

Changes in the management of CDs affecting pharmacists in England

New guidance set out on this and the following three pages is based on a document produced by the Royal Pharmaceutical Society's Practice and Quality Improvement Directorate to help pharmacists in England cope with new arrangements for the management of Controlled Drugs

The Shipman Inquiry was set up on 31 January 2001 and was chaired by Lady Justice Janet Smith as an independent public inquiry into the issues arising from the case of Harold Shipman.

The Inquiry's Fourth Report, published on 14 July 2004, focused on the methods used by Shipman to divert large quantities of potentially lethal Controlled Drugs and the reasons why he could do so for so long without detection. The Shipman Inquiry concluded that there were shortcomings in the systems used for the safe management of CD and made a number of recommendations to improve their management.

The Government response to the fourth report, "Safer management of Controlled Drugs" outlined how some of the report's recommendations would be taken forward. Changes in the CD inspection and monitoring process, outlined in the 2005 Health Bill, are expected in the autumn of this year. Amendments to the Misuse of Drugs Regulations 2001 are expected in early summer. This will lead to a raft of changes affecting not only monitoring and inspection but also the prescribing, record keeping and destruction of CDs.

The changes to primary legislation and to the Misuse of Drugs Regulations will apply to England, Scotland, and Wales. However, the



The new arrangements include the introduction of a standard form for the private prescribing of Schedule 2 and 3 CDs

Table 1: Changes to NHS and private prescriptions

Change	Status	Expected
(1a) Handwriting requirements for Schedule 2 and 3 CD prescriptions have been removed. Only the signature has to be in the prescriber's own handwriting.	Legal (enabling rather than mandatory)*	Current
(1b) The validity of Schedule 2, 3 and 4 CD prescriptions will be restricted to 28 days. This means that the prescription should not be dispensed if more than 28 days have elapsed since the date it was issued and dated. A prescriber who wishes the 28 days to start on a date other than signing, eg, the management of CDs using form FP10(MDA), should endorse the prescription with a specified start date and initial the entry.	Legal requirement	Summer 2006
(1c) Prescriptions for Schedule 2 and 3 CDs will contain a prescriber identifier (for NHS prescriptions this will be the prescriber's NHS number and for private prescriptions a new six-digit identifier starting with the figure 6). As this will be a legal requirement, pharmacists will not be able to dispense prescriptions for Schedule 2 and 3 CDs that do not contain the prescriber's unique identifier.	Legal requirement	Summer 2006
(1d) Standardised private prescription forms will be required for the prescribing of all Schedule 2 and 3 CDs that will be dispensed in community pharmacies or GP dispensing practices. In England these will be called FP10 (PCD). (See question 4, p357.) Until the law is changed, pharmacists may exceptionally dispense against usual private prescriptions.	Legal requirement	Summer 2006 (New prescription forms will be issued in England to private prescribers from March 2006)
(1e) Private prescriptions for schedule 2 and 3 CDs will be sent to the Prescription Pricing Authority or equivalent at the end of each month for collection and analysis purposes. (See question 5, p357.) All pharmacists submitting private CD prescriptions will be allocated a different PPA number, which they will need to use when submitting private CD prescriptions. This number will be different to the PPA number already allocated to each pharmacy in order to maintain a clear distinction between private and NHS activity and to reduce the risk of private products being reimbursed.	Legal requirement	Summer 2006
(1f) Prescription forms will be amended so that there is a space on the back of the form for those collecting Schedule 2 or 3 CDs to confirm that they have done so. (See questions 1 and 3, p357.) This declaration will appear on both NHS and non-NHS forms. Pharmacists will have discretion whether or not to supply if the collector does not sign the back of the prescription.	Good practice	Summer 2006 (New prescription forms will be issued in England from March 2006)
(1g) The quantity of Schedule 2,3, and 4 CDs to be prescribed at any one time should not exceed 30 days' supply. Prescribers will need to be able to justify a supply for more than 30 days.	Good practice	Summer 2006
(1h) Prescribers should not prescribe or administer CDs for themselves, or for close family or friends, except in exceptional circumstances. Each professional regulatory body will have its own guidance, which should be referred to.	Good practice	Immediate effect

* Enabling rather than mandatory means that the legislation has been amended to allow a certain action to occur but that this action does not have to be undertaken, ie, prescribers can now issue CD prescriptions electronically but they can also still handwrite them — they do not have to produce them electronically

arrangements for meeting the new requirements may differ across the three countries. This guidance outlines the changes that will occur in England, subject to legislative approval. Similar changes may occur in Scotland and Wales as systems develop. When further information is available this will be communicated to pharmacists.

