DDA
Dispensing Guidance 2012
Quality in practice
DDA Dispensing Guidance 2012
Edition Number 6

Quality in Practice
Guidance for Dispensing Practices in England, Scotland and Wales

Introduction

Welcome to the 2012 edition of the DDA dispensing guidance for practices in England, Scotland and Wales.

This new, sixth edition of the dispensing guidance aims to reflect the changing environment in which dispensing practices operate. New chapters include information on working with pharmacies, the Electronic Prescription Service, Category M and pharmaceutical Specials. There are also important updates to information on staff training, inter-practice medicines procurement and the regional control of entry regulations.

Keeping this guidance up to date is no mean feat, and so our thanks go to the DDA Board and its associates, who have helped in the production of this edition. Particular thanks must go to DDA Online journalist Ailsa Colquhoun for her help in updating this edition, and to Dr Malcolm Ward, whose work on the previous edition of the DDA dispensing guidance still proves invaluable.

We aim to keep this guidance under constant review to keep pace with legislative and service delivery changes, and we welcome your help in alerting us to any updates, errors or omissions. Please send these to: office@dispensingdoctor.org.

The guidance will be posted in the members’ section of the website, at: www.dispensingdoctor.org, along with any subsequent revisions.

Over the years, the DDA dispensing guidance booklet has become a valuable tool for all those who are involved in dispensing by doctors. Please take the time to read it carefully, bringing the relevant points to the attention of your dispensing team.

Dr Richard West MBE
Chairman
The Dispensing Doctors’ Association
**Historical Context**

There are over 1,300 dispensing practices in the UK, supplying pharmaceutical services to almost four million of their nine million registered patients.

The rules governing who may or may not receive dispensing services have changed little in the last century; it was Lloyd George’s administration that decided that, in rural areas, where patients lived more than a mile from their nearest pharmacy, an exception must be made to the tenet that “doctors prescribe and pharmacists dispense” and they could ask their doctor to dispense directly to them.

Medicine and technology have come a long way since 1911 and the boundaries between pharmacy and medicine have become less rigid; not only do doctors dispense, but increasingly, pharmacists prescribe. So the old tenet is no longer valid.

If we want to retain the ability to provide the dispensing services that our patients value so highly, then it is essential that those services are of the highest quality.

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**Definitions**
Even the best prescriber makes mistakes, and that applies across the whole host of prescribers, whether medical (GPs, doctors, consultants) or non-medical (pharmacists, nurses, dentists, podiatrists, radiographers, etc). The dispensary, therefore, fulfils a very important double-checking role, even when the doctor’s prescribing expertise is extensive and very familiar, to ensure that the right patient gets the right drug, in the right quantity, and in the right dose and strength – every time a drug is dispensed.

The National Patient Safety Agency identifies the following medication errors as the most common:

- wrong dose, strength or frequency of medicine
- omitted medicine
- wrong medicine


Two groups of patients are commonly associated with medication errors:

- Patients with known allergies to certain medicines, particularly to antibiotics
- Children, particularly, aged up to four years. The commonest problems are in dose calculation (including 10-fold errors) and particular medicines (paracetamol, morphine, vaccines, insulin products)

If you in doubt about the prescription seek help from a reputable reference source such as:

- The British National Formulary: www.bnf.org
- MIMS: www.mims.co.uk
- The electronic Medicines Compendium (Summaries of Product Characteristics): www.medicines.org.uk/emc
- Local drug information services

If you are still in doubt, refer back to the prescriber

The National Patient Safety Agency offers a wealth of good advice on preventing medication errors. The seven key actions to improve medication safety are:

1. Increase reporting and learning from medication incidents and identify actions against local risks in an annual medication report
2. Implement and audit NPSA safer medication practice recommendations
3. Improve staff skills and competences
4. Minimise dosing errors, by providing information, training and tools for staff to make calculations of doses easier, and target efforts towards high-risk areas (such as children) and high-risk drugs (such as insulin)

5. Ensure medicines are not omitted, by identifying current levels of omitted medicines and target areas for action (for instance, anticoagulation or other high-risk medication), reviewing medicine storage and medication supply chains

6. Ensure the correct medicines are given to the correct patients by improving packaging and labelling of medicines, and supporting local systems that make it harder for staff to select wrong medicines or give medicines to wrong patients

7. Improve recording of patient allergies, and raise awareness amongst staff of high-risk products and the importance of knowing the patient’s allergy status.

For more information on medication safety, visit the NPSA at: www.nrls.npsa.nhs.uk

1.2 Signing the prescription

Thanks to the use of computerised systems in general practice, prescriptions are generally transmitted electronically to the dispensary. Provided the software safeguards are in place to prevent someone other than the doctor issuing a prescription, the Medicines Act definition of an “electronic prescription” is satisfied, and a handwritten signature is not required prior to dispensing to comply with the criminal law. But, and it is a very large “but” – and common practice notwithstanding – GPs signing a prescription post-dispensing are, technically, in breach of their terms of service.

Schedule 6 of the 2012 NHS Pharmaceutical Services Regulations modify the terms of service of dispensing doctors to:

- **Exempt personally administered items from the requirement to record any order before the drugs or appliances are dispensed**

- **State that dispensing doctors must not unreasonably refrain from issuing a prescription form for dispensing at a pharmacy, if the patient so requests.**

The legislation also intends that the pharmaceutical terms of service of dispensing doctors will become the terms of service of their primary medical services contract with the PCT, and so become enforceable under that contract. This aims to pacify those respondents to the consultation who commented that dispensing doctors should be subject to the same performance sanctions regime as pharmacists and Dispensing Appliance Contractors.
1.3 Prescriptions for Controlled Drug (CDs)

Prescribers can issue computer-generated prescriptions for all Controlled Drugs including Schedule 2 and 3 Controlled Drugs. All details can be computer-generated except for the signature.

Prescriptions for Schedule 2 and 3 Controlled Drugs (exception: temazepam) must meet certain prescription requirements:

- Specific dose: As directed/when required is not acceptable
- Form (even when only one form exists)
- Strength (even if only one strength exists)
- Quantity: must be specified in words and figures
- Instalment dispensing: prescriptions must include the amount of the instalment and the instalment intervals.

For more information

Comprehensive guidelines for the management of Controlled Drugs in primary care (England) are available [online] from the National Prescribing Centre at: [http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_third_edition.pdf](http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_third_edition.pdf)

Standard Operating Procedures on Controlled Drugs are also available to DDA members [online] at: [http://www.dispensingdoctor.org/about.php?id=835](http://www.dispensingdoctor.org/about.php?id=835)

More information on Controlled Drugs is available in section 4.6 of this Guidance

1.4 Prescriptions for pharmaceutical ‘Specials’

Due to their cost, pharmaceutical ‘Specials’ should only be prescribed after extensive consideration of the patient’s pharmaceutical needs, comprising the following step-wise approach:

1. Consider referral to Speech and Language Therapy for a swallowing screening assessment. Speech and language therapists may be able to recommend simple interventions to help patients swallow.

2. Medication Review to check that medication is still required.

3. Use a licensed medicine in a suitable formulation - consider changing the drug or formulation taking into consideration possible differences in bioavailability and ingredients

4. Use a licensed medicine in an unlicensed manner. Prescribers must be satisfied that such use would better serve the patient’s needs than an appropriately licensed alternative that does not require manipulation. A written direction must be documented in the patient’s care plan.

5. Use an unlicensed ‘special’. Special-order (‘special’) liquid medicines are unlicensed and can be expensive.

The prescription for the Special should define exactly what the medicine should consist of (the formulation). Prescribers are advised to specify a batch-produced formulation, where possible.
For more information

Further prescribing guidance for patients with swallowing difficulties is available:
From the DDA [online] at:
http://www.dispensingdoctor.org/content.php?id=1647
From the Medicines and Healthcare products Regulatory Agency [online] at:

More information on endorsing and procuring Specials can be found in Sections 1.7 and 3.5.

1.5 Understanding prescription charges

In England, from April 2012, the charge is £7.65 for each prescription item, preparation or type of appliance including each anklet, legging, knee cap, below knee, above knee or thigh stocking.

Unless a completed declaration of entitlement to exemption or remission is made on the prescription form, a charge is payable for each drug or appliance supplied, including each piece of elastic hosiery.

In Wales, Scotland and Northern Ireland, prescriptions are free.

For more information on prescription charges:

England and Wales: Part XVI of the Drug Tariff for England and Wales [online] at:
http://www.nhsbsa.nhs.uk/924.aspx

Scotland: Annex B of the Scottish Drug Tariff [online] at:
http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish Drug-Tariff/

Single or multiple charges

Part XVI of the Drug Tariff for England, Section 11, Notes on charges payable, lists the rules which govern single and multiple prescription charges.

A single charge is payable where:

- The same drug or preparation is supplied in more than one container
- Different strengths of the same drug are ordered as separate items on the same prescription form
- More than one appliance of the same type [other than hosiery] is supplied
- A set of parts making up a complete appliance is supplied
- Drugs are supplied in powder form with a solvent separate for subsequent admixing
- A drug is supplied with a dropper, throat brush or vaginal applicator
- Several flavours of the same preparation are supplied.

Multiple prescription charges are payable where:

- Different drugs, types of dressings or appliances are supplied
• Different formulations or presentations of the same drug or preparation are prescribed and supplied
• Additional parts are supplied together with a complete set of apparatus or additional dressing(s) together with a dressing pack
• More than one piece of elastic hosiery is supplied.

**Charge exemptions**

The list of exemptions to the prescription charge, now payable in England only, is extensive.

Provided that the appropriate declaration is received, a charge is not payable for drugs or appliances, including elastic hosiery, supplied for:

• Children aged under 16
• Young people aged 16, 17 or 18 in qualifying full-time education
• People aged 60 and over
• People holding a valid exemption certificate, which is issued to:
  • expectant mothers
  • women who have borne a child or women who have given birth to a child in the last 12 months
• people suffering from the following specified conditions who have a valid exemption certificate:
  I. permanent fistula (for example, caecostomy, colostomy, laryngostomy or ileostomy) requiring continuous surgical dressing
  II. a form of hypoadrenalism (for example, Addison’s Disease) for which specific substitution therapy is essential
  III. diabetes insipidus and other forms of hypopituitarism
  IV. diabetes mellitus, except where treatment is by diet alone
  V. hypoparathyroidism
  VI. myasthenia gravis
  VII. myxoedema (that is, hypothyroidism requiring thyroid hormone replacement)
  VIII. epilepsy requiring continuous anti-convulsive therapy
  IX. continuing physical disability which means they cannot go out without the help of another person
  X. cancer - for further information about the exemption for cancer please see the Drug Tariff for England and Wales.

