



SCOTTISH EXECUTIVE

Health Department
Directorate of Primary Care and Community Care

Primary Care Division
St Andrew's House
EDINBURGH
EH1 3DG

May 2006

Dear Colleague

Safer Management of Controlled Drugs (CDs): Private CD Prescriptions and Changes to NHS Prescriptions

Summary

1. This letter advises NHS Boards:
 - of revised arrangements for the prescribing and dispensing of controlled drugs for human use (whether on the NHS or private) and the monitoring of this activity.
 - the new arrangements will come into effect in Scotland on **5 June 2006** and, subject to UK Parliamentary approval, amendments to the Misuse of Drugs Regulations 2001 are expected to come into effect late June 2006.

Action

2. NHS Boards are asked to:
 - put into effect the new arrangements explained in the attached guidance;
 - distribute a copy of this letter and guidance to all doctors, all nurse prescribers and all supplementary prescribers and staff involved in the monitoring of controlled drugs.
3. A copy of this guidance has been sent separately to all dentists and pharmacists.

Yours sincerely

DR JONATHAN PRYCE
Head of Primary Care Division

Addresses

For action

Chief Executives, NHS Boards
Chief Executive, NHS National
Services Scotland

For information

NHS Quality Improvement Scotland
NHS Education for Scotland
NHS24
Scottish Commission for the
Regulation of Care

Enquiries to:

Mary Waugh (general enquiries)
Pharmacy Division
Room 1E-01
St Andrew's House
EDINBURGH
EH1 3DG

Tel: 0131-244 2870

Fax: 0131-244 2375

email:

mary.waugh@scotland.gsi.gov.uk

Lorna Ramage (prescription
stationery enquiries)
Customer Relations Manager
Practitioner Services (Pharmacy)
NHS National Services Scotland
Area 204C
Gyle Square
Edinburgh EH12 9EB

Tel: 0131 275 6699

Fax: 0131 275 7532

email:

lorna.ramage@psd.csa.scot.nhs.uk



Background

Safer Management of Controlled Drugs (CDs): Private CD Prescriptions and Changes to NHS Prescriptions

1. The fourth report of the Shipman Inquiry – “*The Regulation of Controlled Drugs in the Community*”¹ - recommended a number of measures to strengthen and improve the current systems for the management of controlled drugs for human use, whether prescribed and dispensed privately or on the NHS.

2. The Government’s response to the fourth report, “*Safer Management of Controlled Drugs*”² agreed that the current systems should be improved and strengthened. The purpose of this guidance is to inform relevant healthcare professionals and organisations about a programme of action to improve the management of controlled drugs. The changes, which cover both NHS and private prescriptions, include:

- the introduction of a standard private prescription form PPCD(1) for the non-NHS prescription of schedule 2 and 3 controlled drugs;
- modified arrangements for the NHS prescription of schedule 2 and 3 controlled drugs;
- persons collecting schedule 2 and 3 controlled drugs should sign the back of the prescription form;
- a restriction of the validity of any prescription for schedule 2, 3 and 4 controlled drugs to 28 days (currently 91 days) from the date it was signed by the prescriber or a start date specified by the prescriber;
- a recommendation that prescriptions for schedule 2, 3 and 4 controlled drugs should be limited to a quantity necessary for up to 30 days clinical need.

Legislative Underpinning

3. A public consultation³ on a proposed package of amendments to the Misuse of Drugs Regulations 2001 ended on 21 October 2005. The changes explained in this guidance have been formally approved by the Advisory Council on the Misuse of Drugs. New arrangements will come into effect in Scotland on **5 June 2006** and, subject to UK Parliamentary approval, will become mandatory when amendments to the Misuse of Drugs Regulations 2001 come into force, expected to be in late June 2006.

Private Prescriptions

4. Currently private prescriptions (i.e. non-NHS) are not subject to the same monitoring requirements as NHS prescriptions and no information on the private prescribing and dispensing of controlled drugs is held centrally. The lack of information on the totality of controlled drug prescribing was seen by the Shipman Inquiry as a weakness in the current

¹ See *The Regulation of Controlled Drugs in the Community*, The Fourth Report of the Shipman Inquiry (<http://www.the-shipman-inquiry.org.uk/fourthreport.asp>)

² See *Safer Management of Controlled Drugs*, the Government’s response to the Fourth Report of the Shipman Inquiry (http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4097904&chk=isA3Eo)

³ See *Public Consultation – Proposed Changes to Misuse of Drugs Legislation*, Home Office (<http://www.homeoffice.gov.uk/documents/cons-drugs-misuse-280705>)

system and a loophole which could be exploited. The Inquiry recommended that information on private prescriptions for controlled drugs should be collected on a similar basis to that for NHS primary care prescriptions.