The main changes being made to take forward the Shipman Inquiry's recommendations on CDs in England are set out in the tables on p355 and below. The tables outline the changes and when they are expected to happen. Changes in good practice requirements are included as well as changes in legislation.

Table 1 lists changes affecting NHS and private prescriptions for CDs. These changes include the production of new NHS prescription forms and a standardised private prescription form for Schedule 2 and 3 CDs. These are being distributed during March

and will be brought into use from 1 April, although legislation will not be amended to require their use until June, to allow a transitional period.

Table 2 sets out changes affecting CD record keeping. Some of these changes are already in force and others are due in the summer.

Table 3 lists the changes expected in autumn 2006 to improve the inspection and monitoring of health professionals and health care providers who handle CDs.

Table 4 sets out some additional legislative changes expected this summer, including changes affecting the destruction of CDs.

The tables are followed by two further pages setting out more detailed information about some of the changes plus answers to some frequently asked questions. There is also an outline of less imminent changes to CD legislation and a brief guide to resources.

Table 2: Changes in record keeping

Change	Status	Expected
(2a) CD Registers can be kept electronically as long as they comply with national guidance. www.pjonline.com/Editorial/20051112/society/ethics.html	Legal (enabling rather than mandatory)	Current
(2b) A record must be made of the prescriber identifier in the CD register.	Legal requirement	Summer 2006
(2c) Pharmacists should make a record of whether or not they asked for proof of identity of individuals collecting Schedule 2 CDs in the CD register (see p358).	Legal requirement	Summer 2006
(2d) Records should be made of all patient-returned Schedule 2 CDs.	Good practice	Current
(2e) All CD registers should contain a running balance. National guidance www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf	Good practice (will become mandatory once electronic registers are in common use)	Current

Table 3: Changes to improve inspection and monitoring

Change	Status	Expected
(3a) Primary care organisations, NHS trusts and other NHS and private organisations will be required to appoint an accountable officer who will be responsible for the safe management of CDs within their organisation. The duty to appoint an accountable officer is contained in the Health Bill. The legislation will apply to the whole of the UK, although Scotland, Wales and Northern Ireland can write their own regulations to apply the system differently in their own administrations.	Legal requirement	Autumn 2006
(3b) Society inspectors will be incorporating CD monitoring and inspection within their routine visits (England only at present).	Good practice (agreement between DoH and Society)	Autumn 2006
(3c) All community pharmacies, GPs and NHS bodies in England (both NHS and private) will be required to make a periodic declaration and self-assessment stating whether or not they hold stocks of CDs on the premises. Community pharmacists' declarations and self assessments will be made to the Society.	Legal requirement	Autumn 2006
(3d) All health care providers in England who hold a stock of CDs on the premises, which includes community pharmacy, will be expected to have, and comply with, an approved standard operating procedure. (See question 8, p357.)	Legal requirement	Autumn 2006
(3e) Each primary care provider in contract with a PCT in England will undergo a formal Controlled Drugs review once a year. This will involve reviewing benchmark analysis derived from existing information, the provider's self-assessment of their clinical standards in prescribing, administering, storage and disposal of CDs, and a statement that they comply with the Misuse of Drugs Act 1971 and associated regulations.	Legal requirement	Autumn 2006
(3f) Society inspectors will be under a statutory duty to co-operate with other bodies (especially the accountable officer of a primary care organisation).	Legal requirement	Autumn 2006

Table 4: Additional changes

Change	Status	Expected
(4a) Pharmacists will be able to supply CDs against some prescriptions that have a technical error but where the prescriber's intention is clear (ie, where the prescription does not meet all the prescription requirements of the Misuse of Drugs Regulations 2001, such as total quantity in words and figures, but there is no doubt about the prescriber's intention. The Society will be producing further guidance.) (See question 7, p357.)	Legal (enabling)	Summer 2006
(4b) Primary care organisations will have a responsibility for ensuring that safe systems are in place for the safe disposal of "patient-returned" CDs.	Legal requirement	Summer 2006
(4c) The number and groups of people who are authorised to witness the destruction of CDs will be extended. Further guidance will be issued by DoH.	Legal requirement	Summer 2006