• War pensioners holding a War Pension exemption certificate for prescriptions needed for treating their accepted disablement
• People who have purchased a Prescription Prepayment Certificate (PPC), which is valid at the point of dispensing
• Contraceptive substances, drugs used for contraceptive purposes, and listed contraceptive appliances
• Medication administered personally by a GP
• People in receipt of certain State benefits
• People named on, a valid NHS Tax Credit Exemption Certificate
• People named on a valid HC2 certificate (help with healthcare costs)
• Released prisoners who present an FP10 or FP10 (MDA) will not have to pay a prescription charge for any item on that form if the following applies:
  I.  ‘HMP’, the prison name, address and the prison telephone number is printed in the box provided for the practice address on the front of the form, with the prescribing code and responsible Primary Care Trust code.
  II. The patient does not have to sign the declaration, but should print their name and address if different from the front of the form. Should the patient be homeless the use of ‘No Fixed Abode’ is acceptable in part 3 of the form.

Exemption certificates only apply to charges for NHS prescriptions but they cover all prescriptions, not just those for the exempting condition.

Pending receipt of an exemption certificate, patients should ask the dispenser for an NHS receipt (FP57) (which is also a refund claim form) when they pay a prescription charge.

**Medical exemption**

Patients diagnosed with one of the qualifying conditions for medical exemption, who are aged 60 or and over are exempt from NHS prescription charges on age grounds and do not need to apply for a medical exemption certificate.

However, patients who are exempt because they are receiving a relevant benefit, for example income support, may wish to apply for a medical exemption certificate so they are covered if their financial circumstances change.

Applications for medical exemption for all patients, including cancer patients, are made to, and exemption certificates issued by, the NHS Business Services Authority (BSA). Certificates run for five years and are in respect of all NHS prescriptions, not just those for the exempting medical condition.

Certificates can be used until the end date shown. A reminder will be issued automatically and the certificate may then be renewed if the qualifying conditions still apply. Certificates do not have to be returned if the patient’s condition changes. They should be returned on the death of the patient so the system may be noted and no reminders sent.

Application forms FP92A are only available for NHS use. They are normally purchased and distributed by the primary care organisation. They have been revised to include cancer patients.

If a patient receiving private treatment has an NHS doctor, they may apply for exemption if the doctor has access to records to enable him/her to confirm the patient’s statement.

**For more information**

1.6 Obtaining patient declarations

**England:** To secure exemption of or remission from prescription charges when presenting a FP10 prescription form for dispensing, the patient, or a patient representative must complete the declaration on the back of the prescription form. Patients or their representatives are also required to sign the prescription form to declare that a charge has been paid. Charges are retained by the dispensing practitioner whose payment for provision of pharmaceutical services is adjusted accordingly.

**Prescription charge collection**

Dispensing practices levying the prescription charge have a duty to check that the patient has supplied evidence of the exemption status that is being claimed. Practices also have a financial interest.

Any prescription form submitted without a completed reverse declaration will be considered a chargeable item, the prescription ‘switched’ to the chargeable bundle, and a deduction will be made from the practice’s remuneration.

The only exceptions are computer-generated prescriptions for patients with the relevant age exemptions, and those for personally administered items.

Therefore, before submission, practices must make every effort to ensure the patient or patient’s representative has filled in and signed the prescription charge declaration. However, dispensing practices are not expected to be confrontational and if no evidence is seen, they should tick the box in the right hand corner of the reverse of the prescription form to say so.

**Patient representative’s liability**

Dispensing staff or the doctor may also act as the patient’s representative and fill in and sign the declaration on the patient’s behalf. However, they should only do so when there is absolutely no doubt as to the claimed exempt status.

The representative who signs on the patient’s behalf will be held jointly and severally liable by the NHS counter fraud authorities for any incorrect claim made.

**Contraceptives**

In some circumstances, contraceptive products will attract a prescription charge, so the script must be endorsed to show whether a charge has been levied. An example is co-cyprindiol (Dianette/Clairette/Acnocin/Diva/Cicaferm) which is prescribed both as a contraceptive pill and as a specific treatment for acne.

When used for acne only, a prescription charge is due. When used for contraception the prescription form needs to be endorsed by the prescriber with the female gender symbol, ♀, OC or CC to qualify for prescription fee exemption. Patients should also sign the contraceptive exemption declaration on the reverse of the form.

Prescriptions for contraceptive items listed in Parts Ixa and items listed in Part XVI of the Drug Tariff (England and Wales) are automatically exempt from prescription charges. Prescriptions for items not listed in either of these Parts of the Drug Tariff
should be endorsed with the female notation to qualify for prescription fee exemption.

**Policy requirements**

The practice must ensure they have collected charges where appropriate and keep accurate monthly records of:

- The total number of exempt items, and prescription forms dispensed
- The total number of ‘paid for’ items and forms dispensed
- The total amount of fees collected: this should equal the total number of fee-paid items multiplied by the current prescription fee
- The total number of items and forms covered by pre-payment certificates.

Before submission, FP10s should be checked to ensure the declarations have been filled in and signed, except for those relating to personally administered items and computer-generated prescriptions exempted on age criteria.

It may be helpful to ask the prescriber to write exempt items such as the contraceptive pill and personally administered items on separate FP10s, to reduce the administration of tallying and recording charged and exempt items on the Prescription Pricing Authority submission document (form FP34D).

Practices should also check that the prescriber code matches the form type (eg, Nurse prescribers may not use doctors’ prescription forms, and vice versa).

**Off-site deliveries:** When an item is delivered to a patient outside the surgery, the practice must make every reasonable effort to obtain a signed declaration from the patient that they have either paid the charge or are exempt.

However, there will be occasions when repeat prescriptions are delivered to points outside the surgery, or for example for collection from village shops in rural areas. Where a patient is exempt from charges and it is not practical for the patient to sign the form, a dispensing doctor or responsible member of the practice team should mark the reverse of the form as "remote delivery". The back of the prescription form should be signed and a box ticked, even if the patient would not be required to sign it if they picked it up in person.

More information on the transit of medicines off-site is included in Section 2.10 of this Guidance.

**In Wales,** there is no longer any requirement for a patient or their representative to sign the declaration on the reverse of a WP10 to be exempt from paying a prescription charge.

In Scotland, even though prescriptions (GP10) are free, the patient/patients’ representative is required to sign the reverse of the script at Part B as confirmation that the item(s) have been dispensed.
Controlled Drugs

Identity Checks: There is a legal requirement for the dispensary to establish whether a person collecting a Schedule 2 CD is the patient, the patient’s representative or a health care professional acting within their professional capacity. This only applies to Schedule 2 CDs. Where the person collecting the Schedule 2 CD is the patient or the patient’s representative, the dispensary should ask for proof of identity, for example, ask to see photo-ID or a credit or debit card. The dispensary has the discretion to decide whether to ask for proof of identity and also whether to supply the CD. Where the person collecting the Schedule 2 CD is a health care professional, the dispensary must obtain the person’s name and address and must ask for proof of identity unless the health professional is known to them. The dispensary may still supply the CD even if ID is not provided.

Signing the prescription form

Individuals should be asked to sign the back of the prescription form, when they are handed a Schedule 2 or 3 CD, as confirmation of collection. Where the person collecting the CD/s does not agree to sign the back of the form, the dispensary is not obliged to supply the CDs.

1.7 Endorsing the prescription

To ensure that the practice is paid correctly for the prescriptions it dispenses, the prescription must be correctly endorsed. Prescription pricing departments cannot read practices’ minds - only the prescription endorsement in front of them - particularly, as pricing is now done using computer scanners.

The endorsement has the following functions:

- To claim reimbursement for dispensing NHS items
- To account for prescription charges.

Drugs to be reimbursed only in certain circumstances

Some drugs can only be prescribed and dispensed on the NHS in some circumstances. The endorsement is your claim that these circumstances have been met. There are two main endorsements to consider:

- Advisory Committee on Borderline Substances (ACBS)
- Selected List Scheme (SLS).

Most computer systems provide automated ACBS and SLS endorsement, and the prescriber – not the dispenser – should ensure this endorsement is applied.

The Drug Tariff should always be consulted if there is any doubt as to the reimbursement status of a drug. The Tariff can be found at:

ACBS (Advisory Committee on Borderline Substances)

Certain foods and toilet preparations have characteristics of drugs. The circumstances in which such substances may be regarded as drugs, and therefore, supplied to NHS patients, are decided by the Government body, the Advisory Committee on Borderline Substances. To verify that the item is being prescribed for a medical condition, prescriptions must be endorsed ‘ACBS’.

Examples of items requiring ACBS endorsement include: gluten-free foods for coeliac disease, food supplements such as Fortisip and Ensure, complete food preparations such as Nutrison, topical preparations such as E45 emollient bath oil and total UV block preparations.

For more information

For more information on items requiring ACBS endorsement, see:
Part XV of the Drug Tariff for England and Wales
Part 12 of the Drug Tariff for Scotland
MIMS [online] at: www.mims.co.uk
BNF Appendix 7 [online] at: www.bnf.org

SLS (Selected List Scheme)

The SLS comprises ‘black’ and ‘grey’ lists. Drugs on the black list may not be supplied on the NHS, while drugs on the ‘grey list’, may be supplied on the NHS only for specific medical conditions. The endorsement SLS verifies that these circumstances have been met.

Action point: For more information on SLS items, see:
The NHS (General Medical Services) (Prescription of Drugs etc) Regulations 2004 Schedules 1 and 2 [online] at: http://www.legislation.gov.uk/uksi/2004/629/contents/made
Part XVIII of the Drug Tariff for England
Part 12 of the Drug Tariff for Scotland

Endorsements related to reimbursement

The requirements for endorsing prescriptions in relation to reimbursement are set out in the Drug Tariffs.

England and Wales:

For a Generic Product listed in Part VIIIA or Part VIIIB of the Drug Tariff, reimbursement is based on the Drug Tariff price. The only endorsement that may be required is the pack size where there are multiple pack sizes listed in Part VIIIA of the Tariff. For example where the pack used is 56 and the quantity supplied is 28 the fraction 28/56 should be written in the endorsement column.
For a **Generic Product which is not listed in Part VIII A of the Drug Tariff**, reimbursement is based on the manufacturer’s list price of the endorsed product. Endorsement of the brand name is therefore required as well as the pack size where multiple pack sizes of the product are available. If no brand exists, then an endorsement of manufacturer/supplier is required. If the product is less common the net price before discount and ex VAT should also be endorsed. Please note that it should be clear whether the price endorsed is for the prescribed quantity or for the full pack size used.

For a **Generic Product which is not listed in Part VIII B of the Drug Tariff** reimbursement will depend on how the special was sourced. Where the special has been sourced from a manufacturer holding a MHRA specials licence, the contractor will be paid the price endorsed on the prescription form. This price should be invoice price less any discount or rebate which may be linked to the procurement of this product.

