpose of receiving further medicines.
- Licenses are normally issued with an expiry date of one week after the expected return to or departure from the UK. A personal licence has no legal standing outside the UK and is intended to allow travellers to pass through UK customs unhindered. More information can be found at: Personal licence application forms
- The application form for a personal licence should be completed and sent with a letter from the prescribing doctor, nurse or drug worker confirming the following details.
  - the patient's name, address and date of birth
  - country of destination (if travelling out of the UK) and countries being visited
  - dates of departure and return
  - details of the medicines(s) to be carried (name, form, strength and total quantity).

Patients from Overseas requiring Controlled Drugs

The Scottish Government has provided guidance Overseas visitor's liability to pay charges for NHS Care and Services April 2010 and reviews prescribing for this group of patients.

It is for GP practices to exercise their discretion whether to register an overseas visitor as a temporary resident or to treat them privately (including the provision of private prescriptions), They should take into account the terms of The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018 , as amended. GPs can only prescribe CDs privately using a PPCD form. GPs who do not routinely prescribe privately may not have access to these (refer section 7). Patients who require treatment with CDs may therefore need to be registered as temporary residents to allow provision of necessary treatment.

Good Practice (overseas travel)

- Patients should be advised to check with their airline and airport, in advance of travel, that they are permitted to carry the entire amount of medication in their hand luggage.

  Security arrangements may change at any time, e.g. restriction on volume of liquids.

- Other countries have their own import laws for prescription medicines and for CDs.

  It is recommended that travellers contact the relevant Embassy to check these requirements.

- The NHS accepts responsibility for supplying ongoing medication for temporary periods abroad of up to three months.
- Where a person is going to be abroad for more than three months then they are entitled to no more than a sufficient supply of regular medication to get to their destination and to find an alternative supply.
- The BMA have issued guidance around prescribing of all medicines for patients going abroad.

- CDs should be carried in their original packaging in hand luggage with a letter from the prescribing doctor confirming the following:
  - the carriers name, address and date of birth
  - the country being visited
  - outward and return dates of travel
  - drug details including dosages and total amounts.
- Controlled drugs cannot be posted outside of the UK.

Section 20: Out of Hours Services

❖ Legal Framework

- Out of hours (OOHs) services must ensure that they have SOPs in place to cover all aspects of the management of CDs and must cover the ordering, storage, recording and administration of CDs.
- The storage of CDs must be robust and only authorised individuals should have access. All CDs must be stored in a locked receptacle to comply with the legislation. Storage in cars for prolonged periods of time is not recommended as this is not considered a locked receptacle under law and may lead to problems with stability.
- A doctor's bag is a locked bag, box or case for home visits, etc. which should be kept locked at all times except when in immediate use. The person in lawful possession of this bag, or an individual authorised by them, must always retain the keys. Legal precedent holds that such a bag is regarded, once locked, as a suitable receptacle for storing CDs, but a locked car is not.

Good Practice (out of hours)

- When a bag which is used for home visits contains CDs is in the OOHs base, it should be stored in a safe place, in a locked room, away from patient areas. This location should be determined by carrying out a risk assessment.
- OOHs services should refer to the Safe Custody Regulations which specify the minimum specifications for cabinets and safes for the storage of CDs. This is a good practice requirement rather than a legal requirement.

- OOHs services including OOHs medical cover should confirm and agree arrangements for drug misusers who request a prescription for an opiate substitute such as methadone or buprenorphine with
  - local substance misuse prescribing services
  - shared care monitoring groups
  - and/or local drug action teams.

  It is generally inappropriate and potentially dangerous for OOH services to commence prescribing opiate substitution or to replace lost, stolen or broken supplies.

- A local SOP should be developed by OOHs in collaboration with local specialist prescribers to ensure that patients are treated fairly and consistently by OOHs services.

.

