



Department of
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and Public Safety**
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Safer Management of Controlled Drugs

*A guide to good practice in primary care
(Northern Ireland)*

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A guide to good practice in primary care (Northern Ireland)

Foreword



There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the management and use of controlled drugs. These changes include the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 which came into operation on 1 October 2009 and have resulted in the appointment of Accountable Officers (AO) who are responsible for securing the safe management and use of controlled drugs for their organisation(s)

In implementing better controls which support professionals and encourage good practice we must ensure that patients have appropriate and convenient access to controlled drugs to meet their clinical needs.

This document has been developed for primary care in Northern Ireland and is designed to provide guidance on good practice for the management of controlled drugs. It seeks to take account of the important legislative changes and developments in professional practice and accountability.

In commending this guidance to primary care organisations I wish to acknowledge the multidisciplinary input and the extent and quality of the responses to the consultative draft. The application of this guidance will, I believe, make a significant contribution to improving governance and patient safety.

A handwritten signature in black ink, appearing to read 'Norman C Morrow'. The signature is written in a cursive style with a large initial 'N'.

Norman C Morrow

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Section 1

Introduction

Purpose of Safer Management of Controlled Drugs – A Guide to Good Practice in Primary Care (Northern Ireland)

The purpose of this guide is to promote the safe management and use of controlled drugs in healthcare organisations providing primary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government's response to the Fourth Report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in primary care settings and will support primary care providers in the management of controlled drugs. The Pharmaceutical Advice and Services Branch within the Department of Health, Social Services and Public Services (DHSSPS) has taken responsibility for producing this guide, acknowledging the National Prescribing Centre for its permission to adapt "A guide to good practice in the management of controlled drugs in primary care (England) 3rd edition 2009".

The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in "Improving Patient Safety Building Public Confidence"

www.dhsspsni.gov.uk/improving_patient_safety_building_public_confidence.pdf, and included a substantial programme of work to improve the management of controlled drugs. As a result, a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002. The Health Act, which received royal assent in July 2006, enabled

Regulations to be laid relating to governance and monitoring of controlled drugs which came into operation in Northern Ireland on 1 October 2009. These changes are reflected within this guidance.

This guide aims to identify robust systems for obtaining, storing, supplying, recording, monitoring and disposing safely of controlled drugs, while at the same time helping to ensure appropriate and convenient access for those patients who require them. It does not advise on the clinical choice and application of controlled drugs, rather the focus is directed towards defining processes for their appropriate and safe use once selected.

The guide is aimed primarily at developing good practice for the management of controlled drugs in primary care, but also encompasses issues raised at the interfaces between primary, secondary and social care. The DHSSPS has also published a guide to good practice in secondary care, which is available on its website.

<http://www.dhsspsni.gov.uk/safer-management-cda-2009.pdf>

This guidance also reflects the recent changes that have taken place to update working practices: the developing roles of healthcare professionals and the need to optimise skill mix. It describes how these changes work within the existing legal framework for controlled drugs.

Key Audiences

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

- GP and dental practices
- Pharmacies
- Midwifery services
- Out of Hours services
- Patient's own homes
- Registered homes
- Community nursing services
- Community palliative care services
- Substance misuse services
- Hospices
- Prison services
- Ambulance services/paramedics
- Intermediate care services

The emphasis within this document is predominantly on the roles and responsibilities of health care professionals commonly involved in the management of controlled drugs, especially in primary care. The development and use of standard operating procedures (SOPs) are an important means of enshrining good practice into everyday health care activities.

How to use this guide

Each of the main sections of this guide has been formatted, where appropriate, into two categories. The first identifies and clarifies current key legal and regulatory frameworks and the second provides good practice recommendations within these frameworks. Planned regulatory and other changes are also highlighted.

Whilst every care has been taken to ensure the accuracy of this guide, DHSSPS cannot accept liability for any errors or omissions. The contents of the guide will be updated over time to reflect proposed and potential legislative / regulatory changes under consideration. Therefore, individuals looking for guidance and support should ensure they refer to the most recent edition of the guide, plus any other national guidance, legislation and directions, which may have been published.

Additional resources

Accountable Officer website

<http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm>

The DHSSPS has developed a website to support Accountable Officers (AOs), Responsible Bodies and healthcare professionals in the safe management and use of controlled drugs. The website contains resources and information which should be of value to all those involved in the management and prescribing of controlled drugs. The website also contains a section dealing with frequently asked questions (FAQs).

Section 1

Key websites

NPC Controlled drugs website
www.npci.org.uk/cd

Care Quality Commission (CQC)
www.cqc.org.uk

The Department of Health (DH) (England)
www.dh.gov.uk/controlleddrugs

Home Office
www.drugs.homeoffice.gov.uk

National Patient Safety Agency (NPSA)
www.npsa.nhs.uk

National Treatment Agency for Substance Misuse (NTA)
www.nta.nhs.uk

Pharmaceutical Society of Northern Ireland
www.psni.org.uk

General Pharmaceutical Council (GPhC)
www.pharmacyregulation.org

Introduction

Guidance

British National Formulary
www.bnf.org/bnf/

The British Pain Society: Pain and substance misuse: improving the patient experience. Recommended guidelines for pain management programmes for adults
www.britishpainsociety.org

Joint Royal Colleges Ambulance Liaison Committee: Clinical Practice Guidelines
www.jrcalc.org.uk/guidelines.html

NICE: Drug misuse - methadone and buprenorphine
www.nice.org.uk/Guidance/TA114

NPSA: Reducing dosing errors with opioid medicines
<http://www.nrls.npsa.nhs.uk/resources/?entryd45=59888>

NPSA: Ensuring safer practice with higher dose ampoules of morphine and diamorphine
<http://www.nrls.npsa.nhs.uk/resources/?entryd45=59803>

NPSA: Patient safety alert - safer practice with epidural injections and infusions
<http://www.nrls.npsa.nhs.uk/resources/?entryd45=59807>

National Treatment Agency: Drug Misuse and Dependence UK guidelines on clinical management is produced by the Departments of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive
www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf

Royal College of General Practitioners (RCGP) runs training programmes specifically for the management of substance misusers
www.rcgp.org.uk

Section 2

Legislation

Misuse of drugs legislation

The overall legislative framework, which applies to all medicines, is the Medicines Act 1968 (the Act) and its associated legislation - principally the Prescription Only Medicines (Human Use) Order 1997. Controlled drugs are additionally defined and governed by the Misuse of Drugs Act 1971 (MDA) and associated regulations - principally the Misuse of Drugs Regulations (Northern Ireland) 2002 (MDR), the Health Act 2006 and its associated regulations - principally the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, which set out the requirements for the governance and monitoring of controlled drugs.

A list of drugs controlled under misuse of drugs legislation, showing each drug's classifications under both the MDA 1971 and the MDR, can be found on the Home office website

www.homeoffice.gov.uk/drugs/licensing/domestic-licences/

Medicines Act 1968

The Medicines Act 1968 governs the manufacture and supply of medicines for human use. The Act divides medicines into three categories:

- Prescription-only medicines (POMs), which includes all schedule 2, 3 and 4 controlled drugs.
- Pharmacy medicines (P), which includes some Schedule 5 controlled drugs.

- General Sale List medicines (GSL). There are no controlled drugs in this category.

Various pieces of secondary legislation have been made under the Act including the Prescription Only Medicines (Human Use) Order 1997 (POM Order), which details the requirements and exemptions for the prescribing, supply and administration of POMs.

Misuse of Drugs Act 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 or misuse. The drugs that are subject to the control of the Misuse of Drugs Act 1971 are listed in Schedule 2 of the MDA and are termed controlled drugs. The MDA establishes a series of criminal offences for their unauthorised, and therefore unlawful, supply, possession, possession with intent to supply, importation, exportation and production.

Drugs controlled under the Misuse of Drugs Act 1971 are divided into three classes – Classes A, B and C – for the purposes of establishing the maximum penalties that can be imposed in criminal law on persons convicted of any offences under the MDA. The class of a drug may reflect either its relative harm to the individual and/or to Society when misused, in a descending order of severity, from A - C. The maximum penalties for offences of possession and supply of the main controlled drugs within each class are outlined in Table 1 (summary provided by the Home Office).

Table 1: Possession and Supply of Controlled Drugs

Drug Class	Penalties for possession	Penalties for supply
Class A - diamorphine (Heroin), cocaine and crack cocaine, MDA/MDEA/MDMA (Ecstasy), lysergic acid diethylamide (LSD), methamphetamine, more potent opioid analgesics, e.g. methadone	Up to seven years imprisonment or an unlimited fine or both	Up to life imprisonment or an unlimited fine or both
Class B - amphetamine, barbiturates, cannabis, cannabis resin, cannabinal, methylphenidate, less potent opioid analgesics, e.g. codeine	Up to five years imprisonment or an unlimited fine or both	Up to 14 years imprisonment or an unlimited fine or both
Class C – buprenorphine, benzodiazepines (and zolpidem) ketamine, anabolic steroids, and gamma-hydroxybutyrate (GHB)	Up to two years imprisonment or an unlimited fine or both	Up to 14 years imprisonment or an unlimited fine or both
NB: Any Class B drug in an 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, cannabinal and its derivatives were reclassified from Class C to Class B on 26 January 2009.		

The Misuse of Drugs Regulations (Northern Ireland) 2002

The use of controlled drugs in medicine is permitted by the Misuse of Drugs Regulations. The current version of the Regulations, made under the MDA 1971, are the Misuse of Drugs Regulations (Northern Ireland) 2002, which came into operation on 1 February 2002. The Misuse of Drugs Regulations are periodically amended and revised and the MDR have been subject to a number of amendments. The most recent information can be found at the website of the Office for Public Sector Information www.opsi.gov.uk, which should be checked on a regular basis.

Details of these amendments can also be found on the DHSSPS website at the following link:

www.dhsspsni.gov.uk/index/pas/pas-lie/pas-medreg-legislation/pas-misusedrugs-ni-reg02.htm

The MDR divide controlled drugs into five Schedules, which dictate the degree to which a controlled drug's use is regulated. The Schedule in which a controlled drug is placed depends upon its medicinal or therapeutic benefit balanced against its harm when misused. Schedule 1 controlled drugs are subject to the highest level of control, whereas Schedule 5 controlled drugs are subject to a much lower level of control. A summary of legal requirements that apply to controlled drugs is included in Appendix 1 (page 98).

Schedule 1 (CD Licence)

Whilst virtually all drugs listed in Schedule 1 have no recognised medicinal use, Sativex® (Cannabis Sativa L.Extract) is an unlicensed medicine in the UK and is being used in the treatment of multiple sclerosis. Other Schedule 1 drugs include hallucinogenic drugs such as lysergide and mescaline.

Practitioners and pharmacists within Northern Ireland may not lawfully possess Schedule 1

drugs except under licence from the DHSSPS (in Northern Ireland) Exemptions exist where a person takes possession of a controlled drug for the purpose of destruction or for the purpose of handing over to a police officer.

Persons who are required to keep records in respect of controlled drugs in Schedule 1 may only destroy them in the presence of an authorised person (see page 69.)

Sativex®

Sativex®, a cannabis based product is currently being supplied in the United Kingdom on a named-patient basis under licence. Production, possession and supply of drugs in Schedule 1 is on a licensed basis only and is limited to research or other special purposes that are considered to be in the public interest. Sativex® was, however, granted a marketing authorisation in June 2010. As a result of this The Home Office is currently consulting on the rescheduling of this medicine. Sativex® will continue to be prescribed and dispensed under licence until there is a revision of the regulatory position.

An open general licence has been issued for Sativex® which allows pharmacists to dispense the product as an unlicensed medicine under certain conditions. There is no longer the requirement for a prescribing doctor or dispensing pharmacist to contact the DHSSPS in relation to obtaining a licence to prescribe or supply Sativex®.

Record-keeping requirements have been waived and therefore pharmacists do not need to record Sativex® in their controlled drug registers.

It is advised that, where a lockable refrigerator is available, Sativex® should be stored in it prior to supply. Otherwise it should be kept in a refrigerator not visible to the general public.

Prescription requirements still apply - prescriptions must be written in the same way as they are for Schedule 2 drugs with prescriptions including the dose, form, strength and total quantity of the preparation in both words and figures. Private prescriptions for Sativex® should be on the private form PCD1.

Schedule 2 (CD)

Schedule 2 includes drugs such as opiates, the major stimulants, secobarbital and amphetamine.

Schedule 2 controlled drugs are subject to full import and export control. They may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

Supply: Supply is restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess. Practitioners are restricted to supplying their patients. Pharmacies may supply on receipt of a valid prescription or signed order. A pharmacist may supply them to a patient only on the authority of a prescription in the required form (see page 44) issued by an appropriate prescriber. Additional prescription writing requirements exist.

Record: A register must be kept for Schedule 2 controlled drugs and this register must comply with the requirements of the MDR. Amendments to these Regulations came into operation on 1 February 2008 (see page 61).

Storage: Schedule 2 controlled drugs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973). They must be stored in a locked receptacle, such as an appropriate controlled drug cabinet or approved safe, which can only be opened by the person in lawful possession of the controlled drug or a person authorised by them.

Destruction: The destruction of Schedule 2 stock controlled drugs must only take place in the presence of an appropriately authorised person. (For further information on appropriately authorised persons, see page 69). Unused patient Schedule 2 controlled drugs should be returned to pharmacies for destruction and safe disposal. This destruction does not currently have to be witnessed by an authorised person, but good practice would deem that another person

witnesses it and a record of the destruction is made. (For further information on patient returns, see page 70).

Schedule 3 (CD No Register)

Schedule 3 contains a number of substances that are perceived as being liable to abuse, but less likely to be so than schedule 2 controlled drugs. It contains a number of synthetic opioids together with other substances including temazepam.

The majority of Schedule 3 controlled drugs are exempt from safe custody requirements (including Midazolam which was rescheduled on 1 January 2008 from Schedule 4) and may be stored with other medicines in the dispensary. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in accordance with the Safe Custody Regulations.

Schedule 3 controlled drugs are subject to full import and export control.

Midazolam is the only Schedule 3 controlled drug that, in certain circumstances, can be included in a Patient Group Direction (PGD).

Supply: The regulations concerning supply (and the additional prescription writing requirements (with the exception of temazepam)) are similar to Schedule 2 controlled drugs.

Record: There is no legal requirement to record transactions involving Schedule 3 controlled drugs in a CD register. Each private supply must, however, be recorded, in the 'Prescription Only Record' book. The requirements for an authorised witness to attend during the destruction of date expired stock does not apply unless the individual manufactures the controlled drugs. There is a legal requirement to retain invoices for 2 years.

Storage: While safe custody requirements apply, currently most drugs in this Schedule are exempted and can be stored on the open dispensary shelf. Currently the four

Section 2

Legislation

Schedule 3 that do require safe custody are temazepam, flunitrazepam, buprenorphine and diethylpropion which must be stored in a locked receptacle, such as an appropriate controlled drug cabinet or approved safe, which can only be opened by the person in lawful possession of the controlled drug or a person authorised by them.

Destruction: The requirements relating to destruction do not apply to Schedule 3 controlled drugs (only applying to importers, exporters and manufacturers). The Home Office has advised that Schedule 3 drugs should be destroyed / denatured before being placed into waste containers.

Schedule 4 (CD Benzodiazepines and CD Anabolic Steroids)

Schedule 4 is split into two parts.

Part I (CD Benzodiazepines) contains most of the benzodiazepines and other substances including zolpidem, fencamfamin and mesocarb.

Part II (CD Anabolic Steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with 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 by an individual of a drug from Schedule 4 Part 1 (CD Benzodiazepines) without the authority of a prescription in the required form is an offence. Possession by practitioners and pharmacists acting in their professional capacities is authorised.

Drugs in Part 1 (CD Benzodiazepines) are subject to full import and export control. A licence issued by DHSSPS (in Northern Ireland) or by the Home Office (Great Britain) 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 practitioners' prescriptions or in

accordance with Patient Group Directions (PGDs) but there are no additional requirements as to the form of prescription other than those that apply to all Prescription Only Medicines (POMs).

Record: There is no statutory requirement to record the supply of Schedule 4 controlled drugs in a CD register.

Storage: Schedule 4 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to destruction do not apply to Schedule 4 controlled drugs (only applying to importers, exporters and manufacturers). The Home Office has advised that Schedule 4 Part I controlled drugs should be destroyed / denatured before being placed into waste containers.

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain controlled drugs, e.g. codeine, pholcodine, morphine, which are exempt from full control when present in medicinal products in low strengths.

Supply: Some of the controlled drugs 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 of products. The Schedule 5 controlled drugs that are prescription only medicines (including codeine, dextropropoxyphene and dihydrocodeine tablets) 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 controlled drugs in a CD register. Invoices must be retained for a minimum of two years.

Storage: Schedule 5 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to destruction do not apply to Schedule 5 controlled drugs.

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 (the Safe Custody Regulations) impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

The Safe Custody Regulations specifically apply to the following premises:

- those occupied by a retail dealer for the purpose of his business
- any nursing home registered under the Health and Personal Social Services (Quality, Improvement and Regulation (Northern Ireland) Order 2003
- any private hospital within the meaning of the Mental Health (Northern Ireland) Order 1986

All Schedule 2 (except secobarbital) and some Schedule 3 controlled drugs (see page 14) must be stored securely in accordance with the Safe Custody Regulations. These Regulations state that such controlled drugs must be stored in a safe or cabinet locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts. Nothing should be displayed outside the safe or cabinet to indicate that drugs are kept inside it.

A safe with both a key lock and a time delay mechanism is installed in every community pharmacy in Northern Ireland.

The Misuse of Drugs (Notification of and Supply to Addicts) (Northern Ireland) Regulations 1973

These Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under a licence issued by DHSSPS. A licence is not required for the prescribing of these drugs for the treatment of organic disease or injury.

The Regulations also require any doctor who attends a person whom he considers or suspects of being addicted to any drug specified in the schedule to the Regulations to notify the Chief Medical Officer within seven days of the attendance.

Health Act 2006

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

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1 October 2009. These Regulations set out the requirements for certain healthcare bodies to appoint an Accountable Officer (AO) and describe the duties and responsibilities of AOs to secure the safe management and use of controlled drugs for their organisation. The Regulations also require bodies to co-operate with each other, including with regard to sharing information, relating to concerns about use and management of controlled drugs and set out arrangements for powers of entry and inspection.

Section 3

Governance, Inspections and Monitoring

Overview

New arrangements for controlled drugs have been established to encourage good practice in the management of controlled drugs as well as help detect unusual or poor clinical practice / systems, criminal activity or risk to patients. One of the guiding principles of the new arrangements was that they should not interfere with the appropriate use of controlled drugs and good clinical care. Another was that the safer governance principles should apply to all health and social care settings and individual practices where controlled drugs are prescribed, stored, administered or transported.

All HSC Trusts, the HSC Board and independent health and social care providers have a responsibility to assure the quality of their controlled drug management as an integral part of their clinical governance processes: controlled drug management being specifically identified for risk requirements. New requirements for collaboration and information sharing between all health and social care providers and relevant regulators and agencies have also been introduced. The DHSSPS has provided comprehensive guidance on these arrangements entitled 'A Guide to Strengthened Governance Arrangements in Northern Ireland' which can be found at the following link
<http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-guidance.htm>

Figure 1 (overleaf) summarises the agencies involved in the management and use of controlled drugs.

Health Act 2006

The Health Act 2006 provided for regulations to be laid down relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act is primary legislation and applies to the whole of the UK. The Key provisions of the Act are:

- All designated bodies such as HSC organisations and independent hospitals are required to appoint an AO
- A duty of collaboration placed on responsible bodies which include healthcare organisations, the DHSSPS, regulatory bodies, police and the Regulation and Quality Improvement Authority (RQIA) to share intelligence on controlled drugs issues
- A power of entry and inspection for the police and other nominated persons to enter premises to inspect stock and records of controlled drugs.

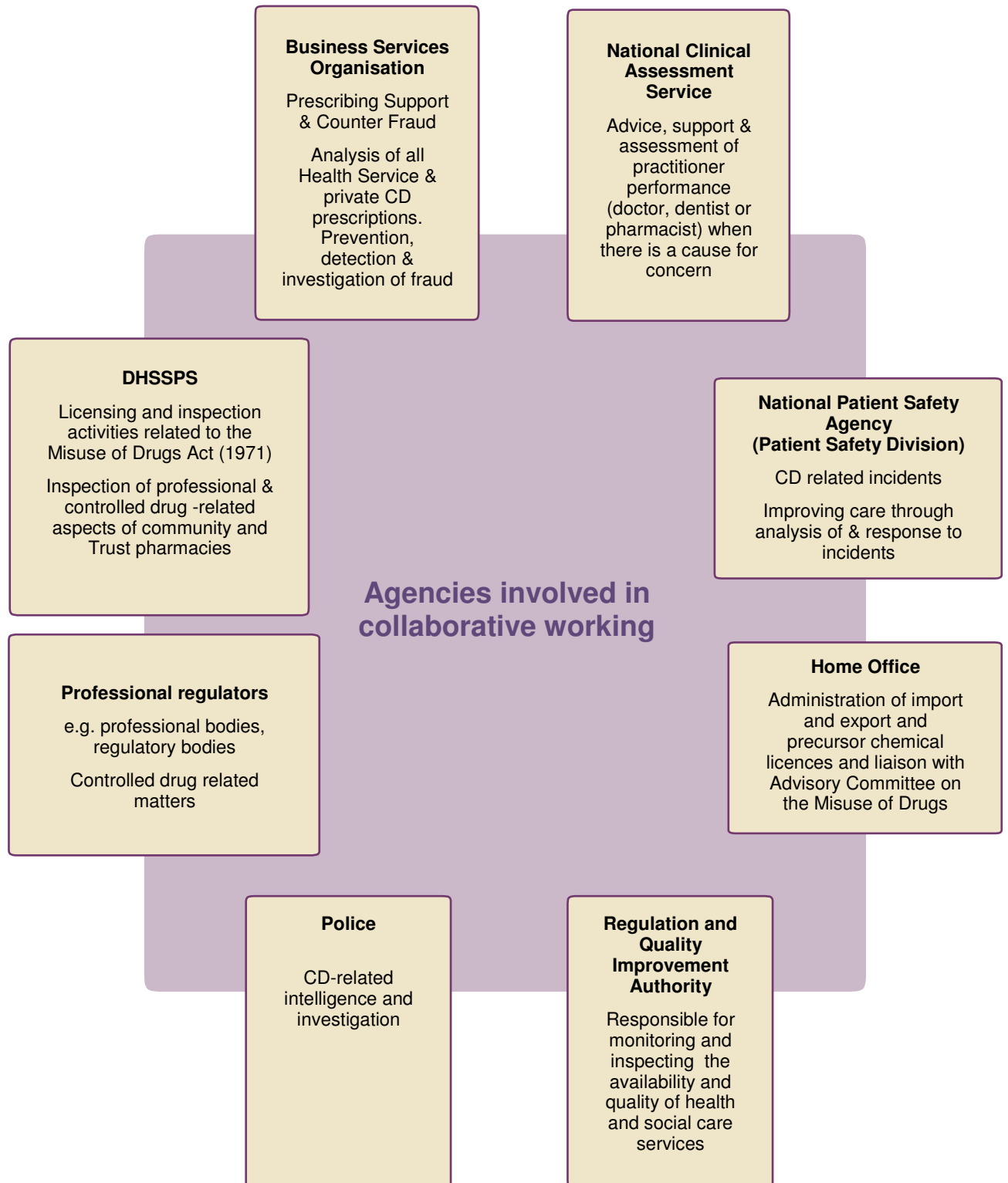
The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

These Regulations came into operation on 1 October 2009
http://www.opsi.gov.uk/sr/sr2009/nisr_20090225_en_1

A summary of the governance arrangements for specific sites is provided in Appendix 2.

Figure 1

Agencies involved in collaborative working



Implications of Regulations

Requirement to appoint an Accountable Officer

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 require that all designated bodies must appoint an AO. Organisations that are designated bodies but do not administer or hold controlled drugs are still required to appoint an AO, although their responsibilities will be reduced accordingly. In Northern Ireland the following are prescribed as designated bodies:

- the Board
- a HSC Trust
- Northern Ireland Ambulance Service (NIAS)
- an Independent hospital*

* Independent hospital means a hospital which is not vested in the DHSSPS or managed by a HSC trust and excludes dental practices.

Characteristics of an Accountable Officer

The Regulations specify who may be appointed as an AO. Irrespective of the designated body, the AO cannot be a person who routinely supplies, administers or disposes of controlled drugs as part of his duties. They must be a senior person in the organisation.

Notification of Accountable Officer

Designated bodies must notify the DHSSPS in writing of the nomination or appointment of their AO, and also the removal of an AO. A web form to make these notifications can be found on the following link

<http://www.dhsspsni.gov.uk/accountable-officer-nomination-form.pdf>

The DHSSPS is required to publish a list of AOs and this can be found at <http://www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf>

Responsibilities of Accountable Officers

The responsibilities of AOs are specified in the Regulations.

Responsibilities of all AOs:

- Ensure the safe and effective management and use of controlled drugs within their own organisation and by any body or person acting on behalf of or providing services to their organisation
- Establish and ensure appropriate arrangements to comply with misuse of drugs legislation
- Ensure adequate and up-to-date Standard Operating Procedures (SOPs) are in place in relation to the management and use of controlled drugs
- AOs must also have regard to best practice in relation to the management of controlled drugs
 - Ensure adequate destruction and disposal arrangements for controlled drugs
 - Ensure monitoring and auditing of the management and use of controlled drugs
 - Ensure relevant individuals receive appropriate training
 - Maintain a record of concerns regarding relevant individuals
 - Assess and investigate concerns
 - Take appropriate action if there are well-founded concerns
 - Establish arrangements for sharing information
- Produce quarterly reports of their controlled drug occurrences and give them to the chair of the Local Intelligence Network. The occurrence report must describe details of any concerns that the organisation has regarding the management of controlled drugs or confirmation that there have not been any concerns in the required timeframe.
- Establish a Local Intelligence Network (LIN). Within Northern Ireland a single network has been established.

Additional responsibilities of the Board Accountable Officer

- Analysing health care and private prescribing of controlled drugs using Business Services Organisation (BSO) data and analysis tools (Compass)[Reg11(2)(a)]
- Requesting a periodic declaration and a self assessment from a general medical practitioner on its primary medical services performers list or from a registered dentist providing general dental services or piloted services under a pilot scheme regarding their controlled drug management and use [Reg 12(1)]
- Ensuring their organisation operates arrangements for periodic inspections of premises used in connection with the management or use of controlled drugs which may not be subject to inspection by RQIA or the DHSSPS [Reg 19]

Specific areas of Accountable Officer responsibility

Standard Operating Procedures

Legal requirements

Regulations made under the Health Act 2006 require each health care organisation to have SOPs for the management and use of controlled drugs. The Regulations require AOs to ensure that their organisation and those providing services to the organisation has adequate and up-to-date SOPs in relation to the management and use of controlled drugs.

The Regulations state that SOPs must cover the following:

- Who has access to controlled drugs
- Where the controlled drugs are stored

- Security in relation to storage, and transportation, of controlled drugs as required by misuse of drugs legislation
- Disposal and destruction of controlled drugs
- Who is to be alerted if complications arise
- Record keeping including:
 - Maintaining relevant controlled drug registers under misuse of drugs legislation
 - Maintaining a record of Schedule 2 drugs that have been returned by patients

Good practice



SOPs should cover all aspects of risk management and they should include audit trails for ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction of controlled drugs, appropriate to the setting and the team.

SOPs should highlight the accountabilities and roles of all members of the relevant healthcare teams.

The DHSSPS document published in October 2009 'Safer management of controlled drugs: guidance on standard operating procedures in Northern Ireland' provides advice on the areas that might be considered for inclusion in an SOP. See DHSSPS website <http://www.dhsspsni.gov.uk/guide-sops-td-dgs-ni.pdf>

Monitoring and auditing of the management and use of controlled drugs by the Board

Legal framework

Regulations specify that arrangements must provide for the following:

- Monitoring and analysing prescriptions for controlled drugs from the health service, hospital or privately written that are dispensed in the community through the use of data and analysis tools available from the Business Services Organisation (BSO)
- Ensuring systems are in place to alert the AO of any complaints or concerns involving the management and use of controlled drugs
- Ensuring an incident reporting system is in place for untoward incidents involving the management and use of controlled drugs
- Ensuring appropriate arrangements are in place for analysing and responding to untoward incidents involving the management and use of controlled drugs

Routine monitoring

AOs should ensure that the management and use of controlled drugs is monitored through routine processes such as data analysis, audit and clinical governance, as an integral part of normal governance arrangements. One example set out below is the use of prescribing data.

Prescribing data

Prescription data which is collected by the Business Services Organisation (BSO) to reimburse dispensing contractors can be used, both by individual practitioners and the Board, to monitor and examine the prescribing of controlled drugs. This is limited to data from private and Health

Service prescriptions dispensed in primary care and excludes prescriptions prescribed and dispensed in secondary care. Detailed data is available via an Access database to Board staff working in the area of medicines management and involved in the provision of support to independent contractors. This database can be used to look at either in-depth or top line prescribing patterns. Individual practitioners can request details of their own information by contacting a member of the Board pharmacy staff. Routine higher level information, in the form of standardised queries, is also provided to Board staff and prescribers on a quarterly basis via the COMPASS report which is produced by BSO using the same prescription data. This report is available in either hard copy or electronically. Further details on any aspect of this are available from the Board's pharmacy staff.

Good practice



CQC Self-assessment for PCTs

In England the Care Quality Commission (CQC) has developed a tool to help Primary Care Trusts (PCTs) check whether they are meeting the guidance and legal requirements regarding the governance of controlled drugs. The self-assessment tool is not a data collection tool, but a recommended resource to help PCTs measure their performance and identify ways in which they can improve. It includes a series of detailed questions around the safe management of controlled drugs, against which PCTs can score their current practices. Whilst this tool describes the different arrangements which exist in England, and is not therefore directly applicable to Northern Ireland, it does provide useful information which can support organisations audit their controlled drug governance and also to identify areas for improvement.

<http://www.cqc.org.uk/guidanceforallhealth/carestaff/managingrisk/controlleddrugs/self-assessmenttool.cfm>

Assessing controlled drug practice

- Good practice would suggest that a systematic audit of the processes for managing controlled drugs in primary care is carried out

Good practice (cont'd)	✓
<ul style="list-style-type: none"> • Results from local audits should be analysed to identify any areas where systems could be improved and better co-ordinated. All audit results should be kept, preferably electronically, for no less than 5 years. • It is the responsibility of the Board to ensure that good practice guidance is routinely followed by practitioners providing services under arrangements with the Board <p>Using quality indicators</p> <p>This list is not comprehensive, but gives a series of indicators that will help the Board, GP practices and pharmacies identify and demonstrate they have systems in place to minimise risk when managing controlled drugs.</p> <ol style="list-style-type: none"> 1. All staff and practitioners should be trained to ensure they have the relevant knowledge and skills to undertake the tasks required of them for managing controlled drugs safely 2. Practitioners and staff who work with controlled drugs should demonstrate reflective learning by relevant inclusions in their CPD portfolio. 3. Risk management systems should be used to help minimise risks in the management of controlled drugs. Such systems should be written and readily accessible to all relevant practitioners and staff. <p>They should include the following:</p> <ul style="list-style-type: none"> • Assessment of risks arising from managing controlled drugs • Procedures for training new members of staff or locums in management of controlled drugs • Identification of tasks, which have to be undertaken in the presence of a witness • Procedures for reporting loss or suspected theft of controlled drugs 	

Good practice (cont'd)	✓
<ul style="list-style-type: none"> • Handling of all records relating to controlled drugs, including requisitions, invoices, private and health service prescriptions, transport and delivery notes, and controlled drug registers • Procedures for monitoring and recording stock reconciliation (in controlled drug cupboards, 'doctors' bags', etc.), including action to be taken if a problem is identified • Procedures for checking expiry dates of controlled drugs and what to do with controlled drugs that have expired • Recording of critical incidents, errors and near misses with controlled drugs through local systems and the confidential National Reporting and Learning System from the NPSA • Complaint procedures for HSC employees and employers, as appropriate • How to report suspected cases of health care fraud • Copies of the Board's policy and processes for raising concerns • Systems for recording and destroying controlled drugs returned from practitioners, patients or their representatives • Audit trails for controlled drug prescriptions • Procedures for missing/stolen/lost prescription forms • Procedures for the storage and distribution of prescription forms <ol style="list-style-type: none"> 4. Managers, staff and healthcare professionals should know which member of staff at the Board to contact if they have a concern regarding the performance or practice of healthcare professionals, or their staff, involving controlled drugs. This would normally be the AO. 	

Section 3

Governance, Inspections and Monitoring

Contact details for Accountable officers can be found at:

<http://www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf>

Sharing information

An AO 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 controlled drugs.

Information sharing

- There are requirements to share information on concerns about relevant individuals [Reg 25 and 26]
- In sharing information, organisations must have regard to the Data Protection Act 1998 and the codes of practice on confidentiality, in particular the Caldicott principles. The Information Commissioner's Office has developed a code of practice entitled 'Framework code of practice for sharing personal information' which can be found on http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/pinfo-framework.pdf
- HSC organisations, those contracted to provide health care services and the independent sector may find the Confidentiality and Disclosure of Information: General Medical Services (GMS) and Alternative Provider Medical Services (APMS) Code of Practice helpful –

http://www.dhsspsni.gov.uk/code_of_practice_on_confidentiality.pdf

Confidential information that relates to, and can identify a patient [Reg 25(2)], should be anonymised where possible. In exceptional circumstances, an organisation may determine that it is in the public interest to share patient identifiable information, or that they are required to do so by statute.

The patient's consent should be sought or they should be notified of the disclosure unless such action would prejudice an investigation.

Local Intelligence Network (LIN)

Responsibility for establishing the Local Intelligence Network lies with the AOs. The LIN will enable agencies that have cause for concern about the activities of any healthcare professional to share them as soon as possible with other local agencies who may be affected or who may have complementary information.

The LIN should include, as defined by the Regulations (although it need not be limited to), the following types of bodies as appropriate:

- the DHSSPS
- Board
- a HSC trust
- NIAS
- RQIA
- Counter Fraud Unit of BSO
- a regulatory body
- the Police Service of Northern Ireland

Co-operation between health bodies and other organisations

- Regulations place a statutory duty of co-operation on responsible bodies to share information about concerns with respect to the management of controlled drugs
- Each organisation will be separately accountable for action within its own remit. The appropriate AO will be responsible overall for ensuring appropriate action is being taken in response to concerns that have been raised

Responsible bodies

Responsible bodies specified in Regulation are:

- the DHSSPS
- Board
- a HSC trust
- NIAS
- RQIA
- BSO
- a regulatory body*
- the Police Service of Northern Ireland

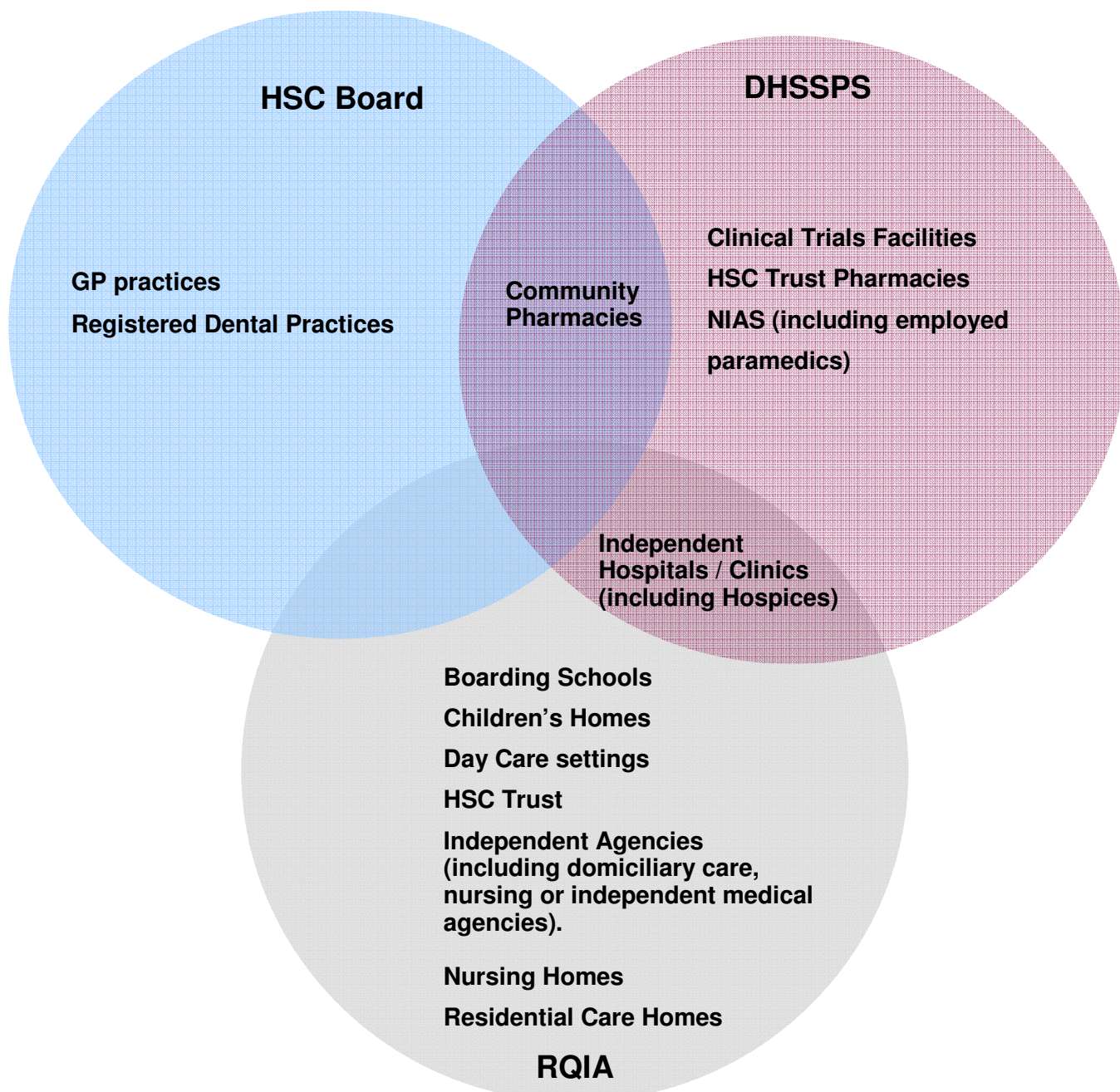
They have the following responsibilities:

- A general duty to co-operate with each other as regards relevant persons
- Duty to co-operate by disclosing information as regards relevant persons
- Have a right to request additional information be disclosed about relevant persons

*A regulatory body (could be GMC/NMC/GDC/HPC/Pharmaceutical Society of NI etc.)

Figure 2

Monitoring of statutory / professional compliance



Nurse Prescribers: Can be included in RQIA themed reviews.

Out of Hours Services: Can be included in RQIA themed reviews.

Police Custody Suites: Can be undertaken by RQIA in conjunction with Criminal Justice Inspectorate.

Private Dental Practices: Can be included in RQIA themed reviews.

Good practice



The Board should ensure that GP practices and pharmacies have ready access to information about the following:

- Practitioners prohibited from prescribing controlled drugs or with restrictions on their prescribing. A healthcare professional convicted or cautioned in connection with a controlled drug offence should report the conviction or caution to their regulatory body, which should then report the facts and its own action to the practitioner's employer and the Board. Regulatory bodies hold all current restrictions annotations relating to a practitioner's registration on their publicly available registers. Anyone wishing to confirm restrictions or annotations on a registrant's practice may search the regulatory bodies on-line register or contact the regulator directly.
- Practitioners with a DHSSPS licence to prescribe diamorphine, cocaine and dipipanone for the treatment of substance
- The Board should ensure that all GP practices and pharmacies are alerted in a timely manner about lost or stolen prescriptions or prescription forms, which may be used to acquire controlled drugs unlawfully

Alerts

Alerts received by the BSO are maintained and managed on a database. On receipt, the alerts are checked against the Primary Medical Performers List (PMPL), which BSO maintains on behalf of the HSCB. In the event that the alert relates to a doctor on the PMPL, BSO informs the HSCB.

In addition, new applicants to the PMPL are checked against the alert database before admittance. Doctors on the PMPL who become subject to conditions or restrictions are flagged on the PMPL. GP practices, Out of Hours etc are advised to check the PMPL (available on line at BSO website) to ensure that any doctor seeking employment with them is not subject to restrictions or that arrangements are in place to enable them to practice within the defined restrictions. Alternatively, they may contact the BSO by telephone.

Declaration and self-assessment

- All healthcare providers must complete a periodic declaration and self-assessment when requested by the relevant agency. Once completed, this assessment will inform inspections and contribute to the monitoring arrangements.
- Responsibility for requesting periodic declaration and self-assessments is as follows:
 - The Board AO for all those listed on the primary medical services performers' list and registered dentists providing general dental services, or pilot services under a pilot scheme
 - The DHSSPS for registered pharmacies.
 - RQIA for HSC trusts and any person registered with them who provides health care.
- The declaration and self-assessment form 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 declaration and self-assessment.
- These assessments will provide an additional check regarding the management and use of controlled drugs at that premises.
- Information from declaration and self-assessments, routine monitoring and other sources will be reviewed to decide whether any further action is needed.
- The review will assess the organisations standards in the prescribing, supply, administration, storage, record keeping and disposal of controlled drugs and assure compliance with the MDA, associated regulations, medicines legislation and any relevant professional codes of practice.

Figure 3

Routine monitoring and inspection arrangements

Body	Role
Board	<p>AO responsible for:</p> <p>Overseeing management and use of controlled drugs (including GPs and registered dentists)</p> <p>Responsible for declarations and self-assessment to GPs and registered dentists</p> <p>Receives assurances from DHSSPS regarding registered community pharmacies</p> <p>Member of LIN</p>
RQIA	<p>HSC Trusts, Independent Hospitals and other registered healthcare providers</p> <p>Routine and targeted inspection</p> <p>Responsible for declarations and self-assessment</p> <p>Member of LIN</p>
DHSSPS	<p>Routine inspection of registered pharmacy premises and Trust pharmacies</p> <p>Responsible for declarations and self-assessment to registered community pharmacies and Trust pharmacies</p> <p>Member of LIN</p>
Police	<p>Police available for wider support with information gathering and investigation</p> <p>Member of LIN</p>

Routine inspections

Legal framework

- The Health Act 2006 contains provisions for a power of entry and inspection for certain designated persons which will facilitate the inspection of controlled drugs
- Inspection remains a useful tool to check physical arrangements for the storage, record keeping and management of controlled drugs, to support individual and organisational development and to 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
<http://archive.cabinetoffice.gov.uk/operations/documents/pdf/policy.pdf>

The Health Act 2006 has created a power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs.

Standards for inspection

Two documents which individuals may find useful are:

Guidelines on inspection visits to primary care settings produced by the Department of Health
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4132228

A competency framework setting out the competencies that those involved in monitoring and inspection will need is available on the NPC website
http://www.npc.co.uk/prescribers/resources/cdi_competency_framework.pdf

The Pharmaceutical Society of Northern Ireland published 'Standards for registered Pharmacy premises (community) in January 2010, which can be found at the following link
www.psnri.org.uk/documents/521/Community+Pharmacy+Premises+Standards.pdf

Reporting concerns

In addition to concerns arising from routine monitoring and inspection, concerns may be raised by individuals. The Public Interest Disclosure (Northern Ireland) Order 1998 was introduced to protect employees who are worried about wrongdoing in their place of work and want to raise concerns. The Order applies to all HSC employees and includes all self-employed health care professionals (i.e. doctors, dentists, opticians, optometrists and pharmacists). For the purposes of the Order, the employer of self-employed health care professionals is deemed to be the Board.

Investigating concerns

The AO will need to ensure that robust systems are in place to enable concerns about controlled drugs to be raised, to log these concerns, and where appropriate to initiate investigations.

The AO may request assistance with an investigation from another responsible body such as the Counter Fraud Unit of the BSO, the DHSSPS, the police or a regulatory body.

If the AO has well-founded concerns he may request that an incident panel be convened by the chair of the local intelligence network (LIN), made up of officers from any of the bodies that are responsible bodies, to investigate the concern and make recommendations.

Good practice	✓
Useful guides to establishing appropriate reporting arrangements:	
The Pharmaceutical Society of Northern Ireland (“Society”) has produced guidance for pharmacists on raising concerns http://www.psnri.org.uk/documents/314/Guidance+on+Raising+Concerns.pdf	
<ul style="list-style-type: none"> • In analysing the reasons underlying an event and determining next steps the NPSA Incident 	
Decision Tree will be helpful in many cases http://www.nrls.npsa.nhs.uk/resources/type/toolkits/?q=0%acroot%ac&entryid45=59900	

Education and training

Regulations state that AOs are to ensure that relevant individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training in relation to the management of controlled drugs, in particular:

- Relevant individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive from time to time, appropriate training to carry out their responsibilities
- Receive information and where appropriate training on local SOPs for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs.

Some training materials, links and guidance can be found on the Accountable officer section of the DHSSPS's website
<http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm>

In addition, an on-line training module entitled ‘Controlled Drugs - Striking a Balance’ is available from The Northern Ireland Centre for Pharmacy Learning and Development (NICPLD)

Good practice	✓
Initial and continuing education and CPD for healthcare professionals should include appropriate material on the need for safe storage, possession and return of all medicines, and on the legal status of controlled drugs. All individuals working in HSC and non-HSC settings, who are involved in controlled drug supply, administration, storage, prescribing, dispensing and destruction, should ensure they have appropriate, timely and up-to-date knowledge of the processes involved in managing controlled drugs.	
It is the responsibility of registered homes to ensure that their formal carers are adequately trained in effective management of all medicines, including controlled drugs.	
Finally, consideration should be given by the appropriate authorities to ensure that undergraduate and pre-registration courses for healthcare professionals contain sufficient information on the prescribing, administering, supplying, destruction and recording of controlled drugs.	

The Chair of the LIN must take steps to protect patients and the public if there are concerns about inappropriate or unsafe use of controlled drugs by a person who is not providing services for any designated body [Reg 30(2)]

Section 4

Possession of Controlled Drugs

Legal framework

The Misuse of Drugs Act 1971 states that a person may not legally have a controlled drug in their possession unless the Regulations allow them to do so. Unlawful possession of any controlled drugs in Schedules 2 to 4 (Part 1) is a criminal offence.

Persons who can legally possess controlled drugs include the following. The list is not exhaustive, but provides an overview of who is authorised to lawfully possess controlled drugs and in what circumstances.

- Practitioners (this includes doctors, dentists and veterinary practitioners or veterinary surgeons)
- Pharmacists or a person lawfully conducting a retail pharmacy business
- Supplementary prescribers where controlled drugs form part of an agreed Clinical Management Plan
- Nurse independent prescribers, but restricted to a specified range of controlled drugs for specific medical conditions
- Any person administering under the direction of a doctor or dentist
- Midwives acting in their capacity as such (only those controlled drugs that she / he may administer in accordance with Medicines Act)
- Registered paramedics, under a Group Authority issued by the DHSSPS, who are engaged by and under the control of the Northern Ireland Ambulance Service HSC Trust (NIAS) may supply diazepam and morphine sulphate to any person who may lawfully have any of these drugs in their possession; registered paramedics may possess diazepam and morphine sulphate as detailed above for the purposes of administration for the immediate necessary treatment of sick or injured persons in the course of that service or employment.
- Private paramedics – those operating outside NIAS engagement and control who possess the relevant licence issued by DHSSPS
- Health professionals supplying or administering certain categories of controlled drugs under a Patient Group Direction (PGD)
- Individuals and corporate bodies licensed by the DHSSPS
- Persons in charge of a hospital or nursing home
- The senior registered nurse for the time being in charge of a ward, theatre or other department in a hospital or nursing home
- Operating Department Practitioner acting in accordance with the directions of a doctor, dentist, supplementary prescriber or nurse independent prescriber
- Someone who is transferring, with permission, a controlled drug to another person who is lawfully allowed to have it in his or her possession. This permission may be granted by the person authorised to possess and should be in writing
- Someone who has legally been prescribed a controlled drug

- Person acting as the patient's representative and collecting or returning on the patient's behalf
- Constables when acting in the course of their duty as such Persons engaged in the business of a carrier when acting in the course of that business
- Persons engaged in the business of a postal operator when acting in the course of that business
- Customs and excise officers when acting in the course of their duty as such
- The owner or master of a ship that does not carry a doctor on board
- 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 controlled drug 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 controlled drug from someone else to stop him or her offending and is immediately taking it to a person who may lawfully possess it.
- Patient's representatives returning unused medication to a pharmacy for destruction after the patient's death

Please refer to the Regulations for a comprehensive list of those authorised to possess these controlled drugs.

The following health care professionals are authorised under the Misuse of Drugs Regulations 2002 to possess, supply and compound controlled drugs in Schedules 2, 3, 4 and 5:

- Practitioners
- Pharmacists

These people may only supply controlled drugs to those who may lawfully possess them, including patients for whom a drug is prescribed.

Compounding

Pharmacists may not supply controlled drug ingredients to patients to allow them to compound controlled drugs themselves. Pharmacists who choose to compound a controlled drug must ensure that they act in accordance with the Code of Ethics and Section 4 of the 'Professional Standards and Guidance for the Sale and Supply of Medicines' document

www.psni.org.uk/documents/313/Standards+on+Sale+and+Supply+of+Medicines.pdf

They must also ensure that such activities are adequately covered by appropriate professional indemnity arrangements as required by the Principle 8.11 of the Code of Ethics. www.psni.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf

Controlled drugs declaration and self-assessment

All healthcare providers must complete a periodic declaration and self-assessment when requested by the relevant agency. Once completed, this assessment will inform inspections and contribute to the monitoring arrangements. For further information, see Section 3 - Governance, inspections and monitoring.

Standard Operating Procedures

- All healthcare providers must have SOPs for the management and use of all controlled drugs, which will be monitored as part of the strengthened governance arrangements
- Minimum requirements for SOPs are outlined in Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The Regulation and Quality Improvement Authority (RQIA) has provided the following guidance for the independent health providers whom they inspect:

Section 4

Possession of Controlled Drugs

"A registered facility's arrangements for the management of controlled drugs are routinely monitored as part of the RQIA medicines management inspection process. The registered facility is required to have an SOP covering the arrangements for the management of controlled drugs. Regulation 12 (3) of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 states that RQIA may request a periodic declaration and a self assessment from a HSC trust or any person registered with them that provides health care. This is currently being developed as part of the arrangements for the monitoring the management and use of controlled drugs."

Section 5

Purchasing and Supply of Controlled Drugs

Overview

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

Practitioners must NOT use patient-specific controlled drug prescriptions to replace or 'top-up' their bags even if the stock was used for that patient initially. This could be considered as a potential offence under the Theft Act 1968 and may be seen as a means of obtaining controlled drugs by deception.

Requisitions

Legal framework (general)

The following can obtain supplies of Schedule 2 or 3 controlled drugs for use in their practice, business or profession:

- A practitioner (this includes doctors, dentists, veterinarians and supplementary prescribers)
- Schedule 2 drugs may be possessed by the person or acting person in charge of a hospital or nursing home that is wholly or mainly maintained by a public authority out of public funds or 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). A doctor or dentist who works there must countersign such requisitions.

- A person in charge of a laboratory that carries out scientific research or education and is attached to a university, university college hospital or approved institution
- The owner or master of a ship that does not carry a doctor on board
- Requisitions supplied by the master of a foreign ship must contain a statement, signed by the appropriate authority (Port health authority officer in England and Wales or Medical officer in Scotland and Northern Ireland), indicating that the quantity of the drug is necessary for the equipment of the ship
- The installation manager of an offshore installation (e.g. an oil-rig)
- Registered paramedics, under a Group Authority issued by the DHSSPS, who are engaged by and under the control of the Northern Ireland Ambulance Service HSC Trust
- Private paramedics – those operating outside NIAS engagement and control who possess the relevant licence issued by DHSSPS

Good practice



Any person or organisation that holds stocks of controlled drugs should keep stock levels to the minimum level sufficient to meet clinical need. Conducting a review of controlled drug usage over a fixed period eg two years can provide an accurate assessment of current stock requirements. The level of stock held should then be reviewed at appropriate intervals and maintained at sufficient quantities to meet need. Requisitions and invoices, as required by MDR, must be kept for a minimum of 2 years. Please also refer to your organisations record retention policy, which may require records to be retained for periods greater than 2 years.

Purchasing by practitioners from wholesalers, or registered pharmacies, for administration or supply within the practice

Legal framework

Schedule 2 and 3 controlled drugs

Practitioners are authorised to obtain controlled drugs from registered pharmacies, or wholesalers, for the practitioner's use upon the production of a written requisition. General Practitioners may use the HS21S requisition (stock order) form to obtain stock of Schedule 2 and 3 controlled drugs from registered community pharmacies. Please note that the HS21S cannot be used by nurses for this purpose.

Schedule 4 and 5 controlled drugs

A requisition which complies with Misuse of Drugs Regulations (Northern Ireland) 2002 is not required before supplying or obtaining Schedule 4 or 5 controlled drugs.

Requisition requirements

Requisitions for Schedule 2 and 3 controlled drugs have to be in writing - either computer generated or handwritten. Requisitions that are handwritten do not need to be in the recipient's own handwriting. The recipient must sign requisitions irrespective of the means of production.

Requisitions must contain the following information:

- The name and address and profession / occupation of the recipient
- The purpose for which it is required, such as 'for use in my role as a practitioner'.
- The total quantity of the drug (this does not have to be in words and figures)
- The signature of the recipient

HS21S requisitions (stock orders) include the practitioner's prescriber identifier code (cipher). The name and address of the supplier must be indelibly recorded. Pharmacists are required to submit the original requisitions (not a copy) to the BSO. The Board AO is able to access information relating to these requisitions to monitor controlled drugs supplied via this route.

On receipt of a requisition (other than a veterinary requisition) in relation to a controlled drug other than a drug specified in Schedule 4 or 5, the supplier shall:

1. Mark on the requisition (in ink or otherwise indelibly) his name and address (e.g. with the pharmacy stamp); and
2. Enter the details of all requisitions for S2 controlled drugs in the CD register.
3. Submit private and HS21S requisitions to the Business Services Organisation using the HS30 in a similar manner to PCD1 forms.

Note: Details of private requisitions for S2 drugs should also be entered in the prescription book. Details of S3 – S5 controlled drugs **must** be entered in the prescription book.

Veterinary requisitions for controlled drugs should be brought to the attention of the pharmacy inspector during inspection visits.

This Regulation does not apply where the supplier is a wholesale dealer or is a person responsible for the dispensing and supply of medicines at a hospital.

Dispensing doctors must not supply controlled drugs against requisitions, as they are not authorised to carry out a wholesale function unless they have a wholesaler's licence.

A wholesaler or pharmacy supplying controlled drugs to a recipient must be reasonably satisfied that the requisition is a genuine document. This means that it should be the original document, hence faxed or other electronically transmitted requisitions are not currently permitted.

Section 5

Purchasing and Supply of Controlled Drugs

In exceptional circumstances where one pharmacy orders a controlled drug from another pharmacy written requisitions should be used.

Suppliers of controlled drugs should provide a delivery note for the purchaser to sign. The person signing the delivery note should be authorised to receive controlled drugs by the prescriber. A copy of the signed delivery note should be retained by the supplier for a minimum of two years.

Where possible practitioners requisitioning a controlled drug should collect the supply in person. The legislation does, however, permit the use of a messenger but this is not recommended practice.

In the event that a messenger is sent to collect the controlled drug, Reg 14(1) of the MDR requires a person collecting on behalf of the recipient to produce to the supplier a statement in writing signed by the recipient (a bearer's note) to the effect that he is empowered by the recipient to receive the drug on their behalf. The supplier needs to be reasonably satisfied that the document is genuine. The bearer's note should be retained by the pharmacy for a minimum of two years.

Retention of requisitions

Legislation requires that requisitions, or a copy thereof, are retained for a minimum of 2 years (see also previous page for submission of requisitions to BSO)

Urgent supplies to practitioners

Where a practitioner represents that a Schedule 2 or 3 controlled drug is urgently required for the purpose of the practitioner's profession, the supplier may, if reasonably satisfied that the practitioner so requires the drug and is, by reason of an emergency, unable to furnish the supplier with a requisition duly signed, supply the drug to the practitioner on the undertaking by the practitioner to furnish such a requisition within 24 hours. Failure to do this is a criminal offence on the part of the practitioner.

This does not permit making a supply of a S2 or S3 controlled drug (except Phenobarbital

for epilepsy) to a patient at a practitioner's request.

For emergency supply of Schedule 2 and 3 controlled drugs to patients, see page 52.

Purchasing by pharmacists and doctors from wholesalers

In addition to the legal requirements and good practice described previously in this chapter, the following applies when purchasing from wholesalers.

Legal framework for purchasing by pharmacists and doctors from wholesalers

A supplier (not being a practitioner) e.g. a wholesaler need not obtain a written requisition before supplying Schedule 2 or 3 controlled drugs and this order is permitted to be submitted electronically.

It is the responsibility of the pharmacist or doctor, when receiving a supply of controlled drugs from the wholesaler, to ensure that the correct item is delivered and that all appropriate entries are made in the CD register on the day of supply, or, if that is not reasonably practicable, on the following day. The task of completing the register may be delegated, but the pharmacist or doctor retains full accountability for this process.

Good practice



Any tamper-evident seals on packs of controlled drugs 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 / administration and once opened the pack should be marked to indicate a "split pack".

If, when the tamper-evident seal is broken, the contents do not match the expected amount stated on the manufacturer's pack, the following action should be taken:

Good practice (cont'd)



- Wherever possible the pack and contents should be kept as evidence to present to the manufacturer and the controlled drug should be dispensed from an alternative pack to the patient
- Where this is not possible because patient care will be compromised, the professional should assure themselves that the contents are suitable for dispensing and then appropriately repackage them for the patient, keeping the original packaging for evidence and action
- Appropriate records should be made in the CD register and all necessary action taken to resolve the discrepancy.

The person receiving controlled drugs from the wholesaler must be authorised to do so by the pharmacist or doctor, and should sign the supplier's delivery note on receipt of these controlled drugs. These arrangements should be defined within an SOP.

Where controlled drugs are transferred between pharmacies, the pharmacist requesting the supply should provide a requisition, and the pharmacist providing the supply should retain this. Both pharmacists must ensure that the correct entries are made in their respective CD registers.

Acquisition of Controlled Drugs by other Health Care Professionals

In addition to the legal requirements and good practice described previously in this chapter, the following applies when other health care professionals acquire controlled drugs.

Midwives

Legal framework

A Registered Midwife who has, in accordance with the provisions of the Nurses, Midwives and Health Visitors Act (1997), chapter 24, notified his/her intention to practice to the Local Supervising Authority (LSA) is

authorised to possess and administer specified controlled drugs as far as is necessary for his / her professional practice. The Misuse of Drug Regulations (Northern Ireland) 2002 covers the possession and administration of controlled drugs by midwives. Registered midwives are authorised to possess and administer certain medicines including diamorphine, morphine, and pethidine in the course of their practice

Midwives Supply Order for Community Practice

Each Local Supervising Authority (LSA), which is accountable to the Board, determines its own systems for providing midwives with supply orders in their area.

Midwives are authorised to obtain specified controlled drugs from a community pharmacy using a Midwives Supply Order, signed by the Supervisor of Midwives (SOM) or other Appropriate Medical Officer who is authorised in writing by the LSA.

- The Midwives Supply Order must state:
- The name and occupation of the midwife
- The purpose for which the controlled drug is required
- The total quantity required.

Midwives must also make all relevant entries in their own CD registers

Copies of the midwife's supply order must be retained by the pharmacist for two years.

Individual patient prescription

Alternatively, a prescription can be written by a doctor, e.g. a patient's GP, if that patient is under their care. The patient obtains the prescribed controlled drug from a pharmacy and keeps it in their home until it is required for administration by the midwife.

Good practice

Where a controlled drug has been prescribed for a patient, but not used during a home birth, then that patient should return the unused medication to a pharmacy for safe destruction and disposal, as it is no longer required for the purpose for which it was prescribed. Midwives should recommend to patients that they should return unused controlled drugs to the pharmacy.

Hospital

Midwife Supply Orders are only issued to community midwives, and not to midwives operating in the hospital setting. The administration of controlled drugs by midwives working in a hospital should be in accordance with locally agreed policies and procedures. See also Safer Management of Controlled Drugs - A guide to good practice in secondary care (Northern Ireland) <http://www.dhsspsni.gov.uk/safer-management-cda-2009.pdf>

NMC guidance states that there must be a clear distinction between controlled drugs that have been obtained by the patient from her GP and those obtained from a midwife's supply order. In the case of drugs supplied by a midwife's supply order, it is the responsibility of the midwife who obtained the drug to return it to the pharmacy or to the Appropriate Medical Officer, who should make arrangements for safe disposal. A record of the return should be made in the midwife's CD register.

Paramedics

Registered paramedics engaged by and under the control of the Northern Ireland Ambulance Service HSC Trust (NIAS) are authorised under a Group Authority to possess and supply diazepam and morphine for the purposes of administration for the immediate necessary treatment of sick or injured persons in the course of that service or employment. Paramedics operating outside of NIAS engagement and control will require a licence to possess and supply controlled drugs. Currently, Victoria Pharmaceuticals (Belfast HSC Trust) supply ambulance stations with these medicines. Small quantities of a specified range of drugs

are packed in "drug packs" and provided with individual seal numbers that are accounted for at the beginning and end of a shift.

Independent hospitals including hospices

Where an independent hospital, including hospices, does not employ a pharmacist, the person or acting person in charge is authorised to obtain controlled drugs via a requisition signed by a doctor (or dentist) employed or engaged there. For hospices in Northern Ireland, the requisition is printed in triplicate by the Business Services Organisation (BSO) and marked "Controlled Drugs only". This is presented to a local community pharmacy with whom a service level agreement (SLA) is in place. The form details the drug description (name, form and strength), quantity (ordered, dispensed and received), any endorsement necessary and BSO code for pricing. Establishments with employed pharmacists can obtain controlled drugs stocks via a requisition, which complies with the Regulations described on page 35. For further guidance on supplies from hospitals to external units see also section 7.11 of Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland) <http://www.dhsspsni.gov.uk/safer-management-cda-2009.pdf>

Out of Hours Services

Controlled drugs are generally not included in the formulary of drugs held by Out of Hours Services. All doctors working for the Out of Hours Services requisition a supply of these drugs through their practice using a HS21S. For doctors not attached to a practice, who do not have access to HS21S, protocols exist whereby they can have access to stock prescriptions supervised by the Medical Managers of the services.

In terms of good practice when managing controlled drugs Out of Hours, reference should be made to the following Regional GP Out of Hours Guidance Manual <http://gpooh.hpssweb.ni.nhs.uk/regional/index.html> This guidance should be used as the basis for local Out of Hours Centres to develop their own SOPs in relation to the management and use of controlled drugs. For further information, refer to page 93.

Section 6

Administration of Controlled Drugs

Legal framework

- Any person is authorised to legally administer to another any drug specified in Schedule 5
- When administration of a Schedule 5 controlled drug is defined in a PGD only those health care professionals specified in the PGD can supply / administer in this circumstance as they cannot delegate this function
- Some professional groups, but not all, are authorised to supply or administer controlled drugs in accordance with a PGD (see page 44)
- For more information about administration of controlled drugs under PGDs, (see page 44)
- A doctor or dentist is authorised to administer to a patient any drug specified in Schedule 2, 3 or 4
- Any person other than a doctor or dentist is authorised to 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 or any person acting in accordance with their directions can administer a limited range of controlled drugs (see Appendix 7)
- A carer / relative can, with consent, administer a controlled drug that has been individually prescribed for a third party. As controlled drugs are included within the legal category of prescription-only medicines (POMs), home carers who are appropriately trained and assessed as competent are authorised to administer orally prescribed controlled drugs (Nurses and Midwives are referred to 'Standards for Medicines Management', NMC, 2008 for fuller guidance on delegation of the administration of medicinal products www.nmcuk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf)
- Midwives are authorised to administer those controlled drugs, which they are authorised to lawfully possess under the Medicines Act (i.e. diamorphine, morphine and pethidine.)
- Under a Group Authority, issued by the DHSSPS, registered paramedics can possess diazepam and morphine for the purposes of administration for the immediate necessary treatment of sick or injured persons in the course of that service or employment

Good practice



Except in exceptional circumstances, the person prescribing the controlled drug should not also personally undertake any of the following tasks: preparation, dispensing, transportation and administration of the controlled drug. It is good practice to ensure that wherever possible another appropriate and competent individual (who may be a carer) witnesses the administration and balance of a controlled drug. There will be occasions, such as the initial treatment of acute myocardial infarction, where this separation of tasks is not possible. Whenever this is the case, it is important that accurate records be kept. See also NMC guidance on Standards of proficiency for nurse and midwife prescribers. www.nmc-uk.org/Publications/Standards/

Depending on the environment of care that the patient is in, each administration should be recorded in the relevant patient clinical notes. This record should specify the date, time, strength, presentation and form of

Good practice (contd)

administration, dose administered as well as the name and occupation of the person administering it.

Safeguards must be in place when any prescribed medicine is administered to residents of residential homes by care workers. A procedure for giving controlled drugs to residents should be in place to minimise the potential for a drug error. This should include a witness to the administration of controlled drugs unless this is not practical. Further information on the management, recording, storage and administration of medicines is given in "Residential Care Homes Minimum Standards"

www.rqia.org.uk/cms_resources/Care%20Standards%20Residential%20Care%20Homes%20Jan%202008.pdf

Controlled drugs given by domiciliary care workers in a person's own home should be treated in the same way as for all other prescribed medicines.

Preparation and administration of injections

Serious medication errors have been reported because of process errors during the preparation and administration of injections, including controlled drugs. Health care organisations should publish policies and procedures that define safe medication practice for the preparation and administration of injections, including controlled drugs.

Any such procedures should include references to information on the following:

- Aseptic preparation
- Manufacture
- Drug compatibility when mixing two or more medicines in a syringe
- Correct labelling of prepared medicines, including an expiry date
- Single-checking, versus double-checking with another practitioner or carer
- Safe administration of bolus doses
- Programming and safe use of syringe-driver pumps

Good practice (contd)

- Warnings about the danger of confusing different strengths and types of controlled drugs during preparation and administration.

See also the following publications for additional guidance:

'Good practice statement for the preparation of injections in near-patient areas, including clinical and home environments', published by the Scottish Executive

www.scotland.gov.uk/Publications/2002/12/16049/15913

'Building a safer NHS for patients', published by the Department of Health (DH), January 2004

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4071443

Patient

Safety

First

www.patientsafetyfirst.nhs.uk/

Good practice**Supervised consumption**

The pharmacist should separate the dispensing process from the supervised consumption process. Patients should be invited to check the label, but the pharmacist should retain the bottle and destroy the label.

NIPSA Guidance

Guidance to protect patients from harm in respect of prescribing, dispensing and administering opioid and opiate (hereafter opioid) medicines has been issued by the National Patient Safety Agency (NPSA). These specify actions that are designed to reduce human-factor error.

In Northern Ireland, the NPSA guidance is managed by the DHSSPS and, where appropriate, issued to relevant organisations for their action. Organisations are required to notify the implementation status of NPSA guidance by a specified date to the relevant Trust, which then provides an assurance through the HSC Board to the DHSSPS that the relevant action has been taken.

See Appendix 6 for further details

Section 7

Prescribing Controlled Drugs

Legal framework

Medical practitioners

Doctors and dentists are authorised to prescribe all controlled drugs in Schedules 2 to 5 for the treatment of organic disease.

Doctors are only able to prescribe diamorphine, dipipanone and cocaine to substance misusers for the treatment of addiction if the prescribers hold a licence issued by DHSSPS. All doctors are authorised to prescribe such drugs for patients, including substance misusers, for the relief of pain due to organic disease or injury without a specific licence.

Note: Doctors are required, under The Misuse of Drugs (Notification of and Supply to Addicts) (Northern Ireland) Regulations 1973, to notify the Chief Medical Officer within seven days of attendance to a person whom he considers or suspects of being addicted to any drug specified in the schedule to the Regulations.

(Note: Supplementary prescribers working within agreed patient specific management plans, who prescribe for substance misusers for the treatment of addiction, are not currently able to apply for a licence from the DHSSPS; licences are restricted to doctors).

Supplementary prescribers are able to prescribe for substance misuse, with the exception of dipipanone, diamorphine and cocaine for addicts. Supplementary prescribers are able to prescribe any controlled drug that forms part of a clinical management plan for organic disease.

Non-medical prescribers

Community practitioner nurse prescribers

Community practitioner nurse prescribers are authorised to only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for community practitioners. No controlled drugs are included in this formulary.

Nurse and pharmacist independent prescribers

Currently, nurse independent prescribers can prescribe from the controlled drugs listed in the table in Appendix 7, for the medical conditions specified.

The Misuse of Drugs Regulations (Northern Ireland) 2002 will be amended to come into operation soon to allow nurse and pharmacist independent prescribers to prescribe, possess, supply, offer to supply, administer and give directions for the administration of any controlled drug specified in Schedules 2 to 5 of the MDR. However, they will not be authorised to prescribe, possess, supply, offer to supply, administer or give directions for the administration of cocaine, diamorphine or dipipanone to addicts, save for the purpose of treating organic disease or injury.

Supplementary prescribers

The MDR were amended in March 2005 to add supplementary prescribers to the list of people authorised to write prescriptions for controlled drugs, providing they are acting in accordance with a Clinical Management Plan. From 11 April 2005, amendments to the General Medical Service / Personal Medical Service Regulations enabled the prescribing of controlled drugs by supplementary prescribers

www.opsi.gov.uk/sr/sr2005/20050119.htm

The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2005

Registered nurses, pharmacists and midwives, as well as chiropodists, podiatrists, physiotherapists, radiographers and ophthalmic opticians who are registered as supplementary prescribers are authorised to now prescribe any controlled drug as long as it is within the Clinical Management Plan specific to that patient and agreed between the Independent Prescriber (doctor or dentist), supplementary prescriber and the patient.

Midwives

Midwives may also train as nurse independent prescribers. Midwives who are not trained as nurse independent prescribers are authorised to administer controlled drugs under Exemption Orders under medicines regulations (see page 38)

Patient Group Directions (PGDs)

Regulations allow the supply and administration of the following controlled drugs under PGDs:

- Diamorphine, but only for the treatment of cardiac pain **by nurses working in coronary care units or hospital accident and emergency departments**
- All drugs listed in Schedule 4 of the Regulations (and midazolam) except:
 - The anabolic steroids in part 2 of Schedule 4
 - Injectable formulations for 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. Under no circumstances can any other Schedule 3 CD be lawfully included in a PGD

It is important to note that most, but not all, registered health care professionals who are authorised to supply or administer medicines generally in accordance with a PGD under Medicines Act legislation are authorised to supply and administer controlled drugs, as specified above, in accordance with a PGD under MDR.

The Regulations allow nurses, midwives, pharmacists, optometrists, chiropodists, radiographers, orthoptists, physiotherapists, ambulance paramedics, occupational therapists, orthotists and prosthetists to operate within the PGD parameters described above.

Prescription requirements

Details and handwriting

Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002, which came into operation on 16 January 2006 removed the requirement for prescriptions for Schedule 2 and 3 controlled drugs to be written in the prescriber's own handwriting, other than their signature, (temazepam was not subject to the handwriting requirements).

Controlled drug prescriptions are permitted to be, but do not have to be, computer-generated. Prescribers are authorised to issue computer-generated prescriptions for all controlled drugs. Only the signature has to be in the prescriber's own handwriting.

Alterations are best avoided but if any are made, they should be clear and unambiguous. Best practice would suggest that if an error is made, the prescriber should cross out, initial and date the error then write the correct information.

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.'

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(Regulation 15 of The Prescription Only Medicines (Human Use) Order 1997).

Potential change in legislation ✓

The use of pre-printed adhesive labels on prescriptions is not recommended. Technically the new legislative requirements for computer-generated prescriptions for controlled drugs do not prevent the use of pre-printed adhesive labels on prescriptions. If and where they are used, such adhesive labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If an adhesive label is used, prescribers should also sign the adhesive label or at least start their signature on the adhesive label. This is a further safe guard to ensure sticky labels are not tampered with or another adhesive label is not placed on top of the one that the prescriber signed for.

Whilst a new legal requirement allows all other details except the signature on the prescription to be 'written in any form', it is good practice that if these other details are handwritten, it is done by the prescriber or by an appropriate health care professional.

Prescriptions for Schedule 2 and 3 controlled drugs (except temazepam)

A prescription for Schedule 2 and 3 controlled drugs (with the exception of temazepam and preparations containing it) must:

Contain the following details, written so as to be indelible, e.g. handwritten 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
- The strength of the preparation (if more than one strength exists)
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

Prescribing Controlled Drugs

- Signed by the prescriber with their usual signature (this must be -- handwritten) and dated (the date does not have to be handwritten)

Note:

In the event that the prescriber intends that the prescription is not to be supplied before a certain date then, in addition to recording the date on which the prescription was signed, he must also indicate the date before which it must not be supplied. This date is referred to as the 'appropriate date' within the MDR.

The address of the prescriber must be stated on the prescription and must be within the UK. (NB: the UK does NOT include the Channel Islands or the Isle of Man)

Prescriptions issued by a dentist must contain the words 'for dental treatment only'.

(See section on private prescribing (page 53) and instalment prescribing (page 48) for additional requirements)

Temazepam and Schedule 4 and 5 controlled drugs

Prescriptions for temazepam and for Schedule 4 and 5 controlled drugs are exempt from the specific prescription requirements of the MDR. 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 controlled drugs being dispensed beyond their clinical need and stored or diverted inappropriately the maximum validity of a prescription form was amended on 7 July 2006. The validity period of Health Service and private prescriptions for Schedule 1, 2, 3 and 4 controlled drugs is now restricted to 28 days. This means that the prescription should not be dispensed if more than 28 days have elapsed since it was signed and dated by the prescriber, or where the prescription has stated a later start date, not more than 28 days from this date.

In the case of a prescription which directs that specified instalments of the total amount are permitted to be supplied at stated intervals, the first instalment must be supplied

no later than 28 days after the 'appropriate date'. However, if the prescription specifies a start date, the prescription can only be dispensed in accordance with the prescriber's directions. See the following website for further details

www.opsi.gov.uk/Sr/sr2006/nisr_20060264_en.pdf

Technical errors on a prescription

Pharmacists are able to supply Schedule 2 and 3 controlled drugs except temazepam (which is exempt from controlled drug prescription requirements), against some prescriptions that have a minor technical error but where the prescriber's intention is clear.

The only errors that pharmacists are permitted to amend are listed below:

- Minor typographical errors or spelling mistakes
- Where the total quantity of the preparation of the controlled drug or the number of dosage units as the case may be is specified in either words or figures but not both (i.e. they are permitted to add the words or the figures to the controlled drug prescription if they have been omitted).

These amendments are permitted provided that:

- Having exercised all due diligence the pharmacist is satisfied on reasonable grounds that the prescription is genuine.
- Having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that he/she is supplying the controlled drugs in accordance with the intention of the prescriber.
- The pharmacist amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes so that the prescription complies with the Misuse of Drugs controlled drug prescription

requirements (Regulation 15). Any changes must be directly attributable to the pharmacist who amends the prescription.

Good practice (general)



- The professional registration number and the profession of the person who signs the prescription should be added to the controlled drug prescriptions they write, to assist with any future audit. The prescriber's full name, address (this is the address and telephone number where the prescriber can usually be contacted) should also be included on the prescription. This information is pre-printed on HS21 prescription forms, therefore the prescriber should use only the prescription pads allocated to him or her
- Dosages and frequencies for all controlled drugs should normally be presented in full by the prescriber, to aid administration by nurses and carers. 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 must be blanked off, e.g. by drawing a line through it to reduce the opportunity for fraud
- Computer systems should be used, wherever feasible, as an additional method to record and audit the prescribing of controlled drugs. If a prescriber makes a domiciliary visit, and a controlled drug is administered or a handwritten prescription for a controlled drug is issued, it is good practice to make a note of this on the patient's computer record as soon as possible after the event. The doctor must record in his or her own CD register the supply or administration of a controlled drug to a patient from the doctor's own stock. The return of out of date stock to a pharmacy for destruction must also be recorded in this register.

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Good practice	✓
<p>Controlled drugs have the potential to be diverted to the illicit market. For this reason, when a patient presents a controlled drug prescription for an acute condition, more than two to three weeks after the prescription was issued, it would be prudent to check with the patient and the prescriber that the supply of the controlled drug is still warranted before dispensing the item</p> <p>Separate guidance is available relating to substance misuse. When patients present more than 3 days after either the date the prescription was written or the start date on the prescription or the patient misses daily pick-up of medicines for more than three days then the pharmacist should check with the prescriber before dispensing. This is because the patient's tolerance to the opioid may have reduced and the same dose taken after 3 days break in treatment could result in the patient overdosing. Pharmacists are advised to inform the prescriber or key worker and agree the most appropriate course of treatment for the patient (e.g. the patient may have to return to the prescriber for reassessment and reiteration of their dose).</p> <p>Prescribers should ensure that pharmacists are part of any local scheme with protocols that include the scenario of delayed pick up by more than 3 days.</p>	

Drug misuse and dependence - UK guidelines on clinical management
http://www.nta.nhs.uk/publications/documents/clinical_guidelines_2007.pdf

For private prescribing, see page 53.

Prescribing Controlled Drugs

Quantity supplied on prescription	✓
<p>The quantity of drug prescribed on each prescription should be appropriate for the clinical need of the patient. Careful consideration should be given to the quantities prescribed, both to anticipate requirements, e.g. over a weekend, and to reduce the amount of excess controlled drugs stored in the patient's home.</p> <p>Although not a legal requirement, there is a strong recommendation that prescriptions for Schedule 2, 3 and 4 controlled drugs are limited to a quantity necessary for up to 30 days clinical need.</p> <p>This is a good practice requirement and not a legal requirement because there may be circumstances where there is a genuine need to prescribe more than 30 days supply.</p>	

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
- Be ready to justify his / her 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 of a Schedule 2, 3 or 4 controlled drug. There may be circumstances where there is a genuine need to prescribe more than 30 days supply and pharmacists should exercise their

professional judgement and assess both the prescription and the situation to check the suitability for the patient.

- It is good practice to make a contemporaneous note of this including the reasons why the supply was made
- Where there is concern that the prescription is not appropriate the prescriber should be contacted.
- The AO monitoring checks are likely to pick up large prescribing amounts

Substitute prescribing in instalments

In Northern Ireland prescribers in secondary care drug addiction clinics must use a Substitute Prescribing Form (SP1 or SP2 produced in triplicate from the BSO, to prescribe methadone or buprenorphine in instalments of up to 14 days supply. GPs can prescribe on an HS21 form.

A prescriber writing a private prescription can also ask for the prescription to be dispensed in instalments.

Most users who seek substitute treatment will be registered with a GP. Where this is the case, referral is made through the GP to a specialist addiction clinic. Voluntary addiction services or counselling services may also have an important advocacy role on behalf of users and facilitate referral into addiction services. Specialist addiction services will accept a user not registered with a GP. Once a user has entered treatment all efforts should be made to have the patient registered with a GP and so benefit from primary care services.

If any prescription forms are lost or cannot be accounted for, the matter should be reported to the designated person with overall responsibility for prescription forms in the Board / BSO, the Accountable Officer and police as necessary.

Details to be specified

To be legally valid, an instalment prescription for a Schedule 2 or 3 CD (except temazepam) must include the following:

The signature of the appropriate practitioner issuing the prescription

- The date
- The address of the appropriate practitioner issuing the prescription
- The dose to be taken ('as directed' is not acceptable, but 'one as directed' is acceptable)
- The form of the preparation (e.g. mixture/tablets/capsules/ampoules)
- The strength of the preparation (if more than one strength is available). In the case of methadone, there is more than one strength available, therefore this must be specified on the prescription
- The total quantity of the preparation in words and figures. This must be in dosage units (that is ml for a liquid, or number of tablets, capsules, ampoules and not the total mg of the drug)
- The name and address of the patient
- The instalment amount and the intervals to be observed:
 1. The number of instalments
 2. The intervals to be observed between instalments; (these intervals should take into account weekends and bank holidays, as the directions for instalments are binding).
 3. Order only such quantity of the drug as will provide treatment for a period not exceeding 14 days
 4. The quantity to be supplied in each instalment.

Points 1, 2 and 3 are required by The Health and Personal Social Services (General

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Prescribing Controlled Drugs

Medical Services Contracts) Regulations (Northern Ireland) 2004. Points 2 and 4 are required under the MDR, Regulation 15.

Collection of instalments

The prescription must be dispensed on the date on which it is due. If the client does not collect an instalment when it is due then that supply is no longer valid; the client cannot collect that supply the following day.

More than one day's supply can be prescribed to be collected e.g. twice a week or three times a week. Good practice recommends that no more than one week's supply is prescribed in a single instalment when prescribing substitute opiate treatment.

If a prescriber has ordered several days' instalments to be collected on one day and the client does not come in on the specified day, then he loses the complete instalment; he cannot have the remainder of the instalment. Pharmacists should endorse the prescription 'NOT COLLECTED' 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 controlled drugs to issue the remainder of an instalment prescription when the person has failed to collect the instalment on the specified day.

This wording overleaf can be used by those prescribing controlled drugs by instalment in accordance with the MDR. 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.

Further guidance can be found in "Drug Misuse and Dependence: UK Guidelines in Clinical Management"

http://www.nta.nhs.uk/publications/documents/clinical_guidelines_2007.pdf

which is published by the National Treatment Agency for Substance Misuse (NTA) on behalf of UK health departments. The guide is referred to as "The Orange Guide". It provides evidence based and clinical guidelines as well as good practice information in providing a service to drug misusers.

Table 2: Summary of approved wording

(From drug misuse and dependence - UK guidelines on clinical management)
www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf

What prescriber intends	Wording required on prescription
If you want patients who pick up their medicine less frequently than daily to be able to collect a part instalment as soon as possible after they miss a dose.	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 days missed may be supplied. Or alternative wording permitted: 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 days missed) may be supplied.
If you want the patient to be supervised consuming their dose on the days that they collect from the pharmacy but still want them to be able to obtain a part instalment of their medicine if they miss their prescribed collection day.	Supervised consumption of daily dose on specified days; the remainder of the supply to take home. If an instalment prescription covers more than 1 day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the days missed may be supplied.
If you want to ensure that the patient is not supplied with their dose if they have missed collecting for 3 days.	Instalment prescriptions covering more than 1 day should be collected on the specified day. If this collection is missed, the remainder of the instalment (i.e. the total amount less the instalments for the days missed) may continue to be supplied in the specified instalments at the stated intervals, provided no more than 3 days are missed.
For bank holidays when unsure which days the pharmacy is closed.	Instalments due on days when the pharmacy is closed should be dispensed on the day immediately prior to closure

The Northern Ireland Guidelines on Substitution Treatment for Opiate Dependence 2004 states: "Take home doses must be dispensed in separate bottles for each day with clic-loc caps"

Various types of controlled drug prescription forms

SP1 Form

SUBSTITUTE PRESCRIBING FORM

Prescribers Details: [] Patient Name: _____ Address: _____ Pharmacy Contractor Number: _____

CHI	Number of Days Treatment	Dispensing	Supervision	CSA Drug Code	No. of Supervision

Start Date: _____

Prescriber Signature: _____ Date: _____

Prescriber Number: 10033
Form Number: _____

Name of Prescriber if different from prescriber pre-printed above (BLOCK CAPITALS)

I declare that the details completed on this claim form are accurate and that the prescription has been dispensed in accordance with the Medicines Act and the Misuse of Drugs Regulations.

Pharmacists Signature: _____ Date: _____

Pharmacist's Stamp: []

Top White Copy (the prescription) to be returned by the pharmacist to CSA
Middle Blue Copy to be retained by the pharmacist
Bottom Pink Copy to be retained by the prescriber

SPECIMEN

SP2 Form

N.I. SUBSTITUTE PRESCRIBING FORM

Age: _____ Name (including forename) and address: _____

DOB: _____

Health & Care No.	For Pharmacy Use Only			
	Dispensing Date	Y / N	CSA Drug Code	Actual Fee

Start Date: _____

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.

Prescriber's Signature: _____ Date: _____

Name of Prescriber if different from pre-printed name (CAPITALS)

I declare that the details completed on this claim form are accurate and that the prescription has been dispensed in accordance with the Medicines Act and the Misuse of Drugs Regulations.

Pharmacist's Signature: _____ Date: _____

SPECIMEN

10022

01796031530

Form Number

HS21 Form

Northern Ireland Health Service

Age: _____ Name (including forename) and address: _____

DOB: _____

Pharmacy stamp: []

No. of days treatment	CHI / H+C No.	Code numbers

Signature of Prescriber: _____ Date: _____

SPECIMEN

PATIENTS - please read the notes overleaf

Form Number: 0001 02028022381

PCD1 Form

Northern Ireland Health Service

Age: _____ Name (including forename) and address: _____

DOB: _____

Pharmacy stamp: []

No. of days treatment	Health Care No.	Code numbers

THIS FORM MUST ONLY BE USED FOR THE PRIVATE PRESCRIBING OF S2 AND S3 CONTROLLED DRUGS

Signature of Prescriber: _____ Date: _____

SPECIMEN

PATIENTS - please read the notes overleaf

Form Number: 400001

This form is the property of the Central Services Agency

Good practice



On SP1 and SP2 prescriptions, and HS21 forms used for unsupervised instalments, it is good practice for the duration of the instalments to be set out on the prescription, e.g. dispense daily for five days starting on x date.

The client should collect the controlled drug in person. If he or she is unable to collect the medication personally, the client is permitted to 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 pharmacist should be convinced beyond reasonable doubt that the note is valid.

The requirements to see identification of the patient (see page 65) on collection only apply to the first dispensing of an instalment prescription.

Repeatable prescriptions

A repeatable prescription is one which indicates that the drugs, medicines or appliances ordered on that form are permitted to be provided more than once and specifies the number of occasions on which they are permitted to be provided. Current legislation does not permit the supply of controlled drugs in Schedule 2 and 3 on a repeatable prescription. However, management systems which allow the patient to receive a prescription (hand signed by a practitioner) without a consultation is not subject to legislation, but is a clinical decision made on a case by case basis. Such prescriptions are valid for one dispensing only and a new prescription will be required on each occasion the medication is requested. It is good practice that patients should be reviewed before prescribing Schedule 2 and 3 controlled drugs.

Repeat Dispensing Scheme

Repeat dispensing is the process by which patients can obtain supplies of their repeat medicines over a defined period from a pharmacy of their choice, without the need to contact their GP practice on each occasion a new supply is needed. Repeat Dispensing is one of eight integrated work strands that form the DHSSPS's "Pharmaceutical Services Improvement Programme". Currently, repeat dispensing is only available from GP practices and community pharmacies trained to provide the service. Schedule 4 and 5 controlled drugs are permitted to be ordered on prescriptions issued under the repeat dispensing scheme. For Schedule 4 controlled drugs, the first prescription must be dispensed within 28 days.

Whilst the Misuse of Drugs Regulations does not explicitly forbid the repeat dispensing of Schedule 2 and 3 controlled drugs, guidance from the Home Office is that, because it is not explicitly permitted the repeat dispensing of such drugs is not allowed under the Regulations. Moreover, clause 293 of the GMS contract prohibits "repeatable prescriptions" for Schedule 2 and 3 controlled drugs. www.dhsspsni.gov.uk/gms-var1.pdf

Potential developments

There are currently proposals being considered to allow repeat dispensing of Schedule 2 and 3 controlled drugs subject to the development of satisfactory controls and safeguards.

Emergency supplies

Emergency supplies (as provided for in the Medicines Act) of Schedule 2 and 3 controlled drugs, for a specific patient, are not permitted either at the request of the patient or a practitioner. The only exception to this rule is phenobarbital for the treatment of epilepsy.

In National Emergency Situations special legislation may be introduced. Special legislation in the event of a pandemic will allow emergency supply of controlled drugs in specific circumstances.

Section 7

Prescribing for self and family

Good practice ✓
<p>Other than in emergencies, no prescriber should prescribe any drug for themselves or anyone with whom they have a close personal or emotional relationship.</p> <p>There may be some cases, such as in an emergency situation in which prescribing for family, friends or self is immediately necessary to:</p> <ul style="list-style-type: none">• Save life• Avoid significant deterioration in the patient's health• Alleviate uncontrollable pain. <p>Such prescribing may be necessary in circumstances where no other person with the legal right to prescribe is available to assess the patient's clinical condition and to delay prescribing would put the patient's health at risk, or cause unacceptable pain</p> <p>Each professional body provides guidance for their members:</p> <ul style="list-style-type: none">• www.gmc-uk.org/guidance/current/library/prescriptions_faqs.asp• Nursing and Midwifery Council Guidance – (Standards of proficiency for nurse and midwife prescribers – www.nmc-uk.org)• General Dental Council Guidance – (Standards for Dental Professionals – www.gdc-uk.org)• Pharmaceutical Society of Northern Ireland (Standards and Guidance for pharmacist prescribers)

Prescribing Controlled Drugs

Good practice ✓
<p>www.psni.org.uk/documents/319/Standards+on+Pharmacy+Prescribing.pdf</p> <p>In addition, the DHSSPS document “Improving Patients’ Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the HPSS in NI” gives guidance on prescribing for pharmacists and nurses www.dhsspsni.gov.uk/patients_access.pdf</p>

Private prescribing

The law relating to prescribing applies to all Health Service and non-Health Service settings and good governance is equally applicable to non-Health Service organisations.

This document details good practice for the management of controlled drugs in primary care both in the Health Service and in non-Health Service settings.

The term ‘private prescribing’ is used to describe the situation when a private prescription is written, either by Health Service or non-Health Service practitioners, in either Health Service or non-Health Service settings.

Legal Framework

Prescribers who write private prescriptions must comply with all legal requirements as detailed in the MDR when ordering, prescribing, dispensing, administering and destroying controlled drugs.

Registrable private doctors, along with independent hospitals and independent clinics (as defined under article 2 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003) are required to be registered with the Regulation and Quality Improvement Authority (RQIA). It is an offence under Article 12 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to carry on or manage a registrable service without first being

registered to do so. Failure to apply for registration could render the practitioner liable to prosecution and could lead to the refusal of the application to register.

Normally, private prescriptions can allow a prescriber to request that the prescription is repeatable* for a specified number of times. However, this is not permitted for Schedule 2 and 3 controlled drugs. It is possible to prescribe Schedule 4 and 5 controlled drugs on a repeat basis, both privately and under Health Service repeat dispensing arrangements.

*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.

Standardised private prescription form

All private prescriptions for human use of Schedule 2 and 3 controlled drugs (including temazepam) that are presented for dispensing in the community (but not in the hospital situation) must be written on a standard prescription form (PCD1) which must include the private prescriber's unique identification number.

To obtain a stock of the PCD1 prescription forms a prescriber must complete an application form and return this to the BSO. Regulation and Quality Improvement Authority is responsible for authorisation of all such applications. The BSO will issue a supply of PCD1 forms to a prescriber once authorisation has been obtained.

Private prescriber identification number

Prescribers who issue private prescriptions for Schedule 2 and 3 controlled drugs that will be dispensed by community pharmacists must have a unique prescriber identification number, namely a cipher number. Any prescriber requiring a cipher number should apply to the Business Service Organisation

Submission of prescription

The private PCD1 prescription forms must be submitted by the community pharmacist to the BSO. Veterinary prescriptions are not submitted to BSO and must be retained within the pharmacy. These should be brought to the attention of the pharmacy inspector during inspection visits.

Prescriptions for prisoners

The Northern Ireland Prison Service has historically used specially designed CD forms. The service has implemented a new system across the three prisons and is using computerised CD prescriptions.

Good practice for private prescribers ✓

The National Clinical Assessment Service (NCAS) and the former Northern Ireland Clinical and Social Care Governance Support team, <http://www.dhsspsni.gov.uk/sqsd-clinical-social-care-governance-support-services>, linked to the NHS Clinical Governance Support Team have suggested the following good practice for private prescribers:

Private prescribers should produce their own guidance for use in their services with respect to:

- treatment, prescribing and review policies
- clinical governance systems training and continuing professional development (CPD)
- These should be rooted in any relevant national good practice guidance, including 'Drug Misuse and Dependence: Guidelines on Clinical Management' published by the Department of Health, London in conjunction with the DHSSPS and other devolved administrations.

Good practice for private prescribers (contd)



Private prescribers should, in most circumstances and with the patient's agreement, contact the patient's private or Health Service GP before initiating treatment and during the course of treatment.

Private prescribers should, in most circumstances, liaise as appropriate with other health care professionals involved in the care of the patient. This should include the pharmacist / dispensing doctor.

Private prescribers should indicate on the prescription when prescribing for a non-UK resident

It should be noted that if a patient is receiving a controlled drug on prescription (either on the Health Service or privately) and then receives a second controlled drug from another prescriber without informing both prescribers that he is receiving a controlled drug from another prescriber, then an offence is being committed.

Section 8

Dispensing of Controlled Drugs

Overview

In this context, the term 'dispense' means to assemble and to supply a medicine (please note 'dispense' is not defined in legislation).

Legal framework for the dispensing of controlled drugs

Details of supplies of Schedule 2 controlled drugs must be entered into the CD register as soon as possible and at the latest the next day following the day of supply.

The date entered in the CD register must be the date of supply (i.e. the date on which the controlled drug is handed to the patient or patient's representative or healthcare professional) and not the date when it is assembled.

The pharmacist / dispensing doctor must endorse prescriptions for Schedule 2 and 3 controlled drugs with the date of supply to the patient, at the time of supply.

As with all dispensed medicinal products (except unlicensed medicines), it is a legal requirement to provide a manufacturer's patient information leaflet when medicines are supplied.

Dispensing a Prescription Originating from the EEA (and Switzerland)

Amendments made to *The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008* on 20 December 2010 now makes provision for pharmacists to dispense prescriptions issued by EEA doctors and dentists for Schedule 4 and 5 controlled drugs.

Pharmacists in Northern Ireland may **not** however dispense prescriptions for Schedules 1, 2 & 3 controlled drugs on the

basis of a prescription issued by an EEA doctor or dentist.

Pharmacists should be satisfied that they are in possession of sufficient information for the purpose of clinical governance and that the prescription is legally valid, before making supplies against EEA prescriptions

Amendments have also been made permitting the emergency sale or supply of Schedule 4 and 5 controlled drugs (not including phenobarbital – S3) where this is pursuant to a request by a doctor or dentist from an EEA country or Switzerland, or their patient, and the normal emergency supply provisions apply.

Further guidance can be accessed at: www.psn.org.uk/documents/589/Dispensing+European+Economic+Area+prescriptionsJuly2010.pdf

Good practice



Signing for the collection of a controlled drug prescription

There is a best practice requirement (not a legal requirement) for patients, or other people collecting Schedule 2 and 3 controlled drugs on their behalf, to sign for them as confirmation of their collection. This applies to both health service and private prescriptions. Patients or their representative will be asked to sign the back of the prescription on collection of the above dispensed medicines.

See page 65 for further information about proof of identity.

If a prescription for a controlled drug is handed in for dispensing, but is not due to be collected until a future date or time, the prescription can be assembled in advance. However, details should not be entered in the CD register until after the controlled drug has been supplied to the patient or patient's representative or healthcare professional.

Good Practice (contd)



It is good practice for a second person to check the quantity / volume and strength of a controlled drug being dispensed, although this may not be practical in all situations.

As with all prescribed medicines, dispensers should ensure that controlled drugs are normally dispensed in child-resistant containers, or with child-resistant closures. Advice to patients, their representatives or carers should include safe and secure storage at home, especially out of sight and reach of children, and safe disposal by returning any unused controlled drugs to a pharmacy.

Potential change



The Fourth Report of the Shipman Inquiry recommended the introduction of a patient drug record card (now known as a Controlled Drug Record Card [CDRC]) to complete the audit trail for Schedule 2 injectable controlled drugs.

The DH, following a number of pilots, is considering how the CDRC could potentially be implemented in practice.

Dispensing against substitute prescribing instalment prescriptions: SP1 and SP2

Legal framework

For instalment prescriptions of Schedule 2 controlled drugs, each supply must be entered, on the day of supply or the next day following, into the relevant section of the CD register. 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, unless specific wording is included on the prescription.

The Standard General Medical Services Contract NHS (General Medical Services Contract) Regulations 2004 specify only a sufficient quantity of drugs as will provide treatment for not more than 14 days can be prescribed on NHS instalment prescriptions. www.dhsspsni.gov.uk/ni_contract_mar04.pdf

Validity of prescriptions

Prescriptions for schedule 2, 3 and 4 controlled drugs are valid for 28 days. The 28-day period starts on the appropriate date entered on the prescription form. This date will be the date of signing or the date specified by the prescriber on the form. The first instalment must be dispensed within the 28-day limit, with the remaining instalments dispensed in accordance with instructions.

Good practice



- Where appropriate, shared care arrangements for the prescribing and dispensing of controlled drugs for substance misusers, should be developed. These are outlined in Northern Ireland Guidelines on Substitution Treatment for Opiate Dependence (February 2004) www.dhsspsni.gov.uk/niguide_substitute_treatment.pdf. Additional information is also provided by "Drug Misuse and Dependence: UK Guidelines in Clinical Management" www.nta.nhs.uk, known as the "Orange Guide".
- If an instalment prescription for a controlled drug is presented, then it should be stamped with the pharmacy / dispensing practice address at the time of the first dispensing. This is 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 when they present for their medicine. The pre-assembled methadone must be stored in a cabinet which meets the legal requirements (see page 73), or be under the direct personal supervision of the pharmacist / doctor.

Section 8

Good practice	✓
<p>If the patient does not collect the instalment, it can be returned to stock, provided it is labelled appropriately as stock, e.g. with batch number and expiry date. Where controlled drugs 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.</p>	
<ul style="list-style-type: none">• Pharmacists dispensing controlled drugs to substance misusers should liaise with the prescriber regarding collection / non-collection of the controlled drugs by these clients.• Patients receiving methadone, diazepam and buprenorphine 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.• The signing of the prescription and the requirement to ascertain that the person collecting is the patient, the patient's representative or a healthcare professional acting in his capacity on behalf of the patient applies the first time the person presents for the prescription. It is at the discretion of the pharmacist to decide if they wish to continue to make the supply where no identification is available. If this course of action is taken, particular care must be exercised when dealing with substitution patients and the associated risk of diversion.• Each pharmacist must ensure that the prescription instalment is supplied to the correct individual.	

Dispensing of Controlled Drugs

Good practice	✓
<ul style="list-style-type: none">• In relation to patients being treated for addiction the patient should, where possible, collect the controlled drug in person. If they are unable to collect prescriptions in person, they are permitted to arrange for a representative to collect it. Where a third party collects a drug, although not a legal requirement, it is good practice that a letter of authorisation from the drug misuser is obtained on every occasion that the named representative collects the medicine and that the letter is retained in the pharmacy. Pharmacists must of course, be satisfied that the letters of authorisation are genuine and should be wary of patients who are using many different agents. It is recommended that this letter is retained for a period so that comparison of signatures can be made.• Such 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. The person collecting may then be asked to sign in a record book. It is at the pharmacist's discretion whether to supply to another person, if for any reason the pharmacist is concerned the request is not genuine.• If a patient regularly sends a third party to collect the supply, it is recommended that the pharmacist notifies either the clinic where the substance misuser is being treated, or the prescriber.	

'Owing' prescriptions for controlled drugs

Legal framework

If the pharmacist or dispensing doctor is unable to supply the total quantity of the drug requested, the entry made in the CD register 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 must be endorsed with the amount dispensed. It is good practice to record the reason why the remainder was not dispensed, e.g. the patient has died.

Dispensed items or owings for Schedule 2, 3 or 4 controlled drugs cannot be supplied more than 28 days after the appropriate date on the prescription. Good practice would suggest that the person collecting the prescription is informed that unless the remainder is collected by a specified date (i.e. 28 days from the appropriate date) then it cannot be supplied.

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. Where a prescription requires a specific quantity of controlled drugs to be dispensed on a specific date, the dispenser is not authorised to dispense a part of this quantity and then the rest at a later date, as this would deviate from the prescriber's 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.

Dispensing Doctors

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 for Dispensing Doctors



The practice (and partners) carries vicarious liability for errors made, or for any breach of the law. A dispenser or other dispensing doctor employee would not normally be expected to dispense a Schedule 2 or 3 controlled drug without first checking the dispensed items with a doctor.

The Dispensing Doctor's Association's Guidelines for dispensing doctors state that 'the doctor should check all prescriptions for controlled drugs'.

Updated guidance on managing the use of controlled drugs is available from the Dispensing Doctor's Association www.dispensingdoctor.org/

Section 9

Recording of Controlled Drugs

Overview

This section applies to all CD registers, whether held by a doctor, a pharmacist or other health care professional (personally or as part of the activities of an organisation).

Legal framework

Records for Schedule 2 controlled drugs must be kept in a CD register. This is not a legal requirement for Schedule 3, 4 or 5 controlled drugs.

All health care professionals who hold personal controlled drug stock must keep their own CD register, and they are personally responsible for keeping this accurate and up-to-date.

Changes were introduced on 1 February 2008 and instead of the previously prescribed format, the Regulations now require that certain headings must appear in the CD register and certain fields of information must be completed.

In the CD register, (or separate part of the register used for each class of drug), a separate page must be used for each strength and form of that drug. Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register.

Entries in the CD register must be recorded under the following headings:

- a. In respect of entries made for drugs obtained –
 - i. Date supply received.
 - ii. Name and address from whom received.
 - iii. Quantity received.

- b. In respect of entries made for drugs supplied
 - i. Date supplied.
 - ii. Name/Address of person or firm supplied.
 - iii. Details of authority to possess – prescriber or licence holder's details.
 - iv. Quantity supplied.
 - v. Person collecting Schedule 2 controlled drug (patient/patient's rep/ healthcare professional) and if a healthcare professional, name and address.
 - vi. Was proof of identity requested of patient/ patient's rep (Yes/No).
 - vii. Was proof of identity of person collecting provided (Yes/No).

These particulars are the minimum fields of information that must be recorded in the CD register. The regulations do not prevent additional related information being recorded that will help guarantee the integrity and accuracy of the audit trail.

The following may (not must) be recorded:

- Running balances.
- Prescriber identification number and/or the professional registration number of the prescriber (where known) and also the name and professional registration number of the healthcare professional supplying the controlled drug.

The following rules apply to the CD register. It must:

- Contain a separate page in respect of each strength and form of drug.
- Have the class, strength and form of the drug specified at the top of each page.

- Have the entries in chronological order and made on the day of the transaction or the next day.
- Have the entries made in ink or otherwise so as to be indelible or in a computerised form in which every such entry is attributable and capable of being audited and is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the NHS Act 1977.
- Not have cancellations, obliterations or alterations; corrections must be made by a 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.
- Be kept for a minimum of two years after the date of the last entry, once completed.
- Not be used for any other purpose.

Electronic controlled drug registers

As an alternative to a bound book, an electronic CD register may be used. The Regulations require that entries made in computerised CD registers must be attributable and capable of being audited. Electronic CD registers 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 to comply with the new requirements.

Full details of the requirements for computerised CD registers are available at the following weblink
www.opsi.gov.uk/Sr/sr2005/20050564.htm

Good practice for computerised controlled drug registers



If the CD register 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.
- Records should be regularly backed-up.

If practitioners operate from more than one set of premises and maintain a stock of Schedule 2 drugs on each premises, they must keep a separate register at, and for, each premises.

All health care professionals who hold personal controlled drug stock must keep their own CD register for any Schedule 2 controlled drugs that they possess, administer or supply, and they are personally responsible for keeping this accurate and up-to-date. This will provide a clear and identifiable audit trail. GPs should not have a shared controlled drugs stock or share a controlled drug register as there would be concerns about the legality of possession, onward supply and audit.

Dealing with discrepancies

SOPs should clearly define the action to be taken if a discrepancy arises in relation to controlled drug balances. Once resolved, a note should be made in the CD register correcting the discrepancy in the balance. It is also advisable to keep appropriate records of the action taken when discrepancies arise.

If the source of the discrepancy cannot be identified during the stock check, then a nominated member of the relevant

Section 9

organisation should be informed and a formal internal investigation undertaken. This process may include discussion with the relevant professional body, or external inspectors. The Accountable Officer should be informed of any concerns in relation to the management and use of controlled drugs. In certain cases, the police may also be informed.

Overages in liquid preparations

Discrepancies can arise with liquid controlled drugs as a result of manufacturer's overage, the measurement process or spillage. Such overage or loss of liquid preparations should be recorded and the running balance adjusted in accordance with organisational policy.

In dealing with discrepancies, be alert to the possibility of, or potential for, diversion. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialled by both the person making the spillage and the second person, if there is one. Spilled product should be treated as controlled drug waste; denatured and rendered irretrievable.

Common sources of error include:

- Un-entered purchases and / or supplies
- Running balance incorrectly calculated
- Not all stock counted during the audit (out of date stock, uncollected prescriptions)

Recording of Controlled Drugs

Good practice

✓

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

Maintaining a running balance of stock

Pharmacists and other health care professionals who supply controlled drugs should maintain a running balance of stock in their registers as a matter of good practice.

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

The running balance of drug remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals.

When any controlled drug subject to safe custody regulations passes its expiry date, it must be stored in the CD cabinet until an authorised person can witness its destruction. While awaiting destruction it is good practice to record the quantity of this stock in the CD register in brackets to highlight that it is out of date and thus not suitable for dispensing.

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

Good practice (cont'd)



Physical reconciliation with stock levels

The running balance recorded in the CD register should be checked with the physical amounts of stock at regular intervals. The decision on how often to carry out stock checks should be in line with any guidance from professional representative bodies and undertaken after a risk assessment has been carried out. Frequency of reconciliation may alter according to local circumstances but should form part of SOPs.

Wherever possible, two members of staff should check all stock received or removed, and both individuals should initial the entry in the CD registers, where the format of the register allows this.

It is good practice for a health care professional / registered manager or registered provider, when first taking over accountability for premises that hold controlled drug stock, and where they will be in regular attendance, to ensure the controlled drug stock levels are correct.

This primarily applies to:

- GPs holding controlled drug stock in the surgery
- Pharmacies
- Dispensing doctor practices
- Registered homes
- Independent hospitals, including hospices, without a pharmacy.

Where changeover of responsibility occurs very frequently, e.g., when multiple locums are required within community pharmacies or Out of Hours providers, it would be impractical to carry out stock checks at every changeover. SOPs for the reconciliation of physical stock with balances should define how often this takes place. If usage of controlled drugs is high, e.g. in drug and alcohol units, palliative care establishments, then stock checks should be carried out regularly and by different, suitably trained members of staff. The day-

Good practice (cont'd)



to-day responsibility for this task can be delegated under SOPs, to another appropriate, suitably trained, member of staff who is routinely present at the premises.

Ultimately, the decision on how often to carry out stock checks should be undertaken after a risk assessment has been carried out. The decision should also be in line with any guidance from the professional representative bodies. The accountability for maintaining the correct balance of controlled drug stock lies with the professional in charge and not with the person to whom they may delegate the day-to-day responsibility.

Preservation of records

Registers, requisitions and orders for controlled drugs must be preserved for two years. The MDR have been amended to allow the information contained in these records to be preserved in the original paper form, or in computerised form.

Standard operating procedures

The Regulations require AOs to ensure that his or her organisation (or a body or person acting on behalf of, or providing services under contract with, his or her organisation) has adequate and up-to-date SOPs in relation to the use of controlled drugs, including record keeping requirements. The DHSSPS has produced guidance to support this requirement which can be found at the link below

<http://www.dhsspsni.gov.uk/guide-sops-td-dgs-ni.pdf>

Section 9

Proof of identity: prescriptions for Schedule 2 controlled drugs

Legal framework

Patients or their representatives may be required to provide evidence of identity when collecting controlled drugs medication.

From July 2006, there has been a new requirement for persons asked to supply Schedule 2 controlled drugs on prescription 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, e.g. a friend, neighbour, or relative, the supplier:

- 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 signing of the prescription and the requirement to ascertain that the person collecting is the patient, the patient's representative or a healthcare professional acting in his capacity on behalf of the patient applies the first time the person presents for the prescription. It is at the discretion of the pharmacist to decide if they wish to continue to make the supply where no identification is available. If this course of action is taken, particular care must be exercised when dealing with substitution patients and the associated risk of diversion.

Where possible patients should collect the controlled drug in person. If they are unable to collect prescriptions in person, they are authorised to arrange for a representative to collect it. However, when supply is for treatment of a drug misuser, it is advisable to obtain a letter of authorisation from the drug

Recording of Controlled Drugs

misuser before making a supply to his agent. Pharmacists must of course, be satisfied that the letters of authorisation are genuine and should be wary of patients who are using many different agents. A separate letter of authorisation should be obtained on each occasion a supply is made to the agent, and retained for a period so that a comparison of signatures can be made.

Such 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 controlled drugs, since they are not the person for whom it was intended - otherwise they are in unlawful possession. It may also prevent misunderstandings or deceit. The person collecting may then be asked to sign in a record book. It is at the pharmacist's discretion whether to supply to another person, if for any reason the pharmacist is concerned the request is not genuine.

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 patient is being treated, or the prescriber

Health care professional

Where the person collecting the prescription is a health care professional acting in his professional capacity on behalf of the patient, the supplier:

- Must obtain that person's name and address;
- Must, unless he is acquainted with that person, request evidence of that person's identity; but
- May supply the drug even if he is not satisfied as to the identity of that person.
- The new requirement placed on the supplier, therefore, allows discretion not to ask patients or patient 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.

From 1 February 2008, it is a requirement to record the following information in the CD register for Schedule 2 controlled drugs 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 supplier did not ask may be included but this is not mandatory); and
- Whether evidence of identity was provided by the person collecting the drug.

Accepted forms of identification

It is good practice to record information to support the proof of identity requirements outlined.

The form of identification for health care professionals should be proof of membership of their professional organisation e.g. GMC registration card.

Types of ID that may be considered suitable include:

- Proof of professional membership for a healthcare professional
- Driving licence (both paper and photo card section)
- Any official photo ID
- Passport
- Cheque guarantee, debit or credit card
- Birth / marriage certificate

- Cheque book
- Utility bills (two different ones but NOT mobile phone statement)
- Pension or benefit book
- Recent bank or building society statement (within last 6 months)
- Bank or building society book
- Store charge card (not a loyalty card)
- National savings book
- Household bills including Northern Ireland rates bill.

Delivery schemes

It is recommended that, 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, this is documented.

Wherever possible a signature should be obtained indicating safe delivery of medicines. The Pharmaceutical Society of Northern Ireland has published guidance for Pharmacists in Northern Ireland on the Provision of Prescription Collection and/or Delivery Services which is available at www.psni.org.uk

'Doctor's bag'

A practitioner is responsible for ordering, receiving and supplying controlled drugs for their stock. This stock will be used within his practice. Such stock must be requisitioned using the HS21S form, or private requisition form, as appropriate, and the practitioner must maintain a CD register for all movement of stock.

Section 9

Recording of 'patient-returned' controlled drugs

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

Legal framework

Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 require SOPs to be in place for maintaining a record of Schedule 2 drugs that have been returned by patients.

Good practice practice in recording of "patient-returned" controlled drugs ✓

It is good practice for pharmacists and doctors to keep a separate book to record all controlled drugs returned by patients. Although it is not a legal requirement to witness destruction of 'patient-returned' controlled drugs by an authorised witness, good practice would recommend that the destruction is witnessed by another competent member of staff. The signatures of both the person witnessing and the person destroying should be entered in a separate book set aside for this purpose (see section on 'patient-returned' controlled drugs, page 70).

Recording of Controlled Drugs

Recording of expired controlled drugs stock

If controlled drugs kept in a doctor's bag expire, they must be returned to a pharmacy for future destruction in the presence of an authorised individual. The appropriate records must be made in the doctor's CD register. The pharmacist should record the receipt of the controlled drugs in the purchase section of the CD register as received for destruction and take care to store any such stock separately in their CD cabinet.

Potential change ✓

Amendments may be proposed to the MDR to impose a new requirement to witness destruction of returns of controlled drugs from patients. This requirement will not be introduced until the pilot of the concept of a CDRC has been evaluated. At this point, further consultation will take place

Example of a compliant register format

Drug class¹ _____ Brand² _____ Strength _____ Form _____

Date	Obtained		Supplied						Balance ³
Date supply received or Date supplied ⁴	Name and address from whom received	Quantity received	Name/ address of person or firm supplied	Details of authority to possess – prescriber or licence holder’s details	Person collecting Schedule 2 controlled drug (patient/patient’s rep/healthcare professional) and if healthcare professional, name and address	Was proof of identity requested of patient/ patient’s rep (Yes/No)	Was proof of identity of person collecting provided (Yes/No)	Quantity supplied	

Note:

Drug class¹

With reference to CD registers the term “drug class” refers to the chemical entity. Morphine and diamorphine, for example, belong to different drug classes and records of their respective products must be made in a separate register or separate parts of the register.

Brand²

While there is no legislative requirement to maintain a separate page for each brand of drug, to do so will facilitate the maintenance of a running balance.

Balance³

Additional related information that will help guarantee the integrity and accuracy of the audit trail may be recorded in the CD register. There is no legislative requirement to maintain a running balance but the maintenance of a running balance is recommended as a matter of good practice. It is anticipated that running balances will become a mandatory requirement for all controlled drug registers when electronic registers are in common use.

Date supply received or Date supplied⁴

Entries in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages of the register

Section 10

Destruction of Controlled Drugs

Legal Framework

Controlled drugs held in stock

The term 'stock' refers to controlled drugs that have not been issued / supplied to a patient. The possession, storage and destruction of controlled drugs stocks are governed by the MDA and MDR as amended.

Those health care professionals and service providers required by law to maintain a CD register are not allowed to destroy expired Schedule 1 or 2 controlled drugs from their stock without destruction being witnessed by an authorised person.

Recording

When a controlled drug is destroyed, details of the drug must be recorded in the CD register. This must include:

- the name of the drug
- form
- strength and quantity
- the date it was destroyed
- the signature of the authorised person who witnessed the destruction of the professional destroying it (i.e. two signatures).

Persons currently authorised to witness the destruction of controlled drugs

Regulation 27 of the MDR enables the DHSSPS to specify groups of people who are authorised to witness the destruction of stock and the DHSSPS has appointed a number of authorised persons.

If controlled drugs kept in a doctor's bag expire, they should be returned to a pharmacy for destruction in the presence of an authorised witness. The appropriate records must be made in the doctor's CD register. The pharmacist must record the receipt of the controlled drugs in the purchase section of the CD register as received for destruction.

Methods of destruction

Controlled drugs must be rendered irretrievable prior to onward safe disposal. Guidance on disposal of controlled drugs is available in General Legal Requirements - A guide for pharmacists in Northern Ireland 2010 Edition - Medicines for Human Use (Part 2) Controlled Drugs

Environmental Protection

Discarded or out of date medicines are “clinical waste” under the Controlled Waste Regulations (Northern Ireland) 2002. Those from households should be returned to a local pharmacy for disposal. The disposal of such medicines should be carried out in accordance with guidance issued in Handling and Disposal of Pharmaceutical Clinical Waste (Health Estates 2002).

www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf

Further guidance on the disposal of injectable controlled drugs by healthcare staff while working in domestic settings can be found in Section 13

Good practice



Storage of expired stock supplies of controlled drugs in registered pharmacies

When any controlled drug subject to Safe Custody Regulations passes its expiry date, it must be stored in the CD cabinet until an authorised person can witness its destruction. These medicines should be segregated and clearly marked as ‘date-expired’ stock to prevent them being issued in error to patients.

While awaiting destruction it is good practice to record the quantity of this stock in the CD register in brackets to highlight that it is out of date and thus not suitable.

The authorised person should sign the entry in the CD register recording details of destruction including drug name, form and strength, quantity of drug to be destroyed and date of destruction.

Patient-returned controlled drugs

These are often known as ‘patient returns’ and are controlled drugs that have been prescribed for and dispensed to a named patient, in the hospital or community, which are no longer required and then returned to a doctor or pharmacist, unused or part-used, for destruction.

Health care professionals should be aware that professional guidance strongly recommends that medicines returned from patient stocks should NOT be re-issued or used to treat other patients.

Controlled drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an authorised person.

Doctors, nurses and midwives may come into contact with controlled drugs in a patient’s home that are no longer required e.g. quantities of tablets or medication within syringe drivers. It should be emphasised that controlled drugs are the property of the patient and only in exceptional circumstances should a nurse remove controlled drugs from the patient’s home for disposal. In general, a patient or their representative will return the unused medication to a pharmacy for destruction. If the doctor, nurse or midwife assesses potential risks in the storage of medication no longer required within the home or is aware of potential misuse by family members they may remove medication for disposal in accordance with local guidance. In such circumstances healthcare professionals should follow strict local protocols which have been approved by the Accountable Officer and ensure that a record of returns is made in the patient’s notes. See also Section 12 ‘Transportation of controlled drugs’

Pharmaceutical Society of Northern Ireland Code of “Ethics and Practice, a Guide for Pharmacists in Northern Ireland” prevents pharmacists reusing patient returns. A breach of this code could lead to disciplinary action.

Legal framework

While there is no requirement currently that 'patient-returned' Schedule 2 and 3 controlled drugs should be destroyed in the presence of an authorised witness, it is strongly recommended that doctors and pharmacists have the destruction of these returns witnessed by another competent member of staff (preferably by a registered health care professional). A record of the destruction should be made in a separate book set aside for this purpose. It is recommended that the following details are recorded:

- Date of return of the controlled drugs
- Name, quantity, strength and form of the controlled drugs
- Role of the person who returned the controlled drugs (if known)
- Name and signature of the person who received the controlled drugs
- Patient's name and address (if known)
- Names, positions and signatures of the person destroying the controlled drugs and the witness
- Date of destruction
- Any other comments relevant to the receipt or destruction of that particular dispensed medicine

Good practice in dealing with "patient-returned" controlled drugs ✓

Community pharmacies can accept controlled drugs returned by patients from their own homes for safe destruction and onward disposal even if they did not originally dispense them.

Controlled drugs can be placed into waste containers only after the controlled drug has been rendered irretrievable (i.e. by denaturing).

Wherever practicable, CD denaturing kits should be used to denature controlled drugs. Where this is not possible or practical other methods of denaturing may be used. Used denaturing kits should be placed in pharmaceutical waste bins that are destined for incineration. Regardless of the methods used, measures should be taken to ensure safety of personnel and non-contamination of the environment, and the disposal of such medicines should be carried out in accordance with guidance issued in Handling and Disposal of Pharmaceutical Clinical Waste (Health Estates 2002).

<http://www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf>

Section 11

Storage of Controlled Drugs

Overview

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

Legal framework

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 imposes controls on the storage of Schedule 2 and Schedule 3 controlled drugs. The Regulations apply to all Schedule 2 controlled drugs (except secobarbital) and the Schedule 3 drugs Buprenorphine, Diethylpropion, Flunitrazepam and Temazepam.

Schedule 2 of the Safe Custody Regulations fully applies to the storage of controlled drugs at community pharmacies. In Northern Ireland, all community pharmacies have time-delay safes for the storage of controlled drugs. These safes are granted annual certificates by the DHSSPS inspectorate under the Safe Custody Regulations. From 20 August 2007, nursing homes, as defined by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, have been subject to the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973.

Regulation 5 of the Safe Custody Regulations requires controlled drugs (other than those specifically exempted by that Regulation) to be kept in a locked receptacle which can only be opened by the person to whom the Regulation applies (or a person authorised by him / her). The exceptions to this are drugs prescribed to persons for treatment purposes and carriers (including the Post Office).

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern

Ireland) 2009 specify that arrangements for controlled drug storage must be covered within SOPs.

Good practice for storage of controlled drugs



If a safe is used to store controlled drugs, then there should be a separate receptacle within the safe that keeps the controlled drugs apart from other items, e.g. money or valuables. Nothing should be displayed outside to indicate that controlled drugs are kept within the safe.

The room housing this safe should be lockable and tidy, to avoid drugs being misplaced. This room should not normally be accessible to patients, nor should the keys required for access. However, if patients do have to enter the area where controlled drugs are stored, it is good practice that they should be continuously supervised until such time as they leave the area.

One designated person within the premises should take overall responsibility for the keys / codes. The number of sets of keys to the CD 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 CD cabinet and should never be accessible to unauthorised persons. The cabinet should only be opened by the designated person, or by a person authorised by them, e.g. a locum. The designated person remains ultimately accountable for the management of the controlled drugs.

Other drugs that are liable to misuse can be locked in the cabinet if the relevant health care professional deems this appropriate

Good practice for storage of controlled drugs ✓

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 controlled drug stock held within any type of premises, the CD register should be stored securely outside the CD receptacle. As the register contains confidential information, access should be restricted to those who make entries in it or are authorised to inspect it.

All controlled drugs should be stored out of sight and reach of children.

It is recommended that patients be advised of the importance of safe and secure storage of all drugs and in particular controlled drugs in their own homes. In circumstances where a risk is identified by health professionals, patients should be advised regarding the use of lockable secured receptacles with appropriate arrangements for access to keys.

For further information on registered homes, please refer to Section 15.

Good practice for storing controlled drugs in a doctor's bag ✓

For a bag for home visits or to take away from the surgery a digital combination lock on a case is often the most practical and convenient solution and avoids problems with keys. Bags containing controlled drugs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods.

Many doctors only use the controlled drug 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.

Normally, only one strength of each controlled drug should be kept in a doctor's bag in order to minimise the risk of confusion, error and inappropriate administration. Oral preparations of controlled drugs would not routinely be considered essential items to be carried in such a bag.

Each professional should also assess the risks and benefits in relation to where they store controlled drugs and registers in relation to each other. A balance has to be achieved between having the CD register readily available to make an entry at the time of administration, and the possibility of the bag and the register both being stolen, with the consequent loss of both the controlled drugs and the audit trail.

Controlled drugs in a 'doctor's bag'

Legal framework for storing controlled drugs in a doctor's bag

A 'doctor's bag' is a locked bag, box or case for home visits or use away from the surgery, 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 controlled drugs, but an unlocked bag in a locked car is not.

The majority of GPs Out of Hours services are managed by an organised provider of e.g. a GP cooperative or a deputising service.

Refer to page 93 for information on managing Out of Hours Services.

NPSA Guidance



Guidance to protect patients from harm in respect of prescribing, dispensing and administering opioid and opiate (hereafter opioid) medicines has been issued by the National Patient Safety Agency (NPSA). These specify actions that are designed to reduce human-factor error.

In Northern Ireland, the guidance is managed by the DHSSPS and, where appropriate, issued to relevant organisations for their action. Organisations are required to notify the implementation status of NPSA guidance by a specified date to the relevant Trust, which then provides an assurance through the HSC Board to the DHSSPS that the relevant action has been taken. See Appendix 6 for further details

Section 12

Transportation of Controlled Drugs

Legal framework

All health care professionals in legal possession of a controlled drug have a professional duty of care to take all reasonable steps to maintain safe custody of that controlled drug at all times.

Nurses, midwives, doctors, pharmacists, pharmacy staff and other health care professionals, plus formal carers and patients' representatives, are legally allowed to transport controlled drugs to a patient, provided the controlled drugs have been prescribed, by an appropriate prescriber, for that patient.

The person authorised to possess a controlled drug may grant permission to a nominated individual, which should be in writing, to allow them to return controlled drugs from the patient to the pharmacy, or the practice, for destruction.

Although it is recommended that healthcare professionals do not routinely return controlled drugs that are no longer required to a pharmacy on behalf of patients, there may be certain exceptional circumstances where this is considered appropriate, for example, when there is a greater risk by leaving the controlled drugs in the patient's home. In the event that the healthcare professional deems that it is in the interests of patient and public safety that the drugs should be returned to a pharmacy for disposal, then this must be done in accordance with local policy which has been approved by the Accountable Officer. A record of this should be made in the patient's notes and this record countersigned by the pharmacist to whom they have been delivered for destruction

Good practice



Health care professionals involved in the delivery of patient care should not routinely transport a patient's own controlled drugs to and from that patient's home. Where this is essential, part of an organised service, or where pharmacies operate collection and delivery schemes to the housebound and other such patients in need, it is good practice to keep the controlled drugs secure and out of view during transit and to have a robust audit trail to trace movement of the medicine from pharmacy to patient.

Community nurses and midwives should not routinely transport controlled drugs. This should only be undertaken in extenuating circumstances when:

- The patient has no main carer to collect or return the controlled drugs on his/her behalf and no pharmacy delivery or collection service is available.
- The patient requires immediate symptom relief

In such exceptional situations, the community nurse/midwife's first response must be to act in the best interest of the patient (NMC (2008) The Code Standards of conduct, performance and ethics for nurses and midwives). The nurse / midwife must review the patient's plan of care and take action to reduce the likelihood of further supply problems. Further guidance for nurses and midwives in relation to returning patient's own controlled drugs can be found Standard 26 of the NMC 'Standards for Medicines Management'

NB Sections 46-56 within Standard 26 provide guidance which is specific to midwives.

Good practice (cont'd)

Prescription forms for Schedule 2 controlled drugs should not routinely be sent to the patients' pharmacy via the postal system, but should be collected from the surgery by a health care professional, a member of their staff, the patient or their representative. However, prescriptions for the treatment of drug addiction are routinely sent to pharmacies, as it is not always practicable for the pharmacist to collect prescriptions from practices that may be some distance away. In addition, it is not always desirable for the prescription to be handed to the patient directly. Good practice would suggest that if prescriptions are transferred by post they should be sent by special delivery item and annotated with the pharmacy details at the point of issue.

If transport of controlled drugs or CD prescriptions via mail, taxi services or equivalent has to be used an SOP should be developed which reflects a risk management assessment and maintains patient confidentiality.

Section 13

Nurses Working in the Community

Administration

Legal framework

Nurses are authorised to administer controlled drugs to a patient in their care, as long as they are acting in accordance with the directions of a doctor or dentist, supplementary prescriber acting within the terms of a clinical management plan, or a nurse independent prescriber, prescribing from the controlled drugs listed in the table on Appendix 7 for the medical conditions specified.

Midwives are authorised to administer diamorphine, morphine and pethidine to their patients, acting on their own professional judgement.

Any controlled drug that is administered by a nurse must be recorded in the nurse's and patient's notes, stating the medicine and dose administered, the date of administration, the method of administration and the person who administered it. If a unit dose e.g. an ampoule is part used and deliberately wasted, this amount should also be recorded in the notes.

Good practice



Administration on a verbal instruction

The NMC has published 'Standards for Medicines Management', which includes guidance on controlled drugs

Remote prescription or direction to administer

The NMC guidance confirms that instructions received by fax, text message or email to change the dose of a controlled drug are **not** permitted

Transportation

Legal framework

Nurses may transport controlled drugs, where patients or their carers / representatives are unable to collect them, provided the nurse is conveying the controlled drug to a patient for whom the medicine has been prescribed, e.g. from a pharmacy to the patient's home

The NMC provide guidance for nurses and this is covered in Standard 7 in their 'Standards for Medicines Management'

<http://www.nmc-uk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf>

SOPs should be developed locally to cover this activity.

Good practice



Nurses should not routinely transport controlled drugs. This should only be undertaken in circumstances where there is no other reasonable mechanism available. Controlled drugs should be kept out of sight during transportation.

Disposal / destruction of controlled drugs

Good practice



Controlled drugs no longer required

– see also Section 10 'Destruction of controlled drugs'

Prescribed drugs including controlled drugs are the property of the patient. However, any controlled drugs remaining after a patient dies cannot pass into the legal possession of anyone else except for destruction or transport to a doctor or pharmacist for destruction

Good practice (cont'd)

The NMC provides guidance for nurses and this is covered in Standard 21 in their 'Standards for Medicines Management'

<http://www.nmc-uk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf>

It should not normally be the responsibility of community nurses to become involved in the disposal of unwanted controlled drugs. However, there may occasionally be exceptional circumstances when it is appropriate for nursing staff to become involved in recovery or disposal of controlled drugs.

If return by relatives / next of kin is not practical or possible then, in these exceptional circumstances, the following action could be taken in the interests of patient and public safety and in accordance with local policy

The nurse could take controlled drugs to a local community pharmacy, where the pharmacist would be asked to countersign the patient's nursing record.

Please note that Standard 26 'Controlled Drugs' of 'Standards for Medicines Management' states that, in relation to midwives, controlled drugs obtained by a woman on prescription from her doctor, for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required, they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction. In the event that the midwife deems that, in the interests of patient and public safety and in accordance with local policy which has been approved by the Accountable Officer, she should return the drugs to a pharmacy for disposal then a record of this should be made in the patient's nursing record and this record countersigned by the pharmacist to whom they have been delivered for destruction.

In circumstances where it is necessary to dispose of the unused contents of an ampoule or syringe, the following guidance is provided.

Controlled drugs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used.

All CDs in Schedule 2, 3 and 4 (part I) can be placed into waste containers only after the controlled drug has been rendered irretrievable (i.e. by denaturing). This may be done by using commercially available denaturing kits or by placing the controlled drug liquid on absorbent material (e.g. paper towels on to which a little soap has been added). This is then placed in the relevant bin to be disposed of by incineration via the usual waste disposal methods for medicines.

Where this is impractical, subject to local policy, injectable controlled drugs may be disposed as follows:

CDs in Syringe Driver: Healthcare staff providing healthcare services within a domestic setting may, subject to local policy (e.g. Trust policy), dispose of residual CD waste from a patient's syringe driver by disposal directly into the sewerage system at the patient's home.

Partially used injectable CDs: Healthcare staff providing healthcare services within a domestic setting may, subject to local policy (e.g. Trust policy), dispose of any remaining liquid in a part used ampoule by disposal directly into the sewerage system at the patient's home.

It is anticipated that volumes disposed by this route should not normally exceed 25mls. Volumes significantly greater than this should not be disposed by this route. Unopened ampoules and other controlled drug formulations, no longer required by the patient, must be returned for appropriate disposal in accordance with current guidance and good practice (see Section 10).

NB empty ampoules and syringes should be disposed of safely in burn bins according to local policy

This permission does not extend to cytotoxic or cytostatic medicines.

Please note that this arrangement may be subject to change in the light of regulatory changes, future Government guidance or technical information.

Section 14

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 controlled drugs can take place across a number of care settings and it is important that robust governance systems are maintained whilst ensuring that patients have appropriate access to medicines.

Good practice



It is good practice to prescribe only quantities of controlled drugs that are needed by the patient for effective symptom control. This can include controlled drugs for regular dosage, plus a quick-acting controlled drug at an appropriate dose for breakthrough pain. The good practice principles for managing controlled drugs described earlier in these guidelines apply equally when using drugs in palliative care.

Where prescribers are prescribing high doses of controlled drugs for palliative care, it is recommended that the specialist palliative care team be contacted for advice and support, wherever feasible. Any actions resulting from such a contact should be recorded in the patient's notes.

Prescribing advisers will routinely analyse prescribing data and contact a prescriber if they have concerns about the prescribing of a controlled drug over a prolonged period.

Palliative care patients may obtain controlled drug prescriptions from more than one source, e.g. GPs, hospices, hospitals, Out of Hours services and specialist palliative care teams. In such circumstances, one professional or key worker in the locality could take on a co-ordinating role to avoid over-supply and to help maintain patient and public safety.

Good practice (cont'd)



Additional sources of information:

Liverpool Care Pathway

www.mariecurie.org.uk/

forhealthcareprofessionals/liverpoolcarepathway.htm

Marie Curie Palliative Care Institute

www.mcpcil.org.uk

End of Life Care Pathway

www.endoflifecare.nhs.uk

National Council for Palliative Care

www.ncpc.org.uk

Out of Hours palliative care

Good practice



There are sometimes problems encountered with the availability of medicines for palliative care patients in the community during the out of hours period. To maintain effective symptom control in patients choosing to be treated at home, or in other care environments, it is important that health care professionals ensure sufficient quantities of appropriate palliative care drugs, including controlled drugs, are available to anticipate deterioration in the patient's condition. The potential needs of deteriorating conditions should be balanced with the safety risk of increased quantities of controlled drugs left in the domiciliary or care setting. For specific recommendations about the manner in which a patient-centred, high quality palliative care service can be provided out of ours, please refer to 'Securing proper access to medicines in the out of hours period' and the accompanying practical guide

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4134235

Good practice (cont'd)

Contact should also be made with local Pharmacy Palliative Care Networks and details of the network in a geographical area can be obtained by contacting the Pharmacy Department in the relevant legacy Board as listed below:

Eastern Health & Social Services Board
028 9032 1313
Northern Health & Social Services Board
028 2531 1000
Southern Health & Social Services Board
028 3741 0041
Western Health & Social Services Board
028 7186 0086

Self-medication

Good practice

If patients are self-medicating, whether in a hospice or hospital, their controlled drugs should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle or bedside locker should not be readily portable. In order to prevent unauthorised access, each receptacle should have an individual key, with a master key kept by the person in charge (on duty). Healthcare organisations may wish to consider the use of electronic patient medicine lockers accessed by means of programmable transponders. Such systems provide a high level of security and a clear record of who has accessed the locker and when.

Where patients are being treated in their own home, they should be provided with advice, support, information and on-going monitoring from the most appropriate professional to ensure that safety and efficacy is maintained.

Section 15

Registered Homes

Legal framework

Legislation governing nursing homes and residential homes has changed following the implementation of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

www.opsi.gov.uk/si/si2003/20030431.htm

There are two main types of registered home:

- Residential Care Homes: These homes are residential and they provide accommodation, meals and personal care
- Nursing Homes: These homes employ registered nurses who provide nursing care to patients with more complex needs.

Although this section primarily applies to nursing homes, much of the good practice also applies to other registered establishments such as residential and children's homes.

Regulation 13 of the Nursing Homes Regulations (Northern Ireland) 2005 and Regulation 13 of the Residential Care Homes Regulations (Northern Ireland) 2005 require registered providers to make suitable arrangements for the ordering, storage, recording, handling, safekeeping, safe administration and disposal of medicines used in or for the purposes of the home. Regulation 20 of the Children's Homes Regulations (Northern Ireland) 2005 requires registered providers to arrange for the recording, handling, safekeeping, safe administration and disposal of any medicines received into the children's home. These Regulations apply to all medicines including controlled drugs.

Supply

The method of supply for registered homes is by prescriptions for individual residents.

Receipt, storage and recording

Legal framework

- With effect from 20 August 2007, nursing homes, as defined by the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003 are subject to the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973.
- It is recommended that the specifications of cabinets and safes set out in Schedule 2 of the Safe Custody Regulations for the storage of controlled drugs should be regarded as a minimum standard in all residential and children's homes (as defined), for the storage of residents' controlled drugs with the exception of self-administered controlled drugs.
- In all types of registered home, residents who are responsible for storing and administering their own medication (as they would in their own home) do not need to use a CD cabinet.

For residents who are self-administering, the controlled drugs should be stored in a locked, non-portable receptacle in the resident's room. This also applies to any monitored dosage systems containing controlled drugs. There is no need to keep a record in the CD record book when the person is wholly independent and is responsible for requesting a prescription and collecting the controlled drugs personally from the pharmacy.

In addition to the records maintained on medicine administration record charts all registered homes should keep a record of controlled drugs in a controlled drug record book. If the person does not arrange the supply and collection of controlled drugs but relies on the care workers to do so, there should be clear records made in the CD record book including:

- Receipt in to the home.
- Supply to the person.
- Any subsequent disposal / transfer of controlled drugs.

This controlled drug record book should contain separate pages for each resident's medicines and should have a column for recording running balances in order to maintain effective control and identify any discrepancies.

In addition:

- The controlled drug record book should be used to record the receipt, administration and disposal of controlled drugs held in the registered home. Each drug, for each resident, should be recorded on a separate page, with the name, dose and strength of the drug written clearly at the top of the page. Where residents are self-administering, each individual dose taken does not need to be recorded
- When receiving a controlled drug from a pharmacist or dispensing doctor the date, name, form and strength of medicine and source from where it was obtained should be entered into the controlled drug record book. This should be initialled by the receiving nurse or authorised member of staff, with a second person as a witness. The correct balance should be verified each time
- When transferring the drug record to a new page in the controlled drug record book, the amount remaining should be identified with 'brought forward from page x' written clearly on the new page

- The controlled drug record book should include details of controlled drugs returned for disposal or the transfer of controlled drugs out of the home (where a resident is discharged from the home or transferred to another care facility).

Administration of controlled drugs

Good practice



- Where residents are not able to self-administer in a Nursing Home, a medical practitioner or a registered nurse should administer the controlled drugs. In Residential care homes, appropriately trained and competent care staff should administer controlled drugs. In both cases, administration of a controlled drug should be witnessed by a second designated member of staff.
- Reference should be made to relevant NPSA safety alerts relating to the administration of medicines (see Appendix 6)
- Staff administering medicines should do so in accordance with the prescriber's instructions
- Before administering the medicine, the nurse/trained carer should check the patient's identity, the personal medication record, medication administration record and medicine label. The dose should then be measured and checked with a competent witness.
- The resident's name, the date, time and route of administration and the dose given, should be recorded in the controlled drug record book immediately after the medication dose has been administered to the resident. The nurse/trained carer and the witness should also verify and record the remaining stock balance and sign the controlled drug record book.

Good practice (cont'd)	✓
<ul style="list-style-type: none"> The resident's medication administration record must also be completed by the nurse/trained carer and the witness. The administration process should be fully completed for each resident, before moving on to the next resident. 	

Disposal of controlled drugs

Legal framework for disposal of controlled drugs in registered homes

- Nursing and residential homes should not retain controlled drugs which have passed their expiry date, where the need for the prescription has ceased, or when the resident has died. Where a resident has died, supplies of all medicines for the resident, including controlled drugs must be kept for at least seven days, as they may be required as evidence for a Coroner's Inquest.
- Registered homes should record the forms and quantities of controlled drugs they are returning.
- Relevant details of any such transfer for disposal should be entered into the CD record book and signed by the authorised member of staff, transferring the drug for the purpose of disposal. The Regulation and Quality Improvement Authority recommend that the person receiving the controlled drug for the purpose of disposal sign the home's CD record book at the time of transfer.
- Where controlled drugs are returned to a resident on discharge or transferred to another care facility, registered homes should record the forms and quantities of controlled

drugs transferred out of the home in the CD register at the time of transfer. The record should be signed by the authorised member of staff transferring the drug and the resident or their advocate receiving them.

Dealing with discrepancies

Good practice	✓
<ul style="list-style-type: none"> Routine checks of all controlled drugs held, and the recorded running balances, should be carried out by two nurses (nursing home), or two authorised members of staff (residential home), on each occasion when responsibility for safe custody is transferred and a record kept Where a discrepancy is found, it should be reported immediately to the registered manager who should investigate promptly If the discrepancy cannot be accounted for, the Regulation and Quality Improvement Authority must be notified who will share the information as needed with the relevant AO. If the discrepancy is found to be an error of subtraction or addition in the calculation of a stock balance, the following procedure should be followed: <ul style="list-style-type: none"> Do not change the balance column or use correction fluid. Under the last entry, details of the following should be made: <ul style="list-style-type: none"> The date The error in subtraction / addition (indicated with an asterisk) The correct balance The signature of the nurse / member of staff and the witnessing nurse / member of staff. <p>If, following these steps, the controlled drugs appear to have gone missing, then all relevant people, including the police, must be notified.</p>	

Section 16

Ambulance Services

Legal framework

Paramedics Engaged by and Under the Control of the Northern Ireland Ambulance Service HSC Trust (NIAS)

The Accountable Officer appointed by the NIAS is responsible for the management and use of controlled drugs which includes their safe storage, supply and destruction. Consideration should be given to a regional approach to the governance arrangements around transport and handing-over of a patient's drugs.

The DHSSPS has licensed registered paramedics engaged by and under the control of the Northern Ireland Ambulance Service HSC Trust (NIAS) to possess and supply diazepam and morphine for the purposes of administration for the immediate necessary treatment of sick or injured persons in accordance with the Prescription Only Medicines (Human Use) Order 1997. Requirements for safe custody and record keeping apply.

Paramedics NOT Engaged by and Under the Control of the Northern Ireland Ambulance Service HSC Trust (NIAS)

Private paramedics seeking to possess diazepam or morphine for use in their professional practice in Northern Ireland must apply to the DHSSPS for an individual licence. Requirements for safe custody and record keeping apply.

Further information can be found on the DHSSPS's website

<http://www.dhsspsni.gov.uk/index/pas/pas-lie/pas-controlled-drug-licensing/paramedics.htm>

Section 17

Educational Establishments

There is a need for effective management of the administration and safekeeping of controlled drugs for individual pupils in educational establishments, e.g. methylphenidate. Any policies pertaining to controlled drugs taken into educational establishments should aim to minimise the risk to children and staff, whilst allowing pupils' medication requirements to be met with minimum bureaucracy and fuss.

Good practice



All schools should have a medicines policy. It is the responsibility of the employing authority to ensure that these are in place.

A guidance document "[Supporting Pupils with Medication Needs](#)" has been written by the Departments of Education and Health, Social Services and Public Safety, in consultation with the Education and Library Boards, the Council for Catholic Maintained Schools, a range of education and health professionals and the Teachers' Unions.

This guidance includes a specific section on controlled drugs, with the following points

- Any member of staff may administer a controlled drug to the pupil for whom it has been prescribed, provided they have received appropriate training.
- Staff administering medicines should do so in accordance with the prescriber's instructions.
- A pupil who has been prescribed a controlled drug may legally have it in their possession. It is permissible for schools and settings to look after a controlled drug, where it is agreed that it will be administered to the child for whom it has been prescribed.

Good practice (cont'd)



- Schools and settings should keep controlled drugs in a locked non-portable container and only named staff should have access. A record should be kept for audit and safety purposes.
- A controlled drug, as with all medicines, should be returned to the parent when no longer required to arrange for safe disposal (by returning the unwanted supply to the local pharmacy).
- Misuse of a controlled drug, such as passing it to another pupil for use, is an offence. Schools should have a policy in place for dealing with drug misuse (DE Circular 1996/16: Misuse of Drugs : Guidance for Schools <http://www.deni.gov.uk/2004-13.pdf>)

Whenever possible, dosing regimens should be designed to allow medicines to be taken outside school hours. Any increase in costs associated with longer acting formulations should be balanced against potential benefits related to the safer management of controlled drugs. For some patients 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. Medicines prescribed for an individual must not be administered to another child.

Controlled drugs are also prescribed for young people in boarding schools, residential special schools and secure children's units. The RQIA is currently responsible for monitoring and inspecting the standards in these establishments.

Section 18

Overseas Travel

Legal framework

With effect from the 1 January 2008, only those persons travelling for over three months and carrying controlled drugs require a personal licence. A list of the most commonly held controlled drugs can be found at www.drugs.gov.uk.

Licence

Personal import / export licences will only be issued to travellers carrying controlled drugs abroad (or into the UK) for periods exceeding three months.

Licences are normally issued with an expiry date of one week after the expected return to the UK (or one week after the expected date of departure from the UK in the case of an import licence.)

A personal licence has no legal standing outside the UK and is intended to allow travellers to pass through UK customs unhindered.

Some countries have their own importation regulations for controlled drugs. It is recommended that travellers contact the Embassy in a particular country to check the regulations in force.

Personal licence application forms can be downloaded from <http://www.homeoffice.gov.uk/drugs/licensing/personal/>

Application forms 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 medicine(s) — name, daily dose prescribed form, e.g. tablets, strength and total quantity to be carried.

Home Office contact details regarding overseas travel licences:

Licensing Section
Drug Licensing and Compliance Unit,
4th Floor, Peel Building
2 Marsham Street
London SW1P 4DF

Direct Line: 020 7035 0475

Fax: 020 7035 6161

Email:

licensing_enquiry.aadu@homeoffice.gov.uk

Full guidance on personal exports is available at

www.drugs.homeoffice.gov.uk/drugs-laws/licensing/personal/

Good practice



If you are travelling for less than three months and you are carrying less than three month supply, you will not need a personal import or export licence to enter or leave the United Kingdom. You are advised to obtain a letter from your prescribing doctor or drug worker, which should confirm your name, travel itinerary, names of prescribed controlled drugs, dosages and total amounts of each to be carried.

Controlled drugs should be transported as follows:

- Carried in original packaging
- Carried in hand luggage
- Carried with a letter from the prescribing doctor confirming the carrier's name, destination, drug details / amounts

Check with the relevant embassy / consulate to enquire about any restrictions in the country/countries to be visited. Home Office link to embassy list.

It is recommended that patients check with the airline and airport prior to travel as security arrangements may change at any time; for example, restriction on volume of liquids.

- The BMA has also issued guidance around prescribing of all medicines for patients going abroad
- The Board would not currently recommend that GPs prescribe more than 3 months treatment and, in the event that travel is for a period greater than 3 months patients are advised to make alternative arrangements for medical care

See:

http://www.bma.org.uk/health_promotion_ethics/drugs_prescribing/InfoOnPrescribing0904.jsp?page=2

Section 19

Out of Hours

Good practice	✓
<p>Throughout Northern Ireland, Out of Hours Centres operate independently of each other and have separate protocols in place for managing the supply arrangements for medicines in an out of hour's medicines service.</p> <p>In general, controlled drugs are not included in the formulary of Out of Hours Centres and Doctors undertaking Out of Hours Services bring a supply of these drugs with them when they undertake a shift. Protocols are available for GPs not attached to a practice to obtain controlled drugs for use during Out of Hours sessions. This is closely monitored by the medical managers of the services.</p> <p>A palliative care network has been set up by the Board to facilitate the supply of controlled drugs to individual patients, where necessary, outside normal working hours. Each Out of Hours centre should ensure that they have up-to-date details of their local network.</p> <p>Out of Hours services should liaise with local substance misuse prescribing services, shared care monitoring groups and/or local Drug Action Teams, plus commissioners, to confirm and agree arrangements for drug misusers who contact the Out of Hours service requesting a prescription for an opiate substitute, such as methadone or buprenorphine. In such circumstances, it is generally inappropriate and potentially dangerous to commence prescribing an opiate substitute drug or to replace a lost, stolen or broken bottle or supply. A local SOP should be produced, in liaison with local specialist prescribers, as to how Out of Hours services should respond to ensure a consistent and fair treatment of patients.</p> <p>NPSA guidance applies to all sectors including Out of Hours provision.</p>	

Good practice	✓
<p>More information pertinent to Out of Hours services can be found elsewhere in this document:</p> <ul style="list-style-type: none">• Ordering controlled drugs (see page 35)• Recording of Controlled drugs (see page 61)• Storage of controlled drugs (see page 73)• 'Doctors' bags' (see page 66)• Palliative care (see page 81)	

Section 20

Controlled Drugs in Prisons

Legal Position

Prisons are not Designated Bodies in regulation and so are not required to appoint an Accountable Officer.

The South Eastern HSC Trust Accountable Officer has the responsibility to assure that the prison has suitable arrangements in place for the safe management and use of controlled drugs. How this happens in practice is for local determination.

Inspection

Prisons / Prison Health are subject to inspection by Her Majesty's Inspectorate of Prisons (HMIP). HMIP have an SLA with the GPhC who undertake the medicines inspection on their behalf. This includes controlled drugs, and the controlled drug element of the inspection report is sent as a matter of routine to the South Eastern HSC Trust Accountable Officer.

Controlled drugs must be used and managed in accordance with local CD policy and SOPs

Good practice



Purchasing and supply of controlled drugs

As prisons are not mentioned in legislation, the good practice guidance suggests that the healthcare professional in charge of the Healthcare Department in the prison takes responsibility for the day to day management of controlled drugs and that any requisitions for stock controlled drugs are countersigned by a medical prescriber employed or engaged at that prison. Controlled Drug requisitions for use within Northern Ireland Prison Service must be handwritten on prison specific forms.

Supply:

Currently controlled drugs are supplied to patients in prison on an individual patient prescription basis. The prison use prison specific prescription forms that are computer generated and signed by GPs/Consultants contracted to provide medical services to the prisons. Additionally a small quantity of controlled drugs is held as part of the emergency medicine stock supplies in the prisons. These are supplied to the prisons by the community pharmacy contractor against a CD requisition on prison specific forms and, if required for patient administration, they are prescribed on the patient's medical record.

Receipt of controlled drugs

For prisons, where there is no pharmacy on site, the most senior member of healthcare staff on duty at that time should sign for the controlled drugs on receipt, secure the drugs in the CD cabinet and make a record in the register. A copy of the delivery note should be returned to the supplying pharmacy.

Good practice (cont'd)**Discharge:**

Under the Prison CD Management policy patients in prison would not be routinely provided with controlled drugs on discharge from prison. For patients on opiate substitute prescribing treatment programmes the appropriate community addiction team would, as part of their discharge planning process, make arrangements for supply from the patient's designated community pharmacy. Where possible the patient receives their daily dose on the morning of release. For other patients in receipt of a CD prescription in prison, a risk assessment is carried out to determine if it is appropriate to supply the remaining quantity of their controlled drug to them at discharge. The risk of overdose and diversion would be taken into consideration. There is currently no provision within NI Prisons for a patient to receive a discharge controlled drug prescription for dispensing in a community pharmacy.

Recording

Although it is not a legal requirement to enter details of Schedule 3 controlled drugs in a register, it is strongly recommended that all prisons record details of any buprenorphine, or buprenorphine /naloxone medication, as for a Schedule 2 controlled drug, to ensure a robust audit trail. Additionally a record of each medicine administered should be made on the patient's individual patient administration record card.

All prison prescriptions/requisitions are sent to BSO for pricing under a private arrangement with the current pharmacy contractor supplying prisons in Northern Ireland. All forms are then returned to the contractor who retains these for a minimum of 2 years.

Good practice (cont'd)

The current Northern Ireland Prison Service (NIPS) CD Management Policy includes SOPs covering:

- Ordering
- Receiving and Storage
- Administration
- Record Keeping
- CD Stock Reconciliation
- Disposal
- Transfer of CDs between establishments

For controlled drug management in prison settings, we point toward the DHSSPS Guidance [Safer Management of Controlled Drugs Guidance-A Guide to Good Practice in Secondary Care](http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-guidance.htm)
<http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-guidance.htm>

Good practice (contd)

This guidance makes reference to regulations in a range of settings, which, for some, will be considered as a minimum standard and, on the basis of risk assessment; a higher level of security may be indicated. For those settings not included in the regulations, the same principles of risk assessment and safe and secure management apply.

Appendices

APPENDIX 1: Summary of legal requirements that apply to controlled drugs in Schedules 2, 3, 4 and 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations)	Schedule 2	Schedule 3	Schedule 4 Part1	Schedule 4 Part 2	Schedule 5
	Includes opioids, (e.g. diamorphine, morphine, methadone), major stimulants (e.g. amphetamines), remifentanyl, secobarbital	Includes minor stimulants, temazepam, diethylpropion, buprenorphine, midazolam flunitrazepam, Barbiturates except secobarbital	Includes benzo-diazepines	Includes anabolic steroids, clenbuterol, growth hormones	Includes low strength opioids
Designation	CD	CD No Reg	CD benz	CD anab	CD inv
Safe custody	Yes, except secobarbital	Yes with certain exemptions ¹	No	No	No
Prescription requirements (including handwriting ²) – apply to outpatient and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
Requisitions necessary	Yes	Yes	No	No	No
Records to be kept in CD Register	Yes	No	No	No	No
Pharmacist must ascertain the role of the person collecting the controlled drug(s)	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy	Yes*	Yes*	Yes*
Validity of prescription	28 days from the appropriate date	28 days from the appropriate date	28 days from the appropriate date	28 days from the appropriate date	6 Months (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	
Private prescription requirements	Yes	Yes	No	No	No

¹ Currently the four Schedule 3 that do require safe custody are temazepam, flunitrazepam, buprenorphine and diethylpropion

² Prescriptions for schedule 2 and 3 controlled drugs are permitted to be typed or computer generated but must be signed by the prescriber

* Up to a quantity sufficient for 5 days treatment

APPENDIX 2: Governance Arrangements and Settings

CD handling site	Governance arrangements
Board	<ul style="list-style-type: none"> • AO with responsibility for all aspects of safe and secure handling of controlled drugs • All controlled drug activity defined in SOPs • Member of the LIN
HSC Trusts	<ul style="list-style-type: none"> • AO with responsibility for all aspects of safe and secure handling of controlled drugs • All controlled drugs activity defined in SOPs • RQIA may require declaration and self-assessment • Member of the LIN
Independent hospitals	<ul style="list-style-type: none"> • All controlled drug activity defined in SOPs • RQIA may require declaration and self-assessment • Member of the LIN
Non-statutory prescribing drug services in community and inpatient (including residential) settings	<ul style="list-style-type: none"> • All controlled drug activity defined in SOPs • Commissioner of service to specify assurance
Private clinics, doctors and dentists	<ul style="list-style-type: none"> • All controlled drug activity defined in SOPs • RQIA may require declaration and self-assessment from those registered with them • For those not registered with the RQIA, the AO of the Board has the right of entry to investigate reported controlled drug concerns
Registered homes	<ul style="list-style-type: none"> • Inspection by RQIA Inspector • All controlled drugs activity defined in SOPs/policies and procedures • RQIA may require declaration and self-assessment • RQIA member of LIN • Individual duty to report concerns to the relevant AO
GPs	<ul style="list-style-type: none"> • Inspection by Board AO • All controlled drug activity defined in SOPs • Board may require Declaration and self-assessment • Individual duty to report concerns to the Board AO
Dentists with Health Service contracts	<ul style="list-style-type: none"> • Inspection by Board AO • All controlled drug activity defined in SOPs • Board may require declaration and self-assessment • Individual duty to report concerns to the Board AO
Prison service	<ul style="list-style-type: none"> • All controlled drug activity defined in SOPs • AO of SEHSCT has overall responsibility for management and use of CDs in prison setting.
Services commissioned by Board	<ul style="list-style-type: none"> • All controlled drug activity defined in SOPs • Commissioner of service to specify assurance
Community pharmacies	<ul style="list-style-type: none"> • Inspection of all aspects of controlled drug management by DHSSPS Inspectors • All controlled drug activity defined in SOPs • Declaration and self-assessment to DHSSPS • DHSSPS member of LIN • Individual duty to report concerns to the AO

APPENDIX 3: Monitoring Prescribing

Monitoring tools have been devised to allow HSCB Medicines Management Advisers to review the prescribing of controlled drugs in primary care. These tools allow identification of prescribers with unusual prescribing patterns for controlled drugs that may warrant further investigation.

Control charts produced by the COMPASS Unit in BSO have been developed to monitor Schedules 1, 2, selected Schedule 3 controlled drugs, strong analgesics, and hypnotics / anxiolytics which have been supplied on Health Service prescriptions and stock orders. In addition, with effect from April 2010, all private prescriptions and requisitions for controlled drugs (other than veterinary) are processed by BSO and will be monitored by HSCB.

The COMPASS reports are produced each quarter for every practice and contain a number of the control charts mentioned above. These CD control charts provide dispensing data on a wide range of controlled drugs across a number of formulations. The control charts use coloured dots as monitoring indicators to represent the level of CD prescribing for these specific drugs and formulations.

The monitoring indicators used are based on the mean of the prescribing of all GP practices in Northern Ireland.

- The red indicator represents prescribing that falls above the upper control limit. This represents the top 1% of prescribing which equates to approximately the top four practices in Northern Ireland. This is based on three standard deviations from the mean for each drug.
- The orange indicator represents prescribing that falls between the mean prescribing and the upper control limit.
- The green indicator represents prescribing that falls between the mean prescribing value and no prescribing.
- The white indicator represents no prescribing.

Practices with red or orange indicators are followed up by Medicines Management Advisers and asked to provide further information on their prescribing patterns for this drug(s). Special attention is paid to the reports of practices where CD prescribing restrictions are in place for GPs, and any unusual patterns followed up. Samples of CD prescriptions are also periodically reviewed to ensure that restricted GPs are not using the prescription pads of other partners in the practice

Prescribing data is reviewed in more detail using a range of tools including:

- Longitudinal charts and
- League graphs

Longitudinal charts

Longitudinal charts show the detailed prescribing patterns in a practice over the previous 2 years and are produced for all practices.

These charts indicate if high prescribing levels are a 'one-off' or historical and can identify the specific areas of high prescribing. They also assist with measuring the progress a practice makes in their attempts to reduce prescribing.

League graphs

League graphs show a practice's position in terms of prescribing a drug in relation to other practices in the legacy Board area.

Any concerns/queries identified which cannot be resolved are brought to the attention of HSCB Medical Advisers and, where appropriate, the Accountable Officer or Designated Officer(s).

APPENDIX 4: Useful Contacts

British Medical Association

BMA House
Tavistock Square
London, WC1H 9JP
Tel: 020 7387 4499
Website: www.bma.org.uk

Business Services Organisation

2 Franklin Street,
Belfast,
BT2 8DQ
Tel: 028 9032 4431
Website: <http://www.hscbusiness.hscni.net/>

Community practitioners' and Health Visitors Association

128 Theobald's Road
Holborn
London, WC1X 8TN
Tel: 020 7611 2500
Website: www.amicustheunion.org/cphva/

Council for Healthcare Regulatory Excellence

11 Strand
London
WC2N 5HR
Tel: 020 7389 8030
Website: www.chre.org.uk

Department of Health (England)

Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 0207 210 4850
Website: <http://www.dh.gov.uk>

Department of Health, Social Services, and Public Safety

Castle Buildings,
Stormont Estate,
Belfast,
BT4 3SQ
Tel: 028 9052 0500
Website: www.dhsspsni.gov.uk

Dispensing Doctors' Association

Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF
Tel: 01751 430835
Website: www.dispensingdoctor.org

Northern Ireland Environment Agency

Klondyke Building,
Cromac Avenue,
Gasworks Business Park,
Belfast,
BT7 2JA
Tel: 0845 302 0008
Website: www.ni-environment.gov.uk

General Medical Council

9th Floor Bedford House
16-22 Bedford Street
Belfast
BT2 7FD
Tel: 028 9031 9945
Website: www.gmc-uk.org/

Healthcare Inspectorate Wales (HIW)

Bevan House
Caerphilly Business Park
Van Road
Caerphilly
CF83 3ED
Tel: 029 2092 8850
Website: <http://www.hiw.org.uk/>

Health Professions Council,

Park House
184 Kennington Park Road
London
SE11 4BU
Tel: 020 7582 0866
Website: www.hpc-uk.org/

Home Office Drugs Licensing and Compliance Unit

Licensing Section
4th Floor, Peel Building
2 Marsham Street
London
SW1P 4DF
Tel: 020 020 7035 3731
Website: <http://www.drugs.homeoffice.gov.uk/drugs-laws>

Medicines and Healthcare products Regulatory Agency

Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 020 7084 2000
Website: www.mhra.gov.uk

**National Clinical Assessment Service
(part of the National Patient Safety
Agency)**

NCAS Northern Ireland Office,
Office Suite 2, Lisburn Square House,
10 Haslem's Lane,
Lisburn BT28 1TW
Tel: 028 9266 3241
Website: www.ncas.npsa.nhs.uk

National Patient Safety Agency

4-8 Maple Street
London W1T 5HD
Tel: 020 7927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association

38-42 St Peter's Street
St Albans
Hertfordshire AL1 3NP
Tel: 01727 858687
Website: www.npa.co.uk

National Prescribing Centre

Ground Floor, Building 2000,
Vortex Court
Enterprise Way
Wavertree Technology Park
Liverpool L13 1FB
Tel: 0151 295 8671
Website: www.npc.co.uk

National Treatment Agency

6th Floor, Skipton House
80 London Road
London SE1 6LH
Tel: 020 7972 1999
Website: www.nta.nhs.uk

NHS Wales

Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ
Tel: 0300 0603300 or 0845 010 3300
Website: <http://wales.gov.uk/topics/health>

Nursing and Midwifery Council

23 Portland Place
London W1B 1PZ
Tel: 020 7333 6550
Website: www.nmc-uk.org

**Pharmaceutical Contractors' Committee
(NI)**

5 Annadale Avenue,
Belfast, BT7 3 JH
Tel: 028 9069 0444

Website: www.pccni.org.uk
**Pharmaceutical Society of Northern
Ireland**

73 University Street,
Belfast, BT7 1HL
Tel: 028 9032 6927
Website: www.psnj.org.uk

Quality Improvement Scotland

Elliott House
8-10 Hillside Crescent
Edinburgh EH7 5EA
Tel: 0131 623 4300
Website: www.nhshealthquality.org

Royal College of General Practitioners

RCGP Substance Misuse Unit
14 Princes Gate
Hyde Park
London SW7 1PU
Tel: 020 7173 6090
Website: www.rcgp.org.uk/practising_as_a_gp/substance_misuse.aspx

Royal College of Midwives

15 Mansfield Street
London W1G 9NH
Tel: 020 7312 3535
Website: www.rcm.org.uk

Royal College of Nursing

20 Cavendish Square
London W1G 0RN
Tel: 020 7409 3333
Website: www.rcn.org.uk

The General Pharmaceutical Council
129 Lambeth Road
London SE1 7BT
Tel: 020 3365 3400
Website: www.pharmacyregulation.org

**The Regulation and Quality Improvement
Authority**

9th Floor Riverside Tower
5 Lanyon Place
Belfast BT1 3BT
Tel: 028 9051 7500
Website: <http://www.rqia.org.uk/>

Ulster Chemists' Association

5 Annadale Avenue,
Belfast, BT7 3JH
Tel: 028 9069 0456
Website: www.uca.org.uk

APPENDIX 5: Glossary

ACMD

Advisory Council on the Misuse of Drugs

Administer

To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in medical legislation as follows: "external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations "parenteral administration" means administration by breach of the skin or mucous membrane

Appropriate date

The later of the date on which a prescription was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied

BMA

British Medical Association

British National Formulary (BNF)

A reference providing UK health care professionals with authoritative and practical information on the selection and clinical use of medicines

BSO

Business Services Organisation

Cipher number

Unique prescriber ID number allocated to prescribers in Northern Ireland by BSO

Controlled Drugs

The drugs listed in Schedule 2 of the Misuse of Drugs Act 1971. These drugs are categorised in schedules 1-5 of the MDR (as amended). Drugs listed in the different schedules of the MDR are subject to differing levels of control but all are controlled drugs

Controlled Drug Record Book

Bound book in which records are made of controlled drugs received and supplied in nursing homes, wards, theatres and other hospital departments

CDRC

Controlled Drug Record Card

Community practitioner nurse prescriber

A person:

- (a) who is a registered nurse or a registered midwife; and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary

CD register

Bound book or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977, as specified in the MDR (as amended) in which records are made of controlled drugs received and issued by pharmacies. See "Register" below

CPD

Continuing Professional Development

DHSSPS

The Department of Health, Social Services and Public Safety

Deputising service

An organisation that provides medical services Out of Hours

DH

Department of Health

Dispense, dispensing

Dispensing of controlled drugs: preparation (including compounding, dissolving, diluting, packing and labelling.) In some contexts, it may include the transfer (supply) of medicines to individual patients

Dispensing doctors

Doctors who provide a dispensing service to some or all of their patients

'Doctor's bag'

A lockable bag containing medicines and medical equipment, occasionally including controlled drugs, that doctors use when outside, and sometimes inside, their surgeries

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

Educational establishments

Premises where people can access education

Formal / home carer

A carer who is paid for the purpose

GMC

General Medical Council

GPhC

General Pharmaceutical Council

Informal carer

A carer who is not employed for the purpose

Independent prescriber

Practitioner (eg, doctor, nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing

"may"

Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances

MDR

(Misuse of Drugs Regulations) Regulations made under the Misuse of Drugs Act (1971)

MHRA

Medicines and Healthcare products Regulatory Agency

"must"

Used in this document in connection with legal requirements e.g. "records of schedule 2 controlled drugs received and supplied by a pharmacy must be kept in a CD register"

NCAS

National Clinical Assessment Service

NMC

Nursing and Midwifery Council

NPA

National Pharmacy Association

NPC

National Prescribing Centre

NPSA

National Patient Safety Agency

Nurse Independent Prescriber

Means a person:

- (a) who is a registered nurse or a registered midwife; and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances

Nursing Home

Defined by Health and Personal Social services (Quality, Improvement and Regulation)(Northern Ireland)Order 2003, these homes have registered nursing staff and provide nursing care for anyone suffering from an illness or infirmity

Out of Hours

Out of Hours services provided to patients outside of the normal working hours

Patient Information Leaflets (PILs)

Information leaflets supplied with medicines, required to be provided by law, which give information to patients about various aspects of the medicine including side effects, storage, dosing, etc

'Patient-returned' controlled drugs

Controlled drugs that have been prescribed and dispensed to a named patient, and then returned unused or part-used

Patient group directions (PGDs)

Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations

Patient medication record (PMR)

Computer record containing personal patient details and medicines supplied to them

Practitioners

Within the Misuse of Drugs Act and Regulations the term practitioner refers to a doctor, dentist, veterinary surgeon or veterinary practitioner

Prescribe

Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines are permitted to be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Prescription Only Medicines (Human Use) Order 1997. The term has however become commonly used to describe authorising - by means of a Health Service prescription - the supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient

Prescribing number

The number allocated to the prescriber when they become registered as such.

POMs

Prescription-only medicines

Private prescribers

Professionals who prescribe medication outside of the Health Service

Professional registration number

The number allocated to the professional upon registration with their professional body

Register

Register means either a bound book, which does not include any form of loose-leaf register nor card index. It may be a computerised system that is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977

Repeat dispensing scheme

Local pharmaceutical services that involve the provision of drugs, medicines or appliances by a pharmacist in accordance with a repeatable prescription / batch issues

Repeatable prescription

A prescription which contains a direction that it may be dispensed more than once.

Residential Care Home

An establishment, defined by Health and Personal Social services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, which provides residential accommodation with board and personal care for those who are old, infirm, disabled or suffer from alcohol or drugs dependence or a mental disorder

RCA

Root Cause Analysis

RCGP

Royal College of General Practitioners

Running balance

The total quantity at any point in time, of any particular controlled drug that is deemed to be held at the premises

Service Level Agreement (SLA)

A written agreement between two parties that specifies the service to be provided

Standard Operating Procedure (SOP)

Specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the management and use of controlled drugs

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

A portable battery operated device used to administer medication subcutaneously over a predetermined time

APPENDIX 6: NPSA Guidance

Guidance to protect patients from harm in respect of prescribing, dispensing and administering opioid and opiate (hereafter opioid) medicines has been issued by the National Patient Safety Agency (NPSA). These specify actions that are designed to reduce human-factor error.

In Northern Ireland, the NPSA guidance is managed by the Department and, where appropriate, issued to relevant organisations for their action. Organisations are required to notify the implementation status of NPSA guidance by a specified date to the relevant Trust, which then provides an assurance through the HSC Board to the Department that the relevant action has been taken.

The NPSA Guidance

Reducing dosing errors with opioid medicines. Rapid Response Report 05, July 2008.

When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, the health care practitioner concerned, or their clinical supervisor, should:

- confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records;

- ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose);

- ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects
Healthcare organisations should ensure local medicines and prescribing policies, including Standard Operating procedures, are reviewed to reflect this guidance.

<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888>

Ensuring safer practice with high dose ampoules of diamorphine and morphine. Patient Safety Notice 12. May 2006.

Recommended actions are to:

- risk assess and have procedures for safely prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections;

- review therapeutic guidelines for the use of diamorphine and morphine injectable products for patients requiring acute care, including post-administration observation of patients who have not previously received doses of opiates;

- update information concerning the safe use of diamorphine and morphine injectable products as part of an ongoing programme of training for healthcare staff on medication practice;

- ensure that naloxone injection, an antidote to opiate-induced respiratory depression, is available in all clinical locations where diamorphine and morphine injections are stored or administered.

<http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59803&p=5>

Health care organisations should ensure local medicines and prescribing policies, including Standard Operating Procedures, are reviewed to reflect this guidance.

Guidance from ‘A guide to good practice in the management of controlled drugs in primary care (England) Third edition 2009’

There is an expectation that organisations and practitioners will adhere to the NPSA’s guidance; however, the responsibility, accountability and liability for failure to implement guidance is as yet untested in law. Therefore, the NPSA is unable to give definitive direction at this time. The following represents the best opinion of the NPSA legal advisors, and their assessment of the situation as it currently stands. We would strongly recommend that organisations obtain their own independent legal opinion.

Guidance could well be relevant in the context of a corporate manslaughter investigation where the acts or omissions of senior management are shown to have substantially contributed to a breach of duty that has caused a fatality. Evidence of ignoring specific relevant guidance from the NPSA, or even a generalised failure to act on such guidance, is likely to weigh in favour of a jury finding that there had been a ‘gross’ management failure, which is a necessary element for a successful conviction.

In order to rebut any suggestion of a gross management failure in such circumstances, an organisation would probably need to argue that it took different, but equally effective measures to minimise the risk in question, or of course try to show that the fatality would have been caused even if the relevant guidance from the NPSA had been implemented.

The nature of the corporate manslaughter offence means that, in terms of deaths arising out of the treatment of patients, those organisations such as General Medical (GP) Practices, Acute Trusts or Foundation Trusts, providing care directly to patients are most likely to be the subject of a prosecution. Such organisations are under a contractual obligation to have regard to all relevant guidance issued by the PCT, the relevant Strategic Health Authority or the Secretary of State, and to have an effective system of clinical governance. A failure to heed NPSA guidance is likely to place the organisation in breach of those requirements and a jury may

view such a failure as particularly serious in such circumstances.

The PCT, as a commissioner of services, is potentially liable if it knew that guidance was not being followed and took no action to address the situation. Even then, a prosecution would find it difficult to establish that the PCT’s failure to act caused death, rather than the actions or omissions of the organisation in question.

In addition to corporate manslaughter, there is scope for organisations providing direct care and/or PCTs to be prosecuted for other (lesser) health and safety offences. Similar considerations would be likely to apply; thus, failure to follow the guidance would be likely to be taken into account in determining liability.

Failure to act on NPSA guidance is likely to be addressed by bodies such as the Care Quality Commission or the Strategic Health Authority, rather than the NPSA itself

APPENDIX 7:

Controlled Drugs prescribable by Nurse Independent Prescribers solely for the medical conditions indicated

Drug	Schedule ¹	Indication	Route of Administration
Buprenorphine	3	Transdermal use in palliative care	Transdermal
Chlordiazepoxide Hydrochloride	4	Treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it	Oral
Codeine phosphate	5	N/A	Oral
Co-phenotrope	5	N/A	Oral
Diamorphine hydrochloride	2	Use in palliative care, pain relief in suspected myocardial infarction or the relief of acute or severe pain after trauma, including in either case post-operative pain	Oral or parenteral
Diazepam	4	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures	Oral, parenteral or rectal
Dihydrocodeine tartrate	5	N/A	Oral
Fentanyl	2	Transdermal use in palliative care	Transdermal
Lorazepam	4	Use in palliative, tonic-clonic seizures	Oral or parenteral
Midazolam	3	Use in palliative, tonic-clonic seizures	Parenteral or buccal
Morphine hydrochloride	2	Use in palliative care, pain relief in suspected myocardial infarction or the relief of acute or severe pain after trauma, including in either case post-operative pain	Rectal
Morphine sulphate	2	Use in palliative care, pain relief in suspected myocardial infarction or the relief of acute or severe pain after trauma, including in either case post-operative pain	Oral, parenteral or rectal
Oxycodone hydrochloride	2	Use in palliative care	Oral or parenteral use in palliative care

¹ Schedule 1 – 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002

For the purposes of nurse independent prescribing, palliative care means the care of patients with advanced, progressive illness

APPENDIX 8: Acknowledgements

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Number	Section / Page	Amendments
1 Update	Section 3 Page 29	<p>Replaced “In addition, an on-line training module entitled ‘Controlled Drugs in Clinical Practice’ is available at http://www.nicpld.org/online/drugs/default.asp This module is scheduled to be revised in 2010”</p> <p style="text-align: center;">with</p> <p>“In addition, an on-line training module entitled ‘Controlled Drugs - Striking a Balance’ is available from The Northern Ireland Centre for Pharmacy Learning and Development (NICPLD)”</p>
2 Correction	Section 5 Page 36	<p>Following Home Office clarification replaced</p> <p>“Requisitions for Schedule 2 and 3 controlled drugs have to be in writing and must not be computer generated. Requisitions do not need to be in the recipient’s own handwriting but the recipient must sign them.</p> <p style="text-align: center;">with</p> <p>“Requisitions for Schedule 2 and 3 controlled drugs have to be in writing - either computer generated or handwritten. Requisitions that are handwritten do not need to be in the recipient’s own handwriting. The recipient must sign requisitions irrespective of the means of production.”</p>
3 Update (See SI 2010 / 1136)	Section 5 Page 38	<p>Replaced: “Certified midwives are authorised to possess and administer certain medicines including diamorphine, morphine, pentazocine and pethidine in the course of their practice”</p> <p style="text-align: center;">with</p> <p>“Registered midwives are authorised to possess and administer certain medicines including diamorphine, morphine, and pethidine in the course of their practice.”</p>
4 Update (See SI 2010 / 1136)	Section 6 Page 41	<p>Replaced: “Midwives are authorised to administer those controlled drugs, which they are authorised to lawfully possess under the Medicines Act (i.e. diamorphine, morphine, pethidine and pentazocine).”</p> <p style="text-align: center;">with</p> <p>“Midwives are authorised to administer those controlled drugs, which they are authorised to lawfully possess under the Medicines Act (i.e. diamorphine, morphine and pethidine.)”</p>

Number	Section / Page	Amendments
5 Correction	Section 7 Page 44	<p>Replaced: “From 15 October 2003, the supply and administration of the following controlled drugs was allowed under PGDs:</p> <ul style="list-style-type: none"> • Diamorphine, but only for the treatment of cardiac pain by nurses working in coronary care units or hospital accident and emergency departments • All drugs listed in Schedule 4 of the Regulations except: <ul style="list-style-type: none"> - The anabolic steroids in part 2 of that Schedule - 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. The legal classification of midazolam changed on 1 January 2008 from a Schedule 4 Part I CD to a Schedule 3 CD. Midazolam is the only Schedule 3 CD that, in certain circumstances, can be included in a PGD. Under no circumstances can any other Schedule 3 CD be legally included in a PGD <p>It is important to note that most but not all registered health care professionals who are authorised to supply or administer medicines generally in accordance with a PGD under Medicines Act legislation are authorised to supply or administer controlled drugs in accordance with a PGD under MDR. The amended Regulations allow nurses, midwives, pharmacists, optometrists, chiropodists, radiographers, orthoptists, physiotherapists, dietitians, ambulance paramedics, occupational therapists, speech and language therapists, orthotists and prosthetists to supply or administer controlled drugs in Schedule 4 (with the exception of anabolic steroids) and Schedule 5.”</p> <p style="text-align: center;">with</p> <p>“Regulations allow the supply and administration of the following controlled drugs under PGDs:</p> <ul style="list-style-type: none"> • Diamorphine, but only for the treatment of cardiac pain by nurses working in coronary care units or hospital accident and emergency departments • All drugs listed in Schedule 4 of the Regulations (and midazolam) except: <ul style="list-style-type: none"> - The anabolic steroids in part 2 of Schedule 4 - Injectable formulations for treating a person who is addicted to a drug • All drugs listed in Schedule 5 of the Regulations. <p>Midazolam is the only Schedule 3 CD that can be included in a PGD. Under no circumstances can any other Schedule 3 CD be lawfully included in a PGD</p> <p>It is important to note that most, but not all, registered health care professionals who are authorised to supply or administer medicines generally in accordance with a PGD under Medicines Act legislation are authorised to supply and administer controlled drugs, as specified above, in accordance with a PGD under MDR.</p> <p>The Regulations allow nurses, midwives, pharmacists, optometrists, chiropodists, radiographers, orthoptists, physiotherapists, ambulance paramedics, occupational therapists, orthotists and prosthetists to operate within the PGD parameters described above.</p>

Number	Section / Page	Amendments
5 Update	Section 8 Page 57	<p>Under: Legal framework for the dispensing of controlled drugs</p> <p>Replaced: Prescriptions issued by EEA prescribers for medicines listed in any schedule of the Misuse of Drugs Regulations (Northern Ireland) 2002 are not legally valid in the UK and cannot be dispensed.</p> <p>Inserted: “Dispensing a Prescription Originating from the EEA (and Switzerland) Amendments made to <i>The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008</i> on 20 December 2010 now makes provision for pharmacists to dispense prescriptions issued by EEA doctors and dentists for Schedule 4 and 5 controlled drugs.</p> <p>Pharmacists in Northern Ireland may not however dispense prescriptions for Schedules 1, 2 & 3 controlled drugs on the basis of a prescription issued by an EEA doctor or dentist.</p> <p>Pharmacists should be satisfied that they are in possession of sufficient information for the purpose of clinical governance and that the prescription is legally valid, before making supplies against EEA prescriptions</p> <p>Amendments have also been made permitting the emergency sale or supply of Schedule 4 and 5 controlled drugs (not including phenobarbital – S3) where this is pursuant to a request by a doctor or dentist from an EEA country or Switzerland, or their patient, and the normal emergency supply provisions apply.</p> <p>Further guidance can be accessed at: www.psni.org.uk/documents/589/Dispensing+European+Economic+Area+prescriptionsJuly2010.pdf</p>
6 Update	Section 9 Page 66	<p>Replaced: “RPSGB Factsheet 1 www.rpsgb.org/pdfs/factsheet1.pdf provides guidance on documentation appropriate where the person collecting the medicine is a delivery driver. It is recommended that, 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, this is documented. Wherever possible a signature should be obtained indicating safe delivery of medicines. A consultation is being undertaken by the Pharmaceutical Society of Northern Ireland in relation to guidance for N. Ireland. This guidance, when completed will be available at www.psni.org.uk”</p> <p>with</p> <p>“It is recommended that, 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, this is documented. Wherever possible a signature should be obtained indicating safe delivery of medicines. The Pharmaceutical Society of Northern Ireland has published guidance for Pharmacists in Northern Ireland on the Provision of Prescription Collection and/or Delivery Services which is available at www.psni.org.uk”</p>
7 Update (See SI 2010 / 1136)	Section 13 Page 79	<p>Replaced: “Midwives are authorised to administer diamorphine, morphine, pentazocine and pethidine to their patients, acting on their own professional judgement.”</p> <p>with</p> <p>“Midwives are authorised to administer diamorphine, morphine and pethidine to their patients, acting on their own professional judgement.”</p>

Number	Section / Page	Amendments
8 Correction	Section 13 Page 79	<p>Replaced: “The NMC guidance states that a verbal order is not acceptable on its own. The fax or email prescription/direction to administer must be stapled to the patient’s existing medication chart. This should be followed up by a new prescription signed by the prescriber who sent the fax/email confirming the changes within normally a maximum of 24 hours (72 hours maximum – Bank Holidays and weekends). In any event, the changes must have been authorised (via text, email or fax) by a registered prescriber before the new dosage is administered. The registered nurse should request the prescriber to confirm and sign changes on the patient’s individual MAR (medicines administration record) chart or care plan.”</p> <p style="text-align: center;">with</p> <p>Remote prescription or direction to administer The NMC guidance confirms that instructions received by fax, text message or email to change the dose of a controlled drug are not permitted</p>
9 Addition	Section 13 Page 80	<p>Inserted: “In circumstances where it is necessary to dispose of the unused contents of an ampoule or syringe, the following guidance is provided.</p> <p>Controlled drugs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used.</p> <p>All CDs in Schedule 2, 3 and 4 (part I) can be placed into waste containers only after the controlled drug has been rendered irretrievable (i.e. by denaturing). This may be done by using commercially available denaturing kits or by placing the controlled drug liquid on absorbent material (e.g. paper towels on to which a little soap has been added). This is then placed in the relevant bin to be disposed of by incineration via the usual waste disposal methods for medicines.</p> <p><u>Where this is impractical, subject to local policy, injectable controlled drugs may be disposed as follows:</u></p> <p>CDs in Syringe Driver: Healthcare staff providing healthcare services within a domestic setting may, subject to local policy (e.g. Trust policy), dispose of residual CD waste from a patient’s syringe driver by disposal directly into the sewerage system at the patient’s home.</p> <p>Partially used injectable CDs: Healthcare staff providing healthcare services within a domestic setting may, subject to local policy (e.g. Trust policy), dispose of any remaining liquid in a part used ampoule by disposal directly into the sewerage system at the patient’s home.</p> <p>It is anticipated that volumes disposed by this route should not normally exceed 25mls. Volumes significantly greater than this should not be disposed by this route.</p> <p>Unopened ampoules and other controlled drug formulations, no longer required by the patient, must be returned for appropriate disposal in accordance with current guidance and good practice (see Section 10).</p> <p><u>NB empty ampoules and syringes should be disposed of safely in burn bins according to local policy</u></p> <p>This permission does not extend to cytotoxic or cytostatic medicines.</p> <p>Please note that this arrangement may be subject to change in the light of regulatory changes, future Government guidance or technical information.”</p>
10	All	Throughout the document: Removal of links to previous Royal Pharmaceutical Society of Great Britain (RPSGB) guidance / fact sheets and change of details to General Pharmaceutical Council (GPhC)

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