### Other common endorsements

#### Broken bulk

`Broken bulk` allow dispensers to claim for reimbursement of the full minimum quantity obtainable from a supplier or manufacturer of a product, even if the patient only requires a smaller quantity (as indicated on the prescription form). This provision only applies to those products where the minimum quantity obtained cannot be readily dispensed for another patients during the next six months – in fact, any subsequent prescription submitted within the following six months for the same item in any quantity up to the quantity already reimbursed will be deemed to have been supplied from the remaining original quantity, and will not be reimbursed. Exceptions to the broken bulk entitlement are listed in the Drug Tariffs.

**The endorsement is:** BB

#### Out of Pocket Expenses (OOPE)

From July 1st, 2012, a new 50p threshold for claims will apply, and entire claims will be paid (no deductions). This replaces the previous system where contractors can only claim where the expense is greater than 10p, and 10p is deducted from all payments for OOPE.

To make claims, practices should endorse prescriptions `XP` or `OOP` along with details of the claim, eg, carriage, P&P. There is no longer any need to total and submit the OOPE claim on the submission form. These prescriptions should be separated from the bulk of prescriptions.

#### Calendar packs:

From July 1st, 2012 the provisions related to calendar packs will be removed to reflect new pack size listings also coming into effect on July 1st.

In the new arrangements, contractors will be paid for the quantity prescribed on all occasions except in the case of special containers, where the current provisions will remain.

For more information
DDA Online: http://www.dispensingdoctor.org/content.php?id=2050

Specials
Since November, 2011, reimbursement prices for commonly-prescribed Specials have been included in a new section of the Drug Tariff for England and Wales, Part VIIIB.

As of April, 2012, Scotland was discussing whether to introduce Tariff prices for Specials.

In England and Wales, items not included in Part VIIIB will be reimbursed according to how the item has been obtained.

Where the item has been obtained from a manufacturer holding a MHRA specials licence, reimbursement will be made according to the price endorsed by the contractor.

Endorsement required
The price endorsed should be the invoice price paid by the dispensing practice less any discount or rebate linked to the procurement of the item, ie, the actual price paid for the item. Dispensing doctor discounts will be applied, as set out in the NHS GMS Statement of Financial Entitlements (SFE).

Contractors are reminded that the endorsement should also include:

- the manufacturer’s/importer’s licence number
- the batch number of the unlicensed medicine.

Where the special has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, by the contractor or by a third party, the contractor shall endorse the names, quantities and cost of the ingredients used in preparing the special.

Remuneration
Following extensive negotiation between the NHS and the GPC/DDA during 2011/12, dispensing practices in England and Wales will now be paid a £20 fee for dispensing any special. The fee must be claimed by endorsing XP on the prescription, together with the amount claimed: £20.

This is set out in the paragraphs of the Drug Tariff “Arrangements for payment for all other Specials and Imported unlicensed medicines” and “Endorsement requirements above Part II Clause 9”.

Each £20 claimed must then be included on the FP34D submission documents sent to the NHSBSA. Further guidance is included on the reverse of the
The General Medical Services Statement of Financial Entitlement was amended, with effect from April 1st, 2012. Section 17 (Dispensing) in paragraph 17.3 (costs in respect of which reimbursement is payable) will read:

(e) professional fees, as provided for in Part IIIA, clause 2A (additional fees for unlicensed medicines), of the Drug Tariff.

Scottish practices are advised to check the arrangements for specials remuneration with the Practitioner Services Division. At the time of going to press (September, 2012), similar arrangements have not been put in place in Scotland.

More information

More information is available from the DDA [online] at: [http://www.dispensing.doctor.org/content.php?id=1917](http://www.dispensing.doctor.org/content.php?id=1917)

Scotland’s Practitioner Services Division can be contacted [online] at: [http://www.psd.scot.nhs.uk/](http://www.psd.scot.nhs.uk/)

### At-a-glance prescription endorsement guide: England and Wales

<table>
<thead>
<tr>
<th>Prescribed Product</th>
<th>Dispensing Endorsements required for reimbursement</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Tariff Part VIII generic medicinal product</strong></td>
<td>None required</td>
<td>Only required if more than one pack size listed in Part VIII</td>
</tr>
<tr>
<td><strong>Proprietary or branded medicinal product</strong></td>
<td>None required</td>
<td>Only required if more than one pack size listed in manufacturers price list</td>
</tr>
<tr>
<td><strong>Non-Part VIII generic medicinal product</strong></td>
<td>Yes</td>
<td>See above</td>
</tr>
<tr>
<td><strong>Drug Tariff Part IX generic medical device</strong></td>
<td>None required</td>
<td>Only required if more than one pack size listed in Drug Tariff Part IX</td>
</tr>
<tr>
<td><strong>Part IX Proprietary or branded medical device</strong></td>
<td>None required</td>
<td>Only required if more than one pack size listed in Drug Tariff Part IX</td>
</tr>
</tbody>
</table>
## Other endorsements

<table>
<thead>
<tr>
<th>Category</th>
<th>Uses and Restrictions</th>
<th>Endorsement Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broken bulk</td>
<td>For products not likely to be readily dispensed over the next six months. Exceptions apply</td>
<td>BB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The pack size supplied must also be endorsed</td>
</tr>
<tr>
<td>Hosiery</td>
<td>Sufficient information about the product being dispensed is needed.</td>
<td>compression class article style quantity knit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If appropriate made to measure eg, Class2, Thigh Length, 2 stockings, Circular Knit</td>
</tr>
<tr>
<td>Not Dispensed</td>
<td>Where an item has not been dispensed the prescribed product name should be <strong>scored out</strong> and an ND endorsement made immediately adjacent to the prescribed product name.</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dispenser is also required to <strong>score out</strong> item in prescribed area</td>
</tr>
<tr>
<td>Price</td>
<td>For less common products (other than unlicensed specials and imports) and for certain appliances, the total net price for the prescribed quantity (before discount and ex VAT) should be endorsed on prescriptions. For unlicensed medicines not listed in Part VIIIB (England and Wales) the total net price for the prescribed quantity (after any discount or rebate and ex VAT) should be endorsed on prescriptions. If the price endorsed relates to the price of the pack size this should be clearly endorsed.</td>
<td>IP</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>£p</strong> (before discount and ex VAT)</td>
</tr>
<tr>
<td>Trusses</td>
<td>Single or double, and side if single. Position, eg, Inguinal, Scrotal Type, eg, Spring truss, Elastic band truss.</td>
<td>single double position type</td>
</tr>
<tr>
<td>Unlicensed specials and imported products</td>
<td>Products not listed in Part VIIIB (England and Wales) should be endorsed with manufacturer/supplier and net price (after any discount or rebate and ex VAT).</td>
<td>net price (after discount or rebate and ex VAT) if appropriate</td>
</tr>
</tbody>
</table>

Source:  PSNC guide to prescription endorsement [online] at:  
Scotland

Probable endorsements:
The four boxes on the pink GP10 prescription form, in the right hand column, represent the pack size boxes. All other endorsements should be printed under the four boxes for each item on the prescription.
The only data included in the box should be the pack size in numeric quantity only.
Please do not enter units of measure such as `g' or `ml'.

Pack endorsement: The pack endorsement is used to indicate the size of pack used to dispense the quantity. Under the pricing rules, the Scottish pricing authority, Practitioner Services Division assumes that you are using the most economical pack sizes available. However, for many products different pack sizes are available. If the pack size you are using differs from the most economical pack size, you will need to add a pack size endorsement to determine payment.
Pack of 28 will be denoted as: 28

Quantity supplied (if not as prescribed): If in dispensing a product, you have to change the quantity so that it differs from the prescribed quantity, an endorsement should be added to show the quantity change.
A quantity change may be required where the prescriber prescribes an amount which cannot be dispensed exactly, due to the nature of the pack. The quantity change allowed is related to the size and number of packs available, and is subject to PSD rules.
Denote 60 quantity supplied as: 60

Manufacturer: To ensure accurate payment for items prescribed generically which are not in the Drug Tariff, you should provide the name of the manufacturer.
In the absence of an endorsement you will be paid from a pecking order from an agreed list.

ALLIANCE HEALTHCARE / ALMUS
AAH
THORNTON AND ROSS (T&R)
APS / TEVA/NORTON/PLIVA/ IVAX/RATIOPHARM
ALPHARMA/ACTAVIS/BERK/COX
CP / WOCKHARDT
GENERICS-UK
KENT
NUMARK
Invoice Price Endorsement

The endorsement is SP, followed by the NHS net cost price, excluding VAT, in format ‘pppp’. The claim below is for £4.58. An invoice should be submitted as evidence of the claim, but the price claimed must be declared on the prescription form or no payment will be made.

Example: SP 458

Out of Pocket Expenses (OOPE)

Where additional expenses have been incurred in obtaining supplies of a drug other than items in Parts 2-7 and 9 of the Scottish Drug Tariff, payment of the amount incurred will be made if the contractor submits a claim. You should provide evidence of cost, including the nature of the expense, and the value claimed. Where the invoice covers more than one prescription form, Out of Pocket expenses should be claimed on one occasion only.

The endorsement is: XP and the cost must be stated in the format pppp.

Example: For out of pocket expenses of £7.95, the endorsement is: XP 795

Items in Short Supply

Where a dispensing practice is unable to obtain an item listed in Part 13 of the Scottish Drug Tariff, at the price listed in the Tariff, they should endorse the prescription with the manufacturer/brand and the net cost price excluding VAT. A copy of the invoice should be paper-clipped to the prescription.

For more information:

Scotland’s Practitioner Services Division [online] at:
http://www.psd.scot.nhs.uk/professionals/pharmacy/information-for-dispensing-doctors.html

Community Pharmacy Scotland [online] at:
http://www.communitypharmacy.scot.nhs.uk/endorsing_guide/Section1/introduction.html
1.8 Submission for pricing

Dispensing of hospital-generated prescriptions

Some hospitals do not provide outpatient dispensing services but instead issue the patient with a FP10 (HP) prescription (England), WP10HP (Wales) or HBP (Scotland). If the patient is on your dispensing list, you may dispense this medicine to him/her.

In England, Scotland, and Wales dispensing practices may also dispense for their dispensing patients prescriptions generated by dentists and by an out of hours service.

Payment for hospital-generated prescriptions

FP10 (HP) or equivalent prescriptions can be submitted for payment by general practices using the normal payment submission routes. FP10 (HP) or equivalent prescriptions should not be transcribed onto practice prescription forms as this will result in the drug costs being attributed to the practice rather than the hospital. The same applies to prescriptions issued by dentists.