More information pertinent to out of hours services can be found elsewhere in this document:

- Ordering (section 5)
- Emergency Supply (section 7)
- Recording of CDs (section 9)
- Storage of CDs (section 12)
- Doctor's bags (section 9, section 12)
- Palliative care (section 15)
- Transportation of CDs (section 13)

Section 21: Patient Information

General Information

NHS Inform is Scotland's national health information service and is available online, via web chat or telephone. It provides details about local services, health rights and accurate information about health and wellbeing. There are also interactive tools such as a self-help guide for information about a range of common health conditions

Patients can contact NHS Inform online to chat to an advisor via webchat or by telephone on 0800 22 44 88.

If patients become ill when their GP surgery is closed, either through the night or at the weekend, and they can't wait until it reopens they can call NHS 24 free on 111. However if they think someone's life is in danger and need an ambulance they should always dial 999

Medicines Information

Members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand should visit www.nhs.uk/medicines/ and enter the name of the medication that they require information for.

Section 22: Controlled Drugs in Prisons

General Information

The legislation to transfer responsibility for primary healthcare services in prison from the Scottish Prison Service to NHS Boards received Royal Assent on 6th August 2010. The delivery of healthcare services in prisons transferred from the Scottish Prison Service (SPS) to the NHS in October 2011. The effect of the legal change means that prisoners became part of resident population of the NHS Board in which the prison is situated.

There are nine health boards in Scotland with prisons within their boundaries, including prisons providing special services.

Provision of Pharmacy Services including medicines supply and clinical input has been provided by external contractors through the NHS procurement process

Controlled Drugs Accountable Officers within the prison health board areas are now responsible for issues relating to the management of controlled drugs and must be informed of any incidents, issues or concerns.

Board Controlled Drugs Accountable Officers will provide advice and support and ensure that prison services have robust standard operating procedures (SOPs) in place regarding the safe management of controlled drugs.

The national “Guidance on the Safe Management of Controlled Drugs in the Scottish Prison Service Standard Operating Procedure” is a minimum standard. It is consolidated by local SOPs which govern the day to day to activities within the service.

HMP premises require a current Controlled Drug Domestic Licence issued by the Home Office

Stock Ordering

Schedule 2 and 3 CDs are ordered for stock using a specially designed requisition form (CDRF) which meets all of the legal requirements.

Storage of Controlled Drugs

All Controlled Drugs are stored securely in accordance with their licence in the Healthcare Centre. Schedule 2 and certain Schedule 3 drugs, stock must be stored in an approved Controlled Drug cabinet.

Prescribing and Administration

Prescribing for prisoners in custody is by Patient Administration Record (PAR) and for home leave on GP10 and HBP prescription. Medicines are provided to prisoners in a combination of “in possession” and under supervision. Controlled drugs used in the treatment of substance misuse and those liable to abuse or diversion are normally administered under supervision by NHS nurses.

Record Keeping

Complete records of all receipts, administrations and destructions for Schedule 2 Controlled Drugs are legally required. It is good practice in prisons to also keep records of all drugs in Schedules 3, 4 and 5

Destruction CD stock for destruction must be destroyed in the presence of an Authorised Witness.

Appendix 1 - Summary of Legal Requirements that apply to Controlled Drugs in Schedule 2, 3, 4 and 5 of the Misuse of Drugs Regulations

Schedule	Schedule 2	Schedule 3	Schedule 4 part I/part II	Schedule 5
Designation	CD POM	CD No Reg POM	CD benz/CD anab POM	CD Inv P or POM
Safe Custody	Yes, except quinalbarbitone	No, except buprenorphine, diethylpropion and temazepam	No	No
Prescription Requirements (including handwriting *)	Yes	Yes	No	No
Requisitions necessary	Yes	Yes	No	No
Records in CD register	Yes	No	No	No
Pharmacist to ascertain identity of individual collecting	Yes	No	No	No
Emergency supplies allowed	No	No; except phenobarbitone for epilepsy	Yes	Yes
Validity of prescription	28 days	28 days	28 days	6 months
Maximum duration allowed	30 days as good practice	30 days as good practice	30 days as good practice	
Private prescription requirements (PPCD Form)	Yes	Yes	No	No

⁎ Prescriptions for Schedule 2 and 3 CDs may be typed or computer generated but must be signed by the prescriber

Appendix 2 - Monitoring Controlled Drug Prescribing

PRISMS is the Prescribing Information System for Scotland. It is a web-based application giving access to prescribing information for all prescriptions dispensed in the community for the past five years.