5. It has been agreed that information about the private prescribing of schedule 2 and 3 controlled drugs will be collected centrally by NHS National Services Scotland (NSS) and made available to NHS Boards for monitoring and analysis purposes. This will require private prescriptions in Scotland to be written on a 'standard' prescription form (PPCD(1)) which can be scanned into the NSS database. An example of the PPCD (1) is attached as Annex B. The changes affect all private prescriptions for schedule 2 and 3 controlled drugs for human use dispensed in the community. NSS will allocate identifier codes to registered pharmacies in Scotland that do not have an NHS dispensing contract for use when submitting private prescriptions for these drugs.

6. Arrangements have been made to enable private prescribers to obtain supplies of forms PPCD (1). This will require them to register with the local NHS Board as private prescribers and an application form for this purpose (ISD PPCD (01)) is attached as Annex D. Application forms are also available from NHS Boards or can be accessed at www.isdscotland.org or www.psd.scot.nhs.uk. Completed application forms should be forwarded by the Board to NSS who will allocate each private prescriber with a prescriber code. (Valid NHS prescriber codes will be used where available). NSS will notify the responsible Board of all non-NHS private prescriber identification codes.

7. Once a private prescriber has been allocated a prescriber code, a supply of prescription forms PPCD (1) can be ordered by the NHS Board from NSS Practitioner Services Division using PSD PPCD Order Form – example attached as Annex E. The Board will invoice the private prescriber or their employer for the cost of supplying the prescription forms. The ordering and invoicing arrangements will be decided by the Board.

8. From **5 June 2006**, private prescriptions for schedule 2 and 3 controlled drugs should be written on form PPCD(1). Private prescriptions not on form PPCD(1) but signed and dated before 5 June 2006 may be dispensed within 91 days (13 weeks) of the prescription being signed.

9. Dispensed forms PPCD(1) should be submitted to NSS monthly. They should be batched and forwarded to NSS covered by dispensary submission document CD34 (Annex F). NHS Boards will be able to request retrieval of individual prescription forms. Information on all prescribing/dispensing of controlled drugs will be made available to NHS Boards by NSS.

10. As a matter of good practice, private prescriptions for schedule 2 or 3 controlled drugs in Scotland should include the patient's Community Health Index (CHI) number.

11. A flow chart at Annex A sets out the steps necessary to register as a private prescriber of schedule 2 and 3 controlled drugs.

NHS Prescribing Arrangements

12. The back of NHS prescription forms will be amended to include a box for the signature of the person collecting the drug – example attached as Annex C. Stocks of amended NHS prescription forms will be distributed as soon as possible.

13. GP system suppliers have been asked to include a function on GP computer systems to identify prescriptions for schedule 2 and 3 controlled drugs by including ‘CD’ in the text (e.g. diamorphine 10mg tablets ‘CD’). If the suffix is not present, pharmacists can still accept the prescription provided they are satisfied that the prescription is legitimate.

14. NHS prescription forms for schedule 2 or 3 controlled drugs in Scotland should wherever possible include the patient’s Community Health Index (CHI) number.

Dispensing NHS and Private Prescriptions

15. People collecting schedule 2 controlled drugs should be asked to sign the back of the prescription form (NHS or private) and to provide evidence of identity. In all cases, if the person collecting the drug declines to sign the form the dispenser has the discretion to supply the drug. In addition, the dispenser will not be required to seek evidence of identity if it is felt that this request would compromise patient confidentiality. If the person collecting the drug is already known to the dispenser evidence of identity need not be requested.

16. Healthcare professionals collecting schedule 2 controlled drugs on behalf of patients or their representatives should provide evidence of identity. The dispenser will have the discretion to supply the drug where evidence is not presented. If the healthcare professional collecting the drug is already known to the dispenser evidence of identity need not be requested.

17. In all cases, where evidence of identity is not supplied a record should be made in the CD register. Further guidance will issue in due course on recording the ID of those collecting controlled drugs on behalf of patients.

18. People collecting schedule 3 controlled drugs should be asked to sign the back of the prescription form (NHS or private). If the person collecting the drug declines to sign the form the dispenser has the discretion to supply the drug.