England

FP10s should be sorted into patient charge group: exempt, paid, paid at the previous year’s rate. Each group should be segregated and secured with a plastic band.

Within each group, prescriptions should be sorted in the order below:

- Resubmitted forms from previous month/s
- Forms FP10MDA by prescriber surname – to be sorted open and flat
- Forms FP10D
- Forms FP10P/SS with relevant practitioner indicator by prescriber surname, eg, PN=Practice Nurse, CN=Community Nurse
- Forms FP10P/SS with supplementary prescriber (SP) indicator by prescriber surname
- Forms FP10SS/NC Hospital forms
- All other FP10 forms by prescriber surname

Dispensing contractors must send in the pink FP34D Submission Document declaration form when making monthly claims for reimbursement and remuneration, and a FP34D Appendix form for high volume personally administered vaccine items.

For more information

For more information on completing the FP34D visit the NHS BSA at: http://www.nhsbsa.nhs.uk/2473.aspx
Wales:
Contractors are asked to separate exempt prescriptions into two groups before submission for pricing:

**Group 1:** Those that can be priced automatically
**Group 1a:** Those prescriptions that need to be priced by an operator
**Group 2** Patient charge has been levied

**Separating scripts into Group 1 and Group 1a**

**Group 1 (to be automatically priced)**
This group should only include regular (WP10SS, WP10IPSS, WP10SPSS & WP10PN) exempt prescriptions which have been dispensed as prescribed and where there is no additional claim or endorsement added i.e. where you would be happy for an automated system to pay you for the prescription as it has been prescribed.

**Group 1a (to be passed to an operator for review and pricing)**
Group 1a should include all of the remaining exempt prescription forms. This group will include all of the remaining prescription form types and any prescription forms where changes or additional endorsement has been necessary i.e. an exception applies.

**Group 1a would therefore include the following:**

---

**Exceptions:**
- Broken Bulk claimed
- Dispensed quantity is different to that prescribed
- Out of Pocket Expenses claim
- Item not dispensed
- Local special scheme endorsed (e.g., WRS)
- Additional items claimed (e.g., droppers)
- NCSA or NCSO items
- Generically prescribed but branded drug indicated on prescription
- Hand written amendment has been made to prescribed information

**Other Prescription Forms:**
- Resubmissions
- WP10HP(AD) (Hospital CD instalment)
- WP10MDA (GP CD instalment)
- All other non standard WP10 forms including Repeat dispensing forms
- All WP10 equivalents e.g., England FP10 series forms
In Wales the submission document is the WP34D. Personally administered items can be submitted online.

For more information
Wales Prescribing Services at:

Scotland
Scotland’s Practitioner Services Division requires the submission document, the yellow GP34A, to be completed with the following information:

- Dispensing month
- Date of dispatch
- Contractor code
- Practice Name and address including postcode
- Practice stamp
- VAT registration number
- Signature of Doctor
- Forms and items as exempt - please align to the left

It is important that the figures detailed on the GP34A declaration agree with the forms being submitted on that occasion.

For more information:
Scotland’s Practitioner Services Division at:
http://www.psd.scot.nhs.uk/professionals/pharmacy/information-for-dispensing-doctors.html

Prescription handling tips

<table>
<thead>
<tr>
<th>Glue:</th>
<th>Avoid sticking a label on the prescription during the dispensing process. Residual glue can jam the high speed scanners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removable items:</td>
<td>Avoid using tape, pins, paperclips, staples or post-it notes, as these have to be manually removed</td>
</tr>
<tr>
<td>Stamping:</td>
<td>Take care when stamping and endorsing prescriptions not to obliterate the age and date of birth box on the front of the prescription form. Difficult to read age/DOB information could lead to the prescription being switched from exempt to chargeable</td>
</tr>
<tr>
<td>Endorsing:</td>
<td>Endorse legibly and clearly, using only the minimum amount of information required. As far as possible, keep endorsements within the left-hand margin of the prescription form. Printed endorsements that are faint or out of line with the prescribed product information risk being referred back. There should not be a gap between consecutive item endorsements. Please ensure that items are separated, and that it is clear where one endorsement ends and another starts</td>
</tr>
</tbody>
</table>
1.9 Understanding the schedule of payments

Since the introduction of new automated prescription scanning equipment in England, prescription pricing accuracy has emerged as an area of concern. All practices, irrespective of location, are advised to check carefully their schedule of payments, particularly for discrepancies relating to prescription charges and expensive items. If you believe that there is a significant discrepancy over reimbursement of a particular bundle you may arrange for the bundle to be sent by the pricing authority to your primary care organisation/health board for inspection. The pricing authorities cannot return individual prescription forms for retrospective correction.

To help identify discrepancies relating to prescription charges, practices should keep detailed monthly records of:

- The total number of exempt prescription forms dispensed including a record of the number of items covered
- The total number of ‘paid for’ items dispensed and the number of related forms
- The total amount of fees collected: this should equal the total number of fee-paid items multiplied by the current prescription fee.
- The total number of items and forms covered by pre-payment certificates.

<table>
<thead>
<tr>
<th>Ticks and marks:</th>
<th>Avoid these as these can interfere with optical character recognitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity owing:</td>
<td>Do not leave information on quantities owing in the endorsement column, as these may be interpreted as quantity dispensed</td>
</tr>
<tr>
<td>Dispatch:</td>
<td>If a courier service is not provided, items should be posted by a track and trace method, no later than the fifth day of the month following the month during which supply was made</td>
</tr>
</tbody>
</table>

For more information:
England and Wales

NHS Prescription Services produces electronic payment schedule data (called 'electronic FP34 data') which contractors can use instead of receiving a paper copy. It is not a like for like replacement of the paper version and practices will need to develop their own IT solution to allow them to read and manipulate the data as it is not readily exported to Microsoft Excel.

Schedules can be received in conjunction with the paper FP34 and a 12-month history is maintained. At an agreed time, the NHS Prescription Services will stop sending paper FP34s.

An example Schedule file is available at: http://www.ppa.org.uk/systems/sys_main_fp34.htm

For more information
NHS Business Services Authority at: http://www.nhsbsa.nhs.uk/PrescriptionServices/2272.aspx

Scotland

Information on dispensing related payments due to Scottish practices is issued each month by the Practitioner Services Division in the form of a Summary of Payments and an attached A3 payment breakdown document. Contractors should pay particular attention to the sections covering deductions and VAT, particularly on Personally Administered items. Payments are made three months in arrears.

1.10 Understanding Category M

Category M was introduced into the Drug Tariff in April 2005 when the new community pharmacy contract was launched. Category M is used to adjust the reimbursement prices of more than 500 generic medicines in England, Wales and Scotland. It uses information gathered from manufacturers on volumes and prices of products sold plus information from the NHSBSA Prescription Services on dispensing volumes to calculate margins in the supply chain. Its purpose is to ensure that the total contract funding available to pharmacies contains the agreed amount of retained purchase profits (£500 million in England, and proportionate amounts in Wales and Scotland).

The mechanism takes no account of dispensing doctors’ remuneration, nor the volumes dispensed or prices paid by dispensing doctors.

Key points about Category M

- Prices have to be set in advance each quarter, and estimated volumes used may differ from actual volumes
- Quarterly adjustments are made to account for any over or under recovery of pharmacists’ retained purchase profits
- Products may not be available to purchase at the Category M reimbursement price. The Department of Health sets Category M prices at levels substantially above the prices notified by manufacturers.
But when the Category M reimbursement price for a particular product falls, it may take time for wholesale prices to respond. During this period, it is essential that contractors exert maximum pressure on wholesalers. There have been a number of examples where manufacturers' prices were below the Drug Tariff price but a product could not be obtained at the Drug Tariff price from a number of wholesalers. Between 2005-2012, there was no increase in the agreed level of retained pharmacy purchase profits, despite significant increases in the number of items dispensed in England.

- From 2011/12, a number of key patent expiries will take place. The prices paid for the new generic equivalent drugs will be determined by Category M. Any under-recovery of RPP (Retained Purchase Profit) as a result of the time-lag in Category M price-setting will be recovered in subsequent quarters. Practices are recommended to consider the impact of the subsequent profit recovery by the Department of Health on cash-flow.

**Source:** The Pharmaceutical Services Negotiating Committee

**For more information**

More information on the implications of Category M for dispensing practices is available from the DDA at: [http://www.dispensingdoctor.org/content.php?id=1963](http://www.dispensingdoctor.org/content.php?id=1963)

Useful information on Category M is also available from the PSNC at: [http://www.psnc.org.uk/pages/category_m.html](http://www.psnc.org.uk/pages/category_m.html)

**1.11 Private sales**

Under the provisions of The Medicines Act 1968 any doctor can supply, on a private basis, all classes of medicines, including those on the General Sales List, Pharmacy List (P) medicines and Prescription-only Medicines. However, while an NHS practice may sell anything that is not a medicine or an appliance, it may not demand or accept a fee for the provision of a service that constitutes treatment, for a prescription or for the supply of any drug, medicine or appliance except in the circumstances set out in clause 484 of the GMS contract (similar restrictions apply in PMS contracts).

As a result, a GP’s NHS contract strictly limits the private supply of medicines to:

- **Private patients**, who can be supplied with any required medication from the practice
- **NHS patients of the practice**:
  1. for treatment consisting of an immunisation for which no remuneration is payable by the PCT and which is requested in connection with travel abroad;
  2. for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in his possession solely in anticipation of the
onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed;

3. if the patient is a dispensing patient of the practice and the medicine is not prescribable under the NHS – ie, is “a Scheduled Drug” medicine listed in Schedule 1 (the ‘Black List’) of the NHS [General Medical Services Contracts] (Prescription of Drugs etc) Regulations 2004. or a drug listed in Schedule 2 (SLS [see above]) for which the patient does not meet the requirements for provision under the NHS.(Clause 484.11)

4. for prescribing or providing drugs for malaria chemoprophylaxis. (Clause 484.12).

The transaction should always be regarded as dispensing a prescription-only medicine and a full record made accordingly and it is suggested that the charge should take account of:

- The cost of the drug
- An on-cost element
- VAT
- A dispensing fee.

For NHS patients of the practice the charge cannot include any fee for the act of private prescribing. The exception to this rule is for prescribing, on a private basis, anti-malarial drugs for travel abroad. Specific provision has been made for this in the GMS contract (clause 484.12).

**Over-the-counter General Sales List (GSL) and Pharmacy medicine (P) items**

Since there is no statutory distinction between POMs, P-list and General Sales list items supplied by doctors, dispensing doctors may not sell to their NHS patients any OTC items that are available on NHS prescription, eg, aspirin, or paracetamol. Such items must be prescribed using an NHS prescription form, and the appropriate prescription charge paid. As a ‘blacklisted’ medicine, Panadol, however, can be supplied privately.