The functionality required to query and analyse Controlled Drug prescribing has always been an integral element of PRISMS. Analysis can be undertaken at several levels including NHS board, CHP, GP practice and prescriber within organisational hierarchies. It can also provide sub-group analysis by prescription type (GP10, GP10A, HBP, PPCD, etc.), formulation (tablets, capsules, injection, etc), CD schedule, product strength and individual product. Analyses can be both snapshots in time or trends over time. The information is held centrally and is updated monthly.

PRISMS allows local users to develop and design reports for local use. However, a suite of standardised reports has been agreed and is available to all users across Scotland.

This data will not detect inappropriate, fraudulent or criminal behaviour because it is not linked to individual patients. The data is simply a means of identifying outliers from the norm. Controlled Drugs Accountable Officers should work with their prescribing adviser colleagues to use the suite of reports as part of their monitoring and management of CDs. This information, in conjunction with other sources of data and local knowledge, can be used to decide if further investigation is required.

PRISMS data is provided for a 60-month historical period only. It is therefore important that historical data is locally archived and stored securely because it may be required as evidence by other bodies.

Appendix 3 – Useful Contacts/Resources

Controlled drugs Accountable Officers' (CDAO) Network Scotland

The CDAO Network has a wide range of documents held on the Knowledge Hub Scotland, Welcome - Knowledge Hub (khub.net) These contain guidance and information relating to the management of CDs and should be referred to as an additional useful resource.

British Medical Association BMA House, Tavistock Square London WC1H 9JP	Website: Tel:	www.bma.org.uk 0207 387 4499
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Care Quality Commission	Tel: Website: Email:	03000 616161 www.cqc.org.uk enquiries@cqc.org.uk
Department of Health Richmond House 79 Whitehall London SW1A 2N	Website: Tel:	www.dh.gov.uk 0207 210 3000
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General Dental Council 37 Wimpole Street London, W1G 8DQ	Website: Tel:	www.gdc-uk.org **020 7167 6000**
General Medical Council Regent's Place 350 Euston Road, London NW1 3JN	Website: Tel:	www.gmc-uk.org 01619236602

General Pharmaceutical Council **General Pharmaceutical Council** **25 Canada Square** **London** **E14 5LQ**	Website: Tel:	http://www.pharmacyregulation.org/ 020 37138000
Healthcare Improvement Scotland Gyle Square, 1 S Gyle Cres, Edinburgh EH12 9EB,	Website: www.healthcareimprovementscotland.org/home.aspx Tel:	0131 623 4300
Home Office Drugs Licensing Branch 2 Marsham Street London SW1P 4DF	Website: Tel:	www.homeoffice.gov.uk 0207 035 4626 or 4646
Home Office Drugs Legislation and Enforcement Unit 2 Marsham Street London SW1P 4DF	Website: Tel:	www.homeoffice.gov.uk 0207 035 4626/0207035446
Health Improvement Scotland (HIS) **Gyle Square** **1 South Gyle Crescent** **Edinburgh** **EH12 9EB** **0131 623 4300**	E-mail:	his.online@nhs.scot
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NHS Scotland Counter Fraud Service 3 Bain Square Livingston EH54 7DQ	Website: Tel:	www.cfs.scot.nhs.uk 01851762017
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The Care Inspectorate Compass House 11 Riverside Drive Dundee DD1 4NY	Website: Tel: Care Inspectorate Enquiries: 0345 600 9527 Email:	www.careinspectorate.com 01382 207 100 enquiries@careinspectorate.gov.scot
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Appendix 4 - List of Abbreviations

BMA	British Medical Association
CPD	Continuing professional development
DH	Department of Health (England)
GPhC	General Pharmaceutical Council
HIS	Healthcare Improvement Scotland – will scrutinise healthcare services including private clinics, private hospitals and hospices
MHRA	Medicines and Healthcare products Regulatory Agency
NCAS	National Clinical Assessment Service
NMC	Nursing and Midwifery Council
NPA	National Pharmacy Association
PGDs	Patient group directions
PMR	Patient medication record — computer record containing personal patient details and medicines supplied to them
POMs	Prescription only medicines
PRISMS	Prescribing Information System for Scotland
PSD	Practitioner Services Division
RCGP	Royal College of General Practitioners
RPS	Royal Pharmaceutical Society
SOPs	Standard operating procedures