Schedules 2, 3 and 4 Controlled Drugs: Validity of Prescriptions

19. From 5 June 2006 both private and NHS prescriptions for schedule 2, 3 and 4 controlled drugs will be valid for 28 days from the date signed by the prescriber or from a start date specified by the prescriber. This requirement will be given statutory backing later in June when, subject to UK Parliamentary approval, changes to the Misuse of Drugs Regulations 2001 are expected to come into force.

Controlled Drugs: Quantity Prescribed

20. Other than in exceptional circumstances, prescribers are strongly advised to restrict prescribing of schedule 2, 3 and 4 controlled drugs to amounts sufficient to meet their patient's clinical need up to a maximum of 30-day supply. Where a prescriber considers it clinically appropriate to supply more than a 30-day quantity and this does not pose an unacceptable risk to patient safety the patient's notes should be annotated to that effect. Prescribers who prescribe more than a 30-day supply should be prepared to justify their decision.

Instalment Dispensing

21. The 28-day validity period will apply as for other prescriptions for controlled drugs. The 28-day period starts on the date of signing by the prescriber or on a start date specified by the prescriber. The first instalment must be dispensed within the 28-day limit, with the remainder dispensed in accordance with the instructions on the form. Patients are not required to sign for each instalment.

Prescriptions for Controlled Drugs to be Generated by Computer

22. From 14 November 2005, amendments to the Misuse of Drugs Regulations 2001 came into force which allow all details on prescriptions for schedule 2 and 3 controlled drugs, apart from the signature, to be computer generated. Practitioners/practices may continue writing prescriptions if they wish. Further amendment to the Misuse of Drugs Regulations allow controlled drug registers for schedule 1 and 2 controlled drugs to be maintained and preserved on computer.

23. A copy of the Home Office circular (number 48/2005) giving further details can be accessed at www.circulars.homeoffice.gov.uk. Advice on writing prescriptions for controlled drugs is contained in the British National Formulary.

24. A list of the drugs currently controlled under the Misuse of Drugs legislation can be accessed at <http://www.drugs.gov.uk/publication-search/drug-licences/controlled-list?view=Binary>

Security & Safe Handling of Prescription Forms: Good Practice

25. The security of prescription forms (NHS or private) is the responsibility of the NHS/employing organisation and the prescriber and NHS Boards will be able to advise on appropriate security arrangements for prescription stationery. Each prescriber should keep a record of the first and last serial numbers of the prescription pads issued to him/her. It is also good practice to record the number of the next unused prescription form on an in-use pad at the end of the working day. These steps will help to identify quickly any forms that are lost or stolen.

26. Blank prescription forms should never be pre-signed and prescription pads should never be left unattended.

27. Prescribers should report a suspected loss or theft of prescription stationery to the local NHS Board as soon as the loss/theft is discovered. They should report the approximate number of prescription forms lost/stolen, their serial numbers and where and when they were lost/stolen. The Board should notify the Fraud Liaison Officer, who is responsible for informing local pharmacists and deciding on the action to be taken. The Fraud Liaison Officer should also notify Counter Fraud Services at the following address:

Counter Fraud Services
Earlston House
Almondvale Business Park
Almondvale Way
Livingston
EH54 6GA

Tel: 01506 705 200
Fax: 08000 15 16 28

28. Following a loss of prescription stationery, the prescriber concerned will be asked to write and sign all prescription forms in a particular colour (usually red) for a period of two months. The NHS Board will inform all community pharmacies in their areas and adjacent NHS areas of the name and address of the prescriber concerned, the approximate number of prescription forms lost/stolen and the period for which the prescriber will write in a specific colour.

Prescriptions for self, close family and those close to the healthcare professional

29. The professional regulatory bodies of healthcare professionals (e.g. GMC, NMC, RPSGB, GDC) have their own codes of conduct/standards/ethics with regard to the prescription of controlled drugs for self, close family or those close to the healthcare professional. These should be read in conjunction with this guidance and adhered to at all times.