Our legal advice is that a dispensing practice can dispense privately for their NHS patients only those items that are blacklisted and only if the patient is a dispensing patient (clause 484.11).

A strict interpretation of clause 483 would preclude a practice from charging a fee for use of credit or debit cards to pay prescription charges

**Contract clause 483**

483. The Contractor shall not, either itself or through any other person, demand or accept from any patient or its representative a fee or other remuneration for its own or another’s benefit

483.1 for the provision of any treatment whether under the Contract or otherwise, or

483.2 for any prescription or repeat prescription for any drug, medicine or appliance, except in the circumstances set out in clause 484.
Controlled Drugs

**England and Wales:** All private prescriptions for human use of Schedule 2 and 3 CDs (including temazepam) that are presented for dispensing in the community must be written on a prescription form which must include the private prescriber’s unique (six digit) identification number issued specifically for their private prescribing activity. There are two types of forms available:

- Personalised FP10 (PCD ) NC – prepopulated with the prescribers’ details
- Non personalised forms FP10 (PCD).

**Scotland:** The PPCD(1) prescription form should be used for the non-NHS prescription of schedule 2 and 3 controlled drugs.

Submission of private prescriptions

The original prescription (not a copy) for a Schedule 2 or 3 CD should be submitted after dispensing to the relevant National Health Service Agency (NHS Business Services Authority for England) along with a CD submission form (FP34PCD or equivalent) for data collection and audit purposes.

For more information

The National Prescribing Centre at: [http://www.npc.nhs.uk/controlled_drugs/](http://www.npc.nhs.uk/controlled_drugs/)

### 1.12 Pandemic flu supplies

The UK Influenza Pandemic Preparedness Strategy 2011 outlines the principle of rapid access to antiviral medicines, antibiotics and healthcare. This principle allows the supply of antiviral medicines at premises that are not a registered pharmacy, and as such, enables dispensing doctors to dispense pandemic related supplies to non-dispensing list patients.

**England:** In England access to antiviral medicines is controlled by Listed Medicines Vouchers, also known as Antiviral Authorisation Vouchers, which will be supplied by the PCT to authorised suppliers of antiviral supplies.

Two types of voucher are available:

- **AVA:** for adults and children aged over one year
- **AVB:** for children aged under one year.

Completed Authorisation Vouchers should be retained on behalf of the PCT, and should detail:

- The name of the authorised staff member issuing the voucher
- The address of the authoriser including postcode
- The PCT area in which antivirals are being authorised
- A contact telephone number for the authoriser
- The practitioner PIN (registration number)
Antivirals supplied using Authorisation Vouchers do not attract a prescription charge.

**For more information:**


Scotland: The majority of patients requiring treatment for pandemic influenza are treated outside the primary care setting. However, GPs may prescribe antivirals to at ‘risk patients’ using the standard prescription form.

**Other points to note:**
- Prescribers must state SLS on all prescriptions for Oseltamivir (Tamiflu) and Zanamivir (Relenza)
- If the antiviral stock is from the national stock pile allocation, then the prescription should also be endorsed “not collected” (or INC). This means that Practitioner Services Scotland (PSD) will not reimburse the cost of the product.

**For more information:**
Community Pharmacy Scotland pandemic advice for contractors [online] at: [http://www.communitypharmacy.scot.nhs.uk/news/Pandemic_Flu.htm](http://www.communitypharmacy.scot.nhs.uk/news/Pandemic_Flu.htm)

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**1.13 Record-keeping**

All items dispensed must be properly recorded and all records kept for at least 11 years.

**Controlled drugs**
There are a number of additional record-keeping obligations for CDs:

- **Running Balances:** As a matter of good practice the dispensary supplying the CDs should maintain a running balance of stock in their Controlled Drug Register (CDRs). This is expected to become a mandatory requirement once electronic registers are in common use.
- **Controlled Drug Registers:** Hard-backed, bound exercise books make acceptable CDRs, but loose-leaf ring binders, which may be tampered with, are not. It is also good practice to append each entry with the signature of the person making the entry. Information should be recorded in the CDR under the following specific headings:
When CDs are obtained:

- Date supply obtained
- Name and address from whom obtained (e.g., wholesaler, pharmacy)
- Quantity obtained.

When CDs are supplied:

- Date supplied
- Name and address of person or firm supplied
- Details of authority to possess—prescriber or license holder details
- Quantity supplied
- Whether the person who collected the drug was the patient, the patient’s representative or a healthcare professional acting on behalf of the patient;
- If the person who collected the drug was a healthcare professional acting on behalf of the patient, that person’s name and address;
- If the person who collected the drug was the patient or the patient’s representative, whether evidence of identity was requested of that person (yes/no); and whether evidence of identity was provided by the person collecting the drug (yes/no).

Electronic Controlled Drug Registers: Electronic CDRs are permitted, provided every computerised entry is attributable and capable of being audited. The computerised register must be accessible from the premises to which it relates and copies of the register, in its computerised or other specified form, must be available for inspection on request.

An electronic CD register must also 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
- There are access control system
- There is adequate backup.

A number of dispensing systems feature an integrated electronic CD register.

For more information


Specials

Where there is a Certificate of Analysis (COA)/Certificate of Conformity (COC) for the special, the contractor must stamp, date, initial and endorse the COA/COC with the invoice price less discount, plus the prescriber’s details, and submit these monthly to the primary care organisation. Where a COA/COC is unavailable, the invoice should be endorsed as above, and submitted to the primary care organisation.

The following records must be kept for five years:

- The source of the special or imported unlicensed product
• The person to whom and the date on which the special or imported unlicensed product was sold or supplied
• The prescriber’s details
• The quantity of each sale or supply
• The batch number of the special.

Chapter 2: The dispensing process

2.1 Staff training and development

In August 1998 the Court of Appeal confirmed that it is lawful for dispensing GPs to delegate to employed staff the act of dispensing medicines for their patients. The DDA encourages and promotes dispenser training. All staff should be adequately trained for all the tasks they are required to perform as part of their job. They should be involved in CPD and encouraged to keep up to date.

Qualifications and standards

There are currently no compulsory qualifications for dispensers in general practice. In order to be eligible for the Dispensary Services Quality Scheme (England and Wales) payments all current staff must have a qualification equivalent to a Level 2 Certificate in Pharmacy Service Skills (NVQ) (QCF). This qualification offers skills in teamwork, health and safety, preparation and issuing of prescribed medicines and the ordering, receipt and storage of pharmaceutical stock.

A higher level of qualification, the Level 3 Diploma in Pharmacy Service Skills (NVQ) (QCF) is now available to dispensing practices, giving dispensers skills in accuracy checking, giving pharmaceutical information and advice, assisting in the validation of prescriptions and the counselling of patients, and making more effective contributions to patients’ medication use reviews (DRUMs).

Registering as a pharmacy technician

It will be helpful for practices to understand the requirements for dispensing staff who wish to register as a pharmacy technician. Staff may apply to register as a pharmacy technician if they have:

• Approved qualifications (competency and knowledge qualifications) and meet the work experience requirements
• They are an EEA national with an EEA pharmacy technician qualification.

The qualifying period of work experience comprises two years’ relevant work based experience in the UK under the supervision, direction or guidance of a pharmacist to whom the technician pre-registrant has been directly accountable for not less than 14 hours per week. During these two years, the technician pre-registrant must have completed at least 1,260 hours of work experience (excluding sickness absence, maternity leave and holidays) and at least 315 hours of work experience in each year.

Until 26 September, 2012, technicians previously registered as a pharmacy technician may re-register, provided they meet the requirements for registration.
From July 1st, 2011 it has been mandatory for pharmacy technicians to register with the General Pharmaceutical Council to practise in England, Scotland and Wales. Employers of pharmacy technicians must satisfy themselves that those working within their organisation are appropriately trained and registered. Only those on the GPhC’s register can work as, or call themselves, a pharmacy technician.

For more information
Information on pharmacy technician registration is available from the General Pharmaceutical Council [online] at: http://www.pharmacyregulation.org/registration/registering-pharmacy-technician

Appraisal
Annual staff appraisals are both good practice, and a requirement for both the DSQS and Quality and Outcomes Framework (QOF) payments.

2.2 Standard Operating Procedures

Standard operating procedures (SOPs) are defined as ‘detailed written instructions to achieve uniformity of the performance of a specific function’ and should be produced for each dispensing activity in the dispensary. They form part of the DSQS and they contribute to patient safety.

Writing an SOP
SOPs should be specific to the practice and should set out in writing what should be done, when, where and by whom. They must be reviewed and updated at least once every 12 months, and whenever dispensing procedures are amended. A written audit trail of amendments should be maintained.

For more information
SOP guidance and model SOPs can be downloaded from the members’ section of the DDA website at: http://www.dispensingdoctor.org/about.php?id=835

2.3 The dispensing process

Most dispensing practices will be fully computerised and this is strongly recommended in the interests of patient safety, providing an audit trail, and saving staff time.

The dispensing process involves six basic stages:
- Prescription interpretation
- Avoiding picking errors
- Containers
- Labelling
- Checking
- Supply to patient

Interpretation
The dispensary’s task is to supply the item in accordance with the prescriber’s instructions, which should state:
- The drug
- The strength
- The quantity
- The correct form.
Dispensers should also consider whether the right drug has, in fact, been prescribed. Any doubts or queries should be referred back to the prescriber (see section 1.1). For this reason, dispensers should have easy access to a doctor at all times during the working day, either in person, by computer email messaging or by telephone. Though training and the use of Standard Operating Procedures, dispensary staff should be clear when, and in what situations they need to seek advice from the prescribing GP.

2.4 Avoiding picking errors

The National Patient Safety Agency reports that over 80% of dispensing errors are picking errors. These errors involve the selection of the wrong strength or formulation of the correct medicine, or the wrong medicine completely. A number of factors are associated with an increased risk of picking errors:

- Not being able to find medicines (illogical or chaotic stock organisation)
- Cluttered and overstocked storage (refrigerators, CD cabinet and shelving)
- Inadequate attention markers for drugs with similar names
- Staff fatigue
- Interruptions.

According to the NPSA, the risk of picking errors may be decreased through good dispensary design, and the use of automation (robots).

For more information

More information on patient-safe dispensary design can be found in Chapter 3 of this Guidance. The NPSA also publishes the Design for patient safety guide to the design of the dispensing environment (online) at:

http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/

2.5 Containers

All dispensed medication must be supplied in an appropriate container (eg, bottle, box, etc). Blister packs or special containers should not routinely be repackaged. If a medicines is repackaged, suitable containers for medicines include:

- small glass or plastic tablet bottles
- brown glass bottles for liquid medication for internal use
- ribbed brown glass bottles for liquid medication for external use
- cartons or bags for blister-packed oral dosage forms
- jars for dispensing of topical preparations
- dropper bottles.

Liquid medicines in small doses

It is no longer appropriate to dilute liquid medicines. Where doses of less than 5ml are required an oral dosage syringe should be supplied. The patient or the patient’s representative should be advised how to use the syringe.
**Child resistant packaging:** It is good practice to dispense medication in child-resistant packaging. The Medicines and Healthcare products Regulatory Agency notes:

- Child-resistant packaging is legally required only for medicines which contain aspirin, paracetamol and those which contain more than 24mg of elemental iron
- Medicines containing dosulepin are required by virtue of the marketing authorisation to be supplied to the market in packs which have been shown to be child resistant.


Dispensers should also consider the following exceptions to supply using a CRC:

- **Specific request** - the patient, carer or representative requests a container that is not child resistant, perhaps due to difficulty in opening a CRC. A poster near the dispensary will help to advise patients of this right of request. The request may be met by supplying a compliance aid or non-CRC lid
- **Original pack** - there may be reasons underpinning why the medicine should remain in the original container. Medicines requiring specific containers are indicated with a black square in the Drug Tariff.
- **No CRC exists** for a particular liquid medicine.

Where appropriate, the patient should be counselled and advised to keep medicines away from the reach and sight of children.

**Monitored Dosage Systems**

Since their UK introduction in 1989, monitored dosage systems (MDS) have become an accepted way of helping patients to medicines compliance. Department of Health guidance on assisted administration of medicines concludes they are a useful way of supporting around one in two people requiring assistance with their medicines use.

However, dispensing practices must consider the liability issues of MDS; drug licence holders are not obliged to produce stability data for the use of their drug in a compliance aid, and without this, drugs are not licensed for use in this situation. Therefore, the decision to fill an MDS may well result in the dispensing doctor effectively dispensing the medicines ‘off-licence’, and taking the resultant liability for that action. The final decision to include or exclude a drug from a compliance aid is therefore left up to the dispensary. Factors that may influence this decision include: previous practice/experience with the drug and any supplier information on the chemical and physical properties of the drug, eg, hygroscopicity and light sensitivity.

**For more information**
The DDA provides advice and guidance on stability of drugs in compliance aids [online] at [http://www.dispensingdoctor.org/content.php?id=1784](http://www.dispensingdoctor.org/content.php?id=1784)
A seven or 28-day prescription may prompt the decision to supply a medicine in an MDS. The NHS takes the position that seven-day prescriptions should only be issued when it is in the best interests of the patient to receive medication in seven-day cycles. As well as those with varying prescriptions, this may include patients such as: vulnerable patients, the elderly or addicts, who cannot cope with larger quantities of medication for a month.

For workload related issues, the dispensary may decide to supply four weeks’ supply at a time, but in four separate cassettes. In this instance, only one prescription should be issued to cover the month’s supply. This is a matter of probity based on the principle that the dispensing fee relates to the physical act of dispensing the quantity of medication detailed on the prescription.

For more information

Choosing the Right MDS: factors to consider:
• Does it accommodate all the doses needed throughout the day?
• Is it easy for the patient or carer to use?
• Are the dosage instructions, time and patient details clearly visible?
• Are the medicines clearly identified on the tray?
• Is the system tamper-evident?
• Can individual doses be removed to take on days out? If so, are their instructions/patient details on each individual dose to maintain continuity of compliance?
• Does it have any features to combat MRSA such as antimicrobial packaging?
• Does it accommodate all tablets and capsules, including hygroscopic.

2.6 Labelling

The Medicines Act 1968 specifies that the following information must appear on the label of every dispensed item, even if the patient is supplied with more than one container of the same medication:
• The name of the patient
• The name and address of the surgery/pharmacy supplying the medication
• The date of dispensing: this should be the date on which the supply is actually dispensed. Labels should not be printed in advance.
• Directions for use: Should include:
  a. The number of tablets to be taken (eg, one tablet to be taken)
  b. The frequency of dosage (eg, three times a day)
  c. Any qualifying information (eg, when required for the relief of pain).
  d. Specific instructions. Avoid phrases such as: ‘as directed’ or ‘as before’,
or Latin terms

- The words “Keep out of the reach of children”
- For medicines for external use, the words “For external use only”.

It is also considered good practice to include on every dispensed label:

- The name and strength of the medication
- The form of the medication (e.g., tablets, capsules, syrup etc),
- The quantity dispensed clear, comprehensive and legible. Latin abbreviations should not be used.
- Specific dosage instructions (e.g., one tablet to be taken three times a day)
- Any relevant cautionary and advisory labels (See BNF Appendix 3).

Other labelling considerations

- Positioning: Labels must not obscure any information on the bottle or packet
- Inner containers: Inner containers should also be labelled, as the outer packaging may be discarded in use
- Handwritten labels: for patient safety reasons, handwritten labels are not recommended.
- Cautions: Where the number of cautionary and advisory labels exceeds the space on the label, a second label may be needed. In the absence of computer-generated warnings, a range of supplementary warning labels should be available
- Medicines dispensed out-of-hours: Medicines dispensed out-of-hours are not exempt from legal requirements. A pre-printed label carrying the doctor’s name and address should be used. All handwritten labels should comply with the legal requirements above
- Additional patient information: Supply as required.

2.7 Checking

Before supplying the medicine to the patient, the dispensary must ensure no dispensing errors have occurred. Misreading the prescription is the most common reason why dispensing errors occur. Therefore, all dispensary tasks (drug selection and labelling) should be checked against the original prescription. A good checklist will include the following checks:

Checklist 1: Looking at the original prescription, have you dispensed?

The right drug
The right strength
The right form
The right quantity
A medicine with an adequate shelf-life

Medicines should not be dispensed if they are out of date or are likely to go out of date before the quantity supplied is used, e.g., a six month supply of oral contraceptive pills with an expiry date for 3 months’ time. Out-of-date stock should be quarantined, and destroyed.

For more information, see Section 3.5.
Checklist 2: Looking at the original prescription, does the label include?
Correct, specific directions
The correct patient’s name
The correct date of dispensing
The relevant cautionary or advisory labels
The name of practice supplying the medication

Checklist 3: Have you?
Used an appropriate container
Recorded who dispensed and who checked the items
A small, adhesive check slip can be incorporated either as part of the main label
or as a small, separate additional label. The initials of the relevant staff will provide
an audit trail of the dispensing process.

Cross-checking
Where two members of staff dispense together, the checking procedure should
involve each staff member checking the other. Where a single member of staff
dispenses alone, extreme care should be taken by the individual to ensure that
everything is double-checked prior to being issued to the patient. Electronic
checking systems using bar codes are ideal for this.
It is good practice for the doctor to check all prescriptions for Controlled Drugs.

2.8 Dispensing audit
Dispensing errors or near-misses should be audited for learning purposes.
They should also be reported to the NHS National Learning and Reporting Service
[online] at: http://www.nrls.npsa.nhs.uk/
Significant errors and any involving CDs should be reported to the relevant officer
at the primary care organisation/health board.
GPs should periodically check that the procedures are being adhered to.

A successful audit will result in the following:
• Full details of errors occurring during the dispensing process will be recorded
• Dispensary staff should be aware of and able to address, the stage/s of
dispensing and circumstances where errors most commonly occur
• Dispensary staff should be aware of, and able to address the type/s of errors
  that most commonly occur
• Dispensary staff should be aware of, and able to address, the causes of errors
  that most commonly occur
• Dispensary staff should be aware of, and able to address, the frequency with
  which they make errors
• Staff will be able to identify appropriate preventative action in response to
dispensing errors.
A dispensing error audit form template

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Labelling Errors</strong></td>
<td>wrong drug name or form on label (e.g., ointment instead of cream)</td>
</tr>
<tr>
<td>Wrong drug/form on label</td>
<td>e.g., 25mg instead of 50mg on label</td>
</tr>
<tr>
<td>Wrong strength on label</td>
<td>e.g., one three times a day instead of one twice a day</td>
</tr>
<tr>
<td>Wrong directions on label</td>
<td>e.g., 28 tablets instead of 56 tablets on label</td>
</tr>
<tr>
<td>Wrong patient name on label</td>
<td>Labels swapped with those belonging to another drug or patient</td>
</tr>
<tr>
<td>Wrong quantity on label</td>
<td>Do not include examples of spelling mistakes</td>
</tr>
<tr>
<td>Wrong label on container</td>
<td></td>
</tr>
</tbody>
</table>

| **2. Selection Errors** | |
| Wrong drug/form selected | Incorrect drug or form dispensed |
| Wrong strength selected | e.g., 25mg instead of 50mg dispensed |
| Wrong quantity counted | e.g., 28 tablets instead of 56 tablets dispensed |

| **3. Bagging Errors** | |
| Wrong name on bag | Do not include examples of spelling mistakes |
| Wrong address on bag | Do not include examples of spelling mistakes |
| Item omitted from bag | e.g., two items in bag instead of three items |
| Extra item in bag | e.g., an extra item from another patient is included in the bag |

**Common causes of errors include:**
- Labelling errors: Typing mistakes, incorrect selection form the computer and using the previous drug/dose on PMR
- Medicine picking errors
- Interruptions
- Novice staff
- Time of day (changing performance levels over time).

**2.9 Issuing medicines to patients**

**Patient counselling**
Counselling should be built into the consultation process by the GP and the practice nurse. At the end of the process, patients should know what their medicines/appliances and inhalers are for, and how they should be taken/used. Dispensers may have a role in double-checking that the patient has understood
and assimilated this information, and should understand what to do if any further information is required. If an unlicensed medicine has been dispensed, staff should take extra care to ensure that the patient is aware of that fact, and knows what to do if they have any problems.

A suitable area should be available to allow patients to discuss matters with dispensary staff in private. An SOP may be written to cover the referral of patient queries back to the GP.

**Patient information leaflets**

Since 1999 all medicines should be supplied with an approved patient information leaflet (PIL). Where original packs have to be broken, for example, when a shorter course of an antibiotic is indicated than provided in the original pack, then the patient information leaflet should be photocopied or a copy downloaded from the manufacturer’s website.

Similarly, when there has to be a change in the form or dosage of the medication, an explanation should be given to the patient both verbally and in the form of a suitable written instruction.

**Other good practice**

**Storage:** A supervised and secure space should be designated for dispensed medicines until they are collected.

**Bag label:** Dispensed medicines/items should be issued in a paper or plastic bag properly labelled with the patient’s name and address.

**Identity check:** On collection, the patient’s name, address and date of birth should be checked from the label on the bag.

**Additional patient support:** Patients may also benefit from colour-coded highlights on their prescription items to help them differentiate between similarly packaged items.

### 2.10 Transit of medicines

**Delivery to a remote site for collection**

When dispensed medicines are delivered to remote villages for later distribution to patients by a designated responsible person, (e.g., the post-mistress/master):

- It is recommended that, wherever possible, a lockable transport container is used.
- All dispensed items should be firmly sealed in properly labelled bags.
- The bag should be labelled with the name and address of the patient and the name, address and telephone number of the issuing doctor.
- The bag should be sealed with staples or adhesive tape.
- The responsible person should take care to properly identify the patient or the patient’s representative.

**Collection book:** A collection book could accompany all sealed packages dispatched to the remote distribution point and, if all parties are willing, could record:
• The date when the medication was dispatched
• The name and address of the patient
• The signature/initials of the dispenser dispatching the medication
• The date on which the medication was collected
• The signature of the patient or patient’s representative collecting the medication.

Controlled Drugs
All healthcare professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times. CDs should not generally be transported via mail, taxi services or equivalent. However, in exceptional circumstances, where urgent clinical need dictates, dispensed CDs can be sent to a patient, or stock CDs to premises, via such routes. Where the mail route is used, the CD should always be sent as a special delivery item to ensure the pathway is auditable. If transport of CDs or CD prescriptions, via mail, taxi services or equivalent, has to be used, a SOP should be developed which reflects a risk management assessment. Wherever possible a signature should be obtained indicating safe delivery of medicines.

For more information
Download the NPC guidance to the management of Controlled Drugs in primary care, from: http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_thirdEdition.pdf

The doctor’s bag
General guidance
For GPs on home visits, the choice of what to include in the GP’s bag is determined by the medical conditions likely to be met; the medicines the GP is confident in using; the storage requirements, shelf-life and costs of such treatments; the extent of ambulance paramedic cover, and the proximity of the nearest hospital.

Controlled Drugs
When CDs are carried in a doctor’s case, this must be lockable. The keys should be kept separate from the case unless it is fitted with a digital combination lock (a more practical option). The case should only be left unattended in exceptional circumstances and must always be locked when it is. If left unattended in a vehicle, it should be kept out of sight, in the boot for example. Both the case and the vehicle should be locked and any additional security features such as an alarm or immobiliser activated.

Doctors are advised to carry the minimum quantity of CDs required to fulfil emergency treatment needs. To avoid packaging and labelling pitfalls it is better not to carry CDs in any form other than injection ampoules for emergency use and, preferably, in only one strength.
Additional guidance

- All CDs transferred to the doctor’s bag must be entered in the CD register.
- Keeping a running total stock balance in the register can ensure that any anomalies are swiftly identified.
- It is good practice (but not a legal requirement) for each doctor who carries CDs in a medical case/bag to have a personal register, segregated for different drugs and formulations, in which he or she records the drugs and dose administered, the date, and the patient’s name.
- The doctor’s bag should be regularly checked to ensure that all drugs and CDs contained are in date.
- Restocking of the bag from practice stock should be witnessed by another member of the practice staff, as should the appropriate entries into the practice’s CDR.
- Where a prescription is written by a doctor following the administration of a CD to a patient, the doctor should endorse the prescription form with the word ‘administered’ and then date it. This aims to avoid unauthorised individuals attempting to reuse such ‘prescriptions’ to obtain CDs illegally. Information should also be entered into the patient’s record as soon as practicable.

2.11 Patient data confidentiality

Dispensary staff should be made aware that the patient medication record is confidential, and that data should not be disclosed to anyone without the consent of the GP and, where relevant, the patient. In exceptional circumstances, for example, when it is in the public interest, it may become necessary for the practice to disclose confidential or sensitive information.

For more information
The GMC has published guidance on confidentiality [online] at: [http://www.gmc.uk.org/guidance/ethical_guidance/confidentiality.asp](http://www.gmc.uk.org/guidance/ethical_guidance/confidentiality.asp)

Chapter 3. The dispensary

When designing or improving your dispensary layout, it is important to consult your dispensers as well as your architect. Dispensers will feel far happier working in an environment that has been planned taking into consideration their views. Particular consideration should be given to: safety, hygiene, security, comfort, lighting, temperature control (<25 deg C), ventilation and space. The overall design layout should facilitate the flow of the dispensing process, and maximise patient safety.

3.1 Location of equipment

Dispensaries require a lot of equipment. When designing the dispensary, thought should be given to the layout of commonly used equipment, to ensure workflow
remains logical, and to reduce staff fatigue - both of which are important for patient safety. The following equipment is usually required:

- Computer terminal
- Printers for scripts and labels
- Scanner (eg, for computerised CD invoices)
- Barcode scanner
- Photocopier
- Shredder
- Telephone(s)/fax
- Designated fridge with effective temperature regulation and thermometer for the storage of appropriate medicines, eg, vaccines (2–8°C)
- CD cupboard
- Electronic pill counter
- Back-up triangular, manual pill counter
- Panic button for staff, connected to main security system or separate alarm.
- Lockable security hatch
- Chair(s), perhaps of the swivel type, with adjustable height to ensure optimum staff comfort/good posture
- Short stepladder for accessing higher shelves
- Storage for consumables and small equipment: labels, bags, bottles, spoons, oral syringes, measuring cylinders, monitored dose system consumables
- Designated stainless steel sink, preferably double, with draining board
- Hand-washing and drying facilities
- Bottle washing and drying facilities if undertaken
- Notice board
- Reference books: Drug Tariff, BNF, MIMS and Dispensing Guidelines
- Waste bins: for clinical waste and for general waste
- Till/cash tin, debit/credit card machine.

### 3.2 Key design features

**Easy cleaning:** Particularly of the work surfaces, floors and sink area  
**Space:** The dispensary should be designed with an adequate walkway. This should be kept free from clutter  
**Flooring:** Should be non-slip, and anti-fatigue  
**Lighting:** Ideal choices include contrast lighting that minimises shadows, incorporating natural lighting where possible  
**Confidential area:** A nearby area/room should be designated for private patient counselling  
**Security:** The practice should have lockable windows and a security alarm. The dispensary door should have a five-lever mortice lock. Other security features include: window security bars, a lockable security hatch, and staff panic button  
**Ventilation and temperature control**  
**Work surfaces:** There should be plenty of space to facilitate methodical working  
**Sink area:** Tiled splash backs are preferable to allow for easy cleaning.
High rotating mixer hot and cold taps with lever handles are ideal for the needs of the dispensary. Standing work (dispensing) should be performed at kitchen worktop height (90cm).

**Office area:** To reduce distractions, another risk factor for error, the computer and telephone should be located separate to the dispensing workbenches. Desk height (76cm) is appropriate for tasks that are usually done seated.

**Shelving:** Space allocation should be determined by the practice’s likely dispensing volumes and stock control efficiency, plus consideration of good item separation and ease of access (patient safety considerations). Central column-type shelving provides good access and space economy. The top shelf should, ideally, be eye level for reasons of safety and ease of access.

**Other storage:** Allow sufficient space for the storage of tote boxes, measuring devices, extemporaneous dispensing equipment and consumables (labels, bottles, etc, dressings and appliances).

**Designated area for returned or waste medicines.**

### 3.3 Controlled Drug storage

Schedule 2 and some schedule 3 CDs (e.g., buprenorphine and temazepam) must be stored in a locked receptacle which can be opened only by an authorised person. For increased security, the CD cupboard should be firmly fixed to the wall with rag bolts, ideally in a location that will not be easily detection by intruders. A designated safe may offer another secure alternative.

**For more information**

The National Patient Safety Agency provides a number of excellent resources designed to improve patient safety, including through good dispensary design [online] at: [http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/](http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/)

### 3.4 Good housekeeping

**The fridge**

The dispensary refrigerator should be designated for cold chain items (products requiring refrigeration). The refrigerator should be equipped with a maximum minimum thermometer. Temperatures should be monitored at least twice weekly and recorded in a book designated for that purpose. Checking the fridge temperature on Fridays and Mondays will help identify and resolve any problems occurring over the weekend. The range of temperatures within the fridge should not fluctuate outside the range between 2°C and 8°C.

**Counting equipment:** Medicines should not be handled directly during the dispensing process. This can be avoided by counting using either a counting triangle or an electronic counter.

**Avoiding cross-contamination:** Cross-contamination from one medicine to another can occur. This is particularly hazardous if dispensing cytotoxic drugs, but can also
be problematic with steroids and antibiotics. Designated dispensary equipment and regular cleaning can help avoid cross-contamination. Disposable gloves should be worn if dispensing cytotoxic drugs.

**Staff cleanliness and hygiene:** Dispensary hygiene can be improved through the use of:
- Alcohol hand-rubs
- Protective clothing
- The use of waterproof dressings on cuts and abrasions
- A ban on eating or drinking in the dispensary.

### 3.5 Procuring medicines

EU Directive 85/374/EEC 25.7.1985 requires that a supplier of a product must be able to identify the manufacturer in order to escape liability in the event of product failure. By implication, this Directive requires all dispensing contractors to ensure that all dispensed items can be linked with the manufacturer. The DDA advises that practices should record the patient name, batch number, supplier and manufacturer for every item dispensed, using either a computerised or paper based system. Invoices should be kept for a minimum of 11 years. Failure to record any details could render a dispensing practice liable in the event of a claim over a faulty product where the manufacturer is untraceable.

**Controlled Drugs**

Doctors or medical practices obtaining Schedule 2 or 3 Controlled Drugs without providing the required signed order or requisition may be considered in unlawful possession of these drugs, and at risk of criminal prosecution. Supplies made to practices without the authority of a signed order or requisition are also unlawful, and may be a criminal offence.

An approved requisition form (see below) should normally be used. This must:
- be signed by the doctor
- state the doctor’s name, address and profession (eg, GP)
- specify the total quantity of drugs (does not need to be in both words and figures)
- state what purpose it is required for (eg, "practice use").

**England:** The standardised CD requisition form is the FP10CDF (for schedules 1-3 CDs)

**Wales:** The standardised CD requisition form is the WP10PCD or WP10PCDSS.

**Scotland:** The requisition form for Schedules 1-3 Controlled Drugs is the CDRF. This carries the same security features as NHS and private CD prescription forms, including a unique serial number.

*A sample CDRF form*
Specials

Special medicines can be very expensive (several hundred pounds for one bottle). As a matter of good practice, dispensing contractors should ensure they source non-Tariff medicines at a reasonable price. If a practice does not operate a Specials formulary, this may involve obtaining quotes from a number of suppliers. The following should inform the choice of Special supplied:

- **The quality of the formulation**: Dispensing contractors should specify to the supplier exactly what they require. The formulation should be chosen so that it delivers the following requirements as fully as possible:
  - Safety: none of the excipients constitute a hazard to the patient
  - Bioequivalence: in terms of efficacy with the alternative licensed medicine or a known bioavailability so the dosage can be adjusted
  - Stability: A known stability profile for all ingredients within the shelf life attributed to the product
  - Patient acceptability: The medicine is acceptable to the patient (e.g., texture, taste, absorption characteristics, dose volume).

**The quality of the manufacturing process**

The manufacturer should be chosen on the basis they:

- Possess a pharmaceutical manufacturing license for the activity they are being asked to undertake
- Use Good Manufacturing Practice (GMP) processes
- Label and package the product in accordance with latest guidelines
- Provide supporting governance documentation of quality (described below)
- Provide a rapid delivery service.

**The quality of the product**

Dispensing contractors should not assume any aspect of quality and take all reasonable steps to ensure that the product supplied:

- Is of a suitable standard, i.e., checking strength, formulation and excipients.
- Comes with a:
  1. **Certificate of analysis (COA)**: A certificate of analysis should be available for any batch manufactured special and is evidence that critical parameters have been confirmed by retrospective physical, chemical or microbiological assay of a sample of the final product.
  2. **Or a Certificate of conformity (COC)**: A certificate of conformity is a signed statement by the manufacturer that they believe the product complies with the purchaser’s specification
- Is pharmaceutically appropriate and suitable for the patient
• Has evidence to support the labelled shelf life of the product
• Ideally comes with an information leaflet although this is not yet a legal requirement.

**Previous supplies**
Dispensing contractors should check if the patient has had the product supplied before (e.g., by questioning the patient or asking to see the product for labelling information). If so, attempts should be made to establish the previous source of the product and continue to access it from the same supplier. This will improve the likelihood of clinical equivalence and continuity of care, minimising the risk of new side effects and adverse reactions due to different formulations.

**When prescribing a pharmaceutical special there is a possibility that it will have a very short expiry - sometimes as low as seven days. Prescribers need to be aware that if this is the case they may need to prescribe four prescriptions for a month’s supply of the pharmaceutical special.**
Dispensing contractors should consider the amount prescribed in the light of expiry date information and contact the prescriber if necessary to:
• Adjust the quantity prescribed should the amount on the prescription lead to wastage
• Minimise the need for patients to request repeat prescriptions less than monthly, arrange for more than one prescription to be written to allow the supply to the patient for several times during a month.

**Patient information**
Dispensing contractors are likely to be the last point of contact with the patient prior to the unlicensed special being administered. The dispensary should check that the patient is aware they have been supplied an unlicensed medicine.

**Source:** The Specials Toolkit (version 3.1) is available from NHS Midlands and East PrescQIPP [online] at: [http://www.clingov.eoe.nhs.uk/prescqipp/index.php/st](http://www.clingov.eoe.nhs.uk/prescqipp/index.php/st)

**Counterfeit medicines**
The World Health Authority defines counterfeit medicines as those medicines that are "deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging."

Counterfeit medicines can harm patients in two ways:
• Improper treatments are a risk to public health, either through increased disease transmission or through the development of antibiotic resistance
• The credibility of a national healthcare system can be harmed if counterfeit medicines get into the legitimate supply chain, which may lead to patients becoming irrationally fearful of legitimate treatments.
Pharmacists or dispensing doctors worried about a counterfeit medicine are advised to:

**Contact the MHRA on the counterfeit hotline by:**
E-mail: counterfeits@mhra.gsi.gov.uk  
Phone: 0207 084 2701 (24-hour)  
Web: Click the green icon on the MHRA website: www.mhra.gov.uk

Dispensing contractors are also advised to:

- Await MHRA instructions – conducting unilateral action may prove ill-advised, unnecessary, confusing and counter-productive
- If a drug alert and recall notice is received, be prepared to:
- Check the current stock held in the dispensary and return any potential counterfeit medicines in line with guidance issued
- If possible, interrogate the PMR systems to reveal which individual patients are on that particular medicine and when it was dispensed
- Contact those patients who have been supplied with that particular medicine within the suggested timeframe to check on their medication.

If a patient is concerned that they have a counterfeit medicine then dispensing staff should make a record of this (ideally, recording patient contact details, reason for patient’s suspicion, product name, dosage, batch number and expiry date) and inform the MHRA immediately.

**Tips for evaluating product sources and detecting counterfeit medicines**

- Establish the integrity of the source prior to need - always purchase medicines from licensed wholesalers and suppliers – establish thorough and regular due diligence checks, and system reviews
- Where possible, establish a list of approved suppliers
- Require that any alternative source of supply provides the following as a minimum:
  I. A pedigree back to the previous source
  II. Certification that it is not a diverted product
  III. Certification that any actions by the alternative source will not alter any original manufacture warranties or guarantees
  IV. Certification that the product has been stored and handled consistent with product labelling requirements.
- Be cautious about product offered at an unusually cheap price and / or in unusually large quantities (particularly in a large quantity of the same batch number)
- Consider developing a list of key pharmaceutical products that will not be purchased from sources other than the manufacturer, or authorised distribution channel
- Look for an altered expiry date. Counterfeiters commonly purchase ‘short-dated’ products and then alter the labels
For more information

Endorsed by the DDA, advice on counterfeit medicines for healthcare professionals is available [online] from the MHRA at: http://www.mhra.gov.uk/home/groups/ei/documents/websiteresources/con2033091.pdf

Changing distribution models

Preventing the risk of counterfeit medicines entering the UK supply chain has been cited as the reason for the introduction of new models of medicines distribution, particularly, the Direct to Pharmacy (DTP) model.

In the DTP model, the manufacturer sells direct to the end customer, the dispensing contractor, using an exclusive or reduced number of wholesaler/s acting as distributors or logistics service providers only. DTP tends to be chosen by the larger firms. Glaxo was first, and Pfizer the second. In 2010 Pfizer, GSK, AstraZeneca and Merck, together, were said to account for just under 30% of the total UK pharmaceutical market.

An increasing number of companies use DTP models to distribute a limited range of lines, usually those that are low volume and high cost. Their other lines are distributed using the Reduced Wholesaler Model (RWM).

RWM schemes

In Reduced Wholesaler Model Schemes (RWM or Reduced Wholesaler Agreements, RWA), a pharmaceutical company will use specific wholesaler/s partners (usually, two, although solo and three-way RWM models also exist). Apart from the restriction on the number of wholesalers used, the RWM model is based on the traditional wholesale business model, ie, the wholesaler/s owns the stock and can offer discounts in the usual way.

Since its introduction, the RWM model has been widely adopted by pharmaceutical suppliers. At the 2011 Dispensing Doctors’ Association conference, it was said that only 20% of all items are supplied outside either an RWM or DTP wholesaling model.

An up to date list of wholesalers using DTP/RWM models and the levels of discount available can be accessed [online] at: http://www.dispensingdoctor.org/listingd.php?pid=31
Medicines shortages
New models of medicines distribution have been cited as a cause of medicines shortages, which have affected UK dispensing contractors since 2009. Other reasons include exchange rate variations that favour medicine exports, consolidation of manufacturing sites and inappropriate quota setting.

During 2011, the Dispensing Doctors’ Association signed up to Best Practice Guidance for Ensuring the Efficient Supply of Medicines, which calls on dispensing practices to maintain UK patient benefit as their first priority. The guidance also sets out:

• The expectation that, under normal circumstances, pharmacies should receive medicines within 24 hours
• That requesting faxed prescriptions prior to supply is not acceptable routine practice and where verification is necessary, dispensers should not disclose patient or prescriber identifiable details
• The importance of regular communication between manufacturers and wholesalers so that all parties have a good understanding of the supply and demand for particular products
• The need for all in the supply chain to have contingency arrangements in place to source supply where there are supply difficulties.

Implications for prescribers
Prescribers should be flexible in their approach and response to difficulties experienced by their patients when medicines are in short supply. This may include the consideration of a change in medication, though such choice may not be possible or appropriate if patients are to receive optimal therapy. Any such decision should take into consideration the clinical history of the patient, consider the therapeutic equivalence of the medicines and be taken in consultation with the patient. Doctors should bear in mind their primary duty to act in their patient’s best interests, while making efficient use of available resources. Prescribing decisions should not be influenced by the dispensing status of the patient, or any commercial or financial reasons.

Co-operation with other professionals to minimise the effects of supply problems is essential.

For more information

Updated GMC guidance, Good practice in prescribing and managing medicines and devices was expected as this Guide went to press. Check for updates [online] at: http://www.gmc-uk.org/guidance/news_consultation/9203.asp

The Best Practice Guidance for Ensuring the Efficient Supply of Medicines is available [online] from the DDA at: http://www.dispensingdoctor.org/content.php?id=1549
Detailed information on medicines reported by pharmacists to be in short supply is available [online] from the Pharmaceutical Services Negotiating Committee at: http://www.psnc.org.uk/pages/manufacturer_quota_schemes_.html

3.6 Disposing of medicines

Out of date or returned medicines should not be dispensed, as it is impossible to vouch for the condition of these drugs. Instead, they should be quarantined, and put aside for disposal.

Most primary care organisations will have contracted a designated firm to provide a medicine disposal service within their area. These firms provide sealable plastic containers and separate, special containers for the disposal of Controlled Drugs. If you are not aware of such a service in your area, contact your local Pharmaceutical Adviser for more information.

**Controlled Drugs: General disposal guidance**

**Denaturing:** CDs must be rendered irretrievable prior to onward safe disposal. Contact your local Pharmaceutical Adviser for details

**Storage prior to disposal:** All CDs awaiting disposal should be placed in a segregated, marked area in the CD cupboard to prevent them being issued in error to patients.

**Recording:** When a CD is destroyed, details of the destruction must be recorded. This should include: the name of the drug; form; strength and quantity; the date it was destroyed; and the signature of the authorised person who witnessed the destruction and the professional destroying it (ie, two signatures).

**Out-of-date CDs**

Destruction of all out-of-date CDs must be witnessed by a serving police officer or other person authorised by the Secretary of State, such as a Home Office inspector or, more usually nowadays, an authorised PCO person such as a PCO-employed pharmacist. In some areas, the local Water Authority may have guidelines for limited disposal of CDs via the sewage system.

**Returned, unused CDs**

Dispensed CDs returned by a patient should be handled as follows:

- Record CD returns in a separate CD register to the main CD register
- The CD returns register should be organised by drug formulation. Entries under the drug formulation should also show the date, the drug quantity and strength, and the name of the person who returned the CD[s]. The doctor or dispenser should sign against the entry
- Patient returned CDs must also be clearly marked to minimise the risk of errors and inadvertent supply
- It is good practice for the destruction or collection to be witnessed
- Controlled Drugs (Supervision of Management