Appendix 5

- Glossary of Terms

Authorised Witness	The **authorised witness** is a person who is not involved in the day-to-day handling of **controlled drugs** who has been appointed by the CDAO to oversee the management and governance of activities related to **controlled drugs** including overseeing CD stock destruction.
British National Formulary (BNF)	A reference providing UK health care professionals with authoritative and practical information on the selection and clinical use of medicines
Care home	A home providing either residential and / or nursing care to residents
CBMP	Cannabis Based Medicinal Products
Controlled drugs (CDs)	Controlled drugs — drugs that are controlled under Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001
CDAO	Controlled drugs accountable officers (CDAOs) are responsible for all aspects of controlled drugs management within their organisation
CD register (CDR)	Legally compliant, bound register in which the movement of CDs into and out of the premises / doctor's bag is recorded
Dispensing doctors	Doctors who provide a dispensing service to some or all of their patients
Doctor's bag	A lockable bag containing medical equipment and medicines, occasionally including CDs, that doctors use for immediate treatment of their patients
Domiciliary visit	A visit made by a health care professional to a patient at home
Drug and Alcohol Unit	A unit set up to deal with the treatment of drug and/or alcohol misuse / dependence
Formal / home carer	A carer who is paid for the purpose
GP10	Prescription form used by General Practitioners in primary care within the NHS in Scotland
GP10N	Prescription form used by nurse prescribers
GP10P	Prescription form used by pharmacist prescribers

GP10A	Prescription form used by GP to order stocks of medicines, including CDs, for personal administration to patients
GPhC inspectors	Personnel employed by the GPhC to inspect registered pharmacies against standards and investigate issues.
Informal carer	A carer who is not employed for the purpose
Independent prescriber	A health care professional who has successfully undertaken the training required to become an independent prescriber to
JIC Box	These medicines often given by injection, are called '**just in case**' medicines and may be provided in a specially marked container called a '**just in case**' **box**. JIC prescribing includes the most important medicines which might be required to manage predictable and distressing symptoms, or in the event that the patient cannot manage necessary oral medications.
Local educational authorities	Council-owned authorities with a responsibility for education within their locality
MAR Chart	Medication Administration Record-MAR charts are the formal record of administration of medicine within the care setting These can also be used to review medication for the purposes of monthly ordering
NHS Boards	Organisation providing healthcare services in a geographical area within Scotland
Out-of-hours (OOH)	Healthcare services provided to patients during the period services such as GP practices are closed (evenings, weekends, bank holidays)
PAR	Patient Administration Record- The main tool used to direct and record administration of medicines in a hospital setting is the PAR
Patient information leaflets (PILs)	Information leaflets which by law, must be supplied with medicines, which give information to patients about aspects of the medicine including side effects, storage, dosing, etc
Patient-returned CDs	CDs that have been prescribed and dispensed to a named patient and then returned unused or part-used
Practice stock	Stock of drugs held centrally within a practice to which all partners in the practice have access and can use
Prescribing number	The unique identifier allocated to the prescriber when they become registered as such by their NHS Board.

Professional registration number	The number allocated to the professional upon registration with their professional body
Private prescribers	Professionals who prescribe medication outside of the NHS
Running balance	The total quantity at any point in time, of any particular CD that is deemed to be held at the premises
The Care Inspectorate	Social Care and Social Work Improvement Scotland – will scrutinise social work and social care services e.g. care homes, including child protection and children's services
Supplementary prescriber	A health care professional who has successfully undertaken the training required to become a supplementary prescriber to provide continuing care to patients
Syringe driver/syringe pump	A mechanism by which medication is administered to patients over a prolonged period, normally subcutaneous delivery over 24 hours

Appendix 6 - Acknowledgements

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Royal Pharmaceutical Society