Re-issuing of Medicines

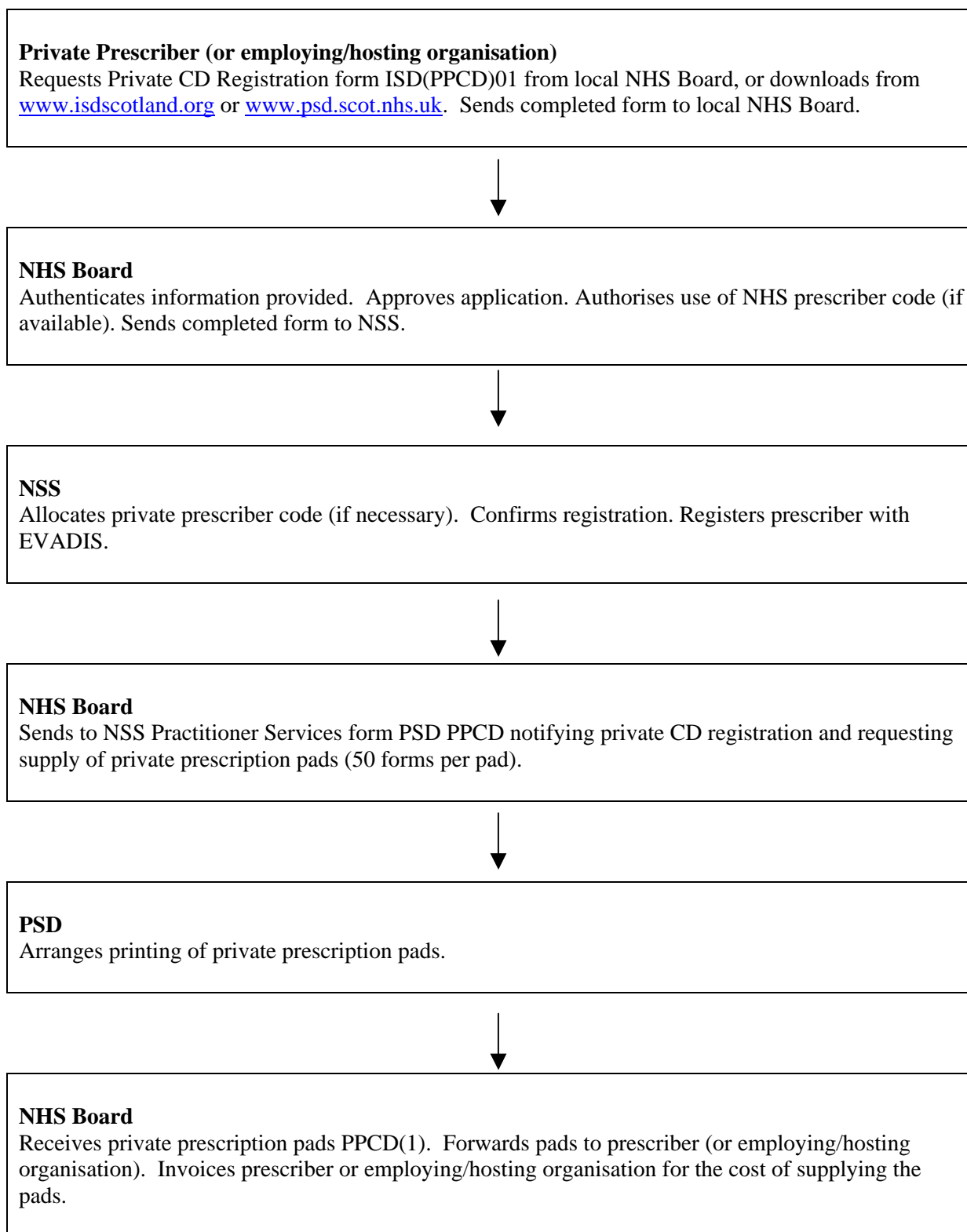
30. Professional guidance strongly recommends that medicines returned from patient stocks should not be re-issued or used to treat other patients. The Pharmacists' Code of Ethics prevents them from re-using patient returns. A breach of this requirement could form the basis of disciplinary action by the RPSGB.

Additional Guidance

31. Additional guidance will be issued to support the implementation of further amendments to the Misuse of Drugs Regulations. This will include guidance on 'technical' errors on prescription forms, recording the identity of persons collecting controlled drugs on behalf of patients (both public and professional) and broadening the groups of people entitled to witness the destruction of controlled drugs.

32. Further guidance is also being prepared on new strengthened governance arrangements for controlled drugs.

FLOW CHART: APPLICATIONS FOR REGISTRATION TO PRESCRIBE PRIVATELY SCHEDULE 2 & 3 CONTROLLED DRUGS



Annex B - F not available online – Please contact Lorna Rammage - see contact details on Page 1