Frequently asked questions about the new requirements for CDs

- 1. Will pharmacists be able to supply Schedule 2 and 3 Controlled Drugs if the person collecting the medicine has not signed or refuses to sign the back of the prescription?** Yes, pharmacists will be expected to use their professional judgement in regards to supplying a Schedule 2 or 3 CD if the person collecting the medicine does not wish to sign the back of the prescription.
- 2. Will the CD requirements for take home medicines (TTAs) — dispensed internally in the hospital — be altered in any way?** No. There will be no additional requirements for CDs prescribed as TTAs. However, the requirements outlined above will apply to hospital outpatient prescriptions that are to be dispensed in a community pharmacy.
- 3. Will a patient collecting a CD in instalments via an FP10(MDA), or equivalent, be required to sign the back of the prescription form each time they collect the medicine?** Patients will not have to sign for each instalment, nor will a third party collecting the CD on the patient's behalf. However, care should be exercised when a third party collects a CD for a patient being treated for drug addiction. A letter of authenticity from the patient should be obtained on every occasion that the representative collects the medicine and this letter should be retained in the pharmacy.
- 4. Will pharmacists be required to send the actual private CD prescription to the Prescription Pricing Authority or equivalent at the end of each**



Pharmacists will be required to send private CD prescriptions to the PPA

month? In the interim period between 1 April 2006 and the actual changes to the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (expected June), community pharmacists in England should send a photocopy of the private prescriptions forms for Schedule 2 and 3 CDs (FP10(PCD)) to the PPA and keep the original for their own records. This will ensure that the pharmacy satisfies the legislation as it stands at the moment. Once the legislation changes, pharmacists should send the original private prescription forms for Schedule 2 and 3 CDs to the PPA. Pharmacists may want to keep a copy of the private prescription for their own records.

- 5. Can prescribers use sticky labels on CD prescriptions for the patient's details?** Although not encouraged as good practice, the patient's details (eg, name and address) can be attached to the CD prescription by means of an adhesive label as long as the label is tamper-evident. If an adhesive label is used, prescribers should also sign on the label or at least start their signature on the label.
- 6. What technical errors will pharmacists be able to amend?** Pharmacists will be able to supply CDs against some prescriptions that have a technical error so long as the prescriber's intention is clear. Legislation to allow this is expected in summer 2006. The type of errors that pharmacists will be able to make a supply against are those prescription requirements that are purely requirements of the Misuse of Drugs Regulations 2001 (eg, requirement to include the total quantity in words and figures or form of the preparation). The Royal Pharmaceutical Society and the Department of Health will provide further guidance on what technical errors can be amended.
- 7. What will the standard operating procedure for CDs look like?** The content of the SOP will include arrangements for checks on stocks and their reconciliation against the running balance in the CD register; arrangements for the safe custody of CDs and access by practice or provider staff. The SOP needs to be agreed with the PCO (potentially with the accountable officer). The Department of Health will be issuing guidance for England about the development of these SOPs.

Who can currently prescribe, supply and administer Controlled Drugs?

The following information applies in England, Scotland and Wales

Doctors, dentists and veterinary surgeons can prescribe all CDs in Schedules 2 to 5. Doctors may only prescribe diamorphine, dipipanone or cocaine to substance misusers for the treatment of addiction if they hold a licence issued by the Home Office. All doctors can prescribe such drugs for patients, including substance misusers, for relief of pain due to organic disease or injury, without a specific licence.

Extended formulary nurse prescribers can prescribe, supply or administer, or direct other nurses to administer, the following:

- Diamorphine, diazepam, lorazepam, midazolam, morphine or oxycodone for use in palliative care
- Buprenorphine or fentanyl for transdermal use in palliative care
- Diamorphine or morphine for pain relief of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief
- Chlordiazepoxide hydrochloride or diazepam for the treatment of initial or acute alcohol withdrawal symptoms
- Codeine phosphate, dihydrocodeine tartrate or co-phenotrope (no restrictions)

The following CDs can be supplied or administered under patient group directions (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 except anabolic steroids and

injectable formulations for the purpose of treating a person who is addicted to a drug

- All drugs listed in Schedule 5 of the Regulations

Supplementary nurse and pharmacist prescribers can prescribe and administer any CD as long as it is within the clinical management plan specific to that patient and agreed between the independent prescriber, the supplementary prescriber and the patient.

Any person can administer any CD in accordance with the directions of a supplementary prescriber acting under and in accordance with the terms of a clinical management plan.

Midwives can possess, supply and administer diamorphine, morphine, pethidine and pentazocine, provided it is in the course of their professional midwifery practice.

Providing proof of identity when collecting a Schedule 2 Controlled Drug

Legislation will not require pharmacists to ask everyone who collects a Schedule 2 CD for proof of identity. It will be up to pharmacists to use their discretion when to ask for ID and also whether or not to supply the CD if ID is not provided. However, pharmacists will be required to record, in the CD register, whether they asked for identity or not and what proof of identity, if any, was seen.

In order not to deny patients' access to the drugs that they require, it will not be a criminal offence to supply the CD without proof of identity, even when the person is not known to the pharmacist.

The circumstances in which ID may not be required include the collection of the

CD by a person known to the pharmacist (the patient, close relative or friend, or a local health care professional) or when the pharmacist feels that asking for ID may compromise patient confidentiality.

The name, and status if a health care professional, of the person collecting the Schedule 2 CD will need to be recorded in the CD register, as will the type of ID shown. If no ID is seen this also will need to be recorded, along with the reason why.

Types of ID that may be considered suitable include:

- Driving licence (including photocard section)

- Any official photo ID
- Passport
- Cheque guarantee, debit or credit card
- Birth or marriage certificate
- Cheque book
- Utility bills (two different ones and NOT mobile phone statement)
- Pension or benefit book
- Council tax payment book
- Recent bank or building society statement (within previous six months)
- Bank or building society book
- Store charge card (not a loyalty card)
- Council rent book
- National savings book
- Household bills

Destruction of Controlled Drugs returned to the pharmacy by patients

The destruction of Controlled Drugs returned by patients is classified as waste treatment, and would normally require a waste management licence. The Environment Agency, the regulatory authority for the waste legislation in England and Wales, has acknowledged that certain activities undertaken in pharmacies are low risk. Having considered the risks posed by the destruction of Controlled Drugs at a pharmacy the agency has decided that it does not believe it is in the public interest to expect pharmacies to obtain a waste management licence for the destruction of patient-returned CDs. However, the Environment Agency will keep this under review and may amend or revoke its position at any time. Therefore, pharmacists should ensure that denaturing is undertaken in a way that does not harm the environment.

Controlled Drugs returned by patients from their own homes and

residential homes, can be sorted, popped from blister packaging and denatured in the pharmacy. Ideally, CD denaturing kits should be used but, where alternative methods are adopted, these should safeguard the environment and the health of employees and members of the public.

Further guidance on the destruction of CDs and waste management is being developed and will be made available on the Society's website (www.rpsgb.org).

The groups of people who are authorised to witness the destruction of CDs is to be expanded. The additional authorisation is expected to come into force in June 2006. The current list is available from the policy and guidance section of the Department of Health website (www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/PrimaryCareArticle/fs/en?CONTENT_ID=4125202&chk=yB3Of5).

Further changes expected in the future

The Government's response to the fourth report of the Shipman Inquiry outlined further changes to the management of CDs that are expected to occur at some time in the future. Further guidance will be provided as required.

- Patient drug record cards (PDRCs), currently the subject of a pilot trial, could become a legal requirement for all Schedule 2 injectable CDs. The card records when a CD is prescribed, dispensed, administered and returned for destruction.
- Software for electronic transmission of prescriptions will capture both the time of issue of a prescription and the time when the dispensed CDs are handed to the patient.
- Information about prescribers who have restrictions placed on their prescribing of CDs will be made accessible to all pharmacies over time.
- The name and professional ID of the pharmacist or dispensing doctor who dispenses a Schedule 2 CD will be recorded in the CD register.
- Prescriptions for Schedule 2 and 3 CDs will contain a patient identifier. This will be the patient's NHS number and will apply to both NHS and non-NHS prescriptions.

- The use of electronic CD registers will become mandatory, as will the keeping of running balances. CD registers will be expected to be kept for up to 11 years (maybe indefinitely).
- GP practices and pharmacies will be required to send information on their CD requisitions to the PPA or equivalent.
- Recording and witnessing of patient-returned CDs will be a requirement.
- CD prescriptions will be identifiable via a special marker.
- The Government is considering changes to the systems for CD requisitions.

Wales and Scotland

The Society's Welsh Executive is producing an amended version of the guidance that tracks the developments in Wales. This will be available on the Welsh Executive briefing page of the Society's website (www.rpsgb.org).

Guidance for pharmacists in Scotland is being developed by the Society's Scottish Department and will be made available on the Scottish Department section of the Society's website in due course.

Resources

Department of Health The Department of Health has produced detailed guidance on the changes to the inspection and monitoring process for Controlled Drugs. It is available to download from the Department's website (www.dh.gov.uk/assetRoot/04/13/14/61/04131461.pdf). The Department has also developed detailed guidance on the new prescription forms and changes affecting prescribing of CDs. This is also available from the Department's website (www.dh.gov.uk/assetRoot/04/13/14/66/04131466.pdf).

Royal Pharmaceutical Society The Royal Pharmaceutical Society will provide more detailed guidance on a number of issues, such as amendment of technical errors, and this will become available once the Society is aware of the legislative requirements.

National Prescribing Centre The National Prescribing Centre is providing training on "The safer management of CDs: meeting your obligations around the role of accountable officer and intelligence networks" in England (May and July 2006).

The NPC is providing online training on "CDs — the changes and implications" (expected summer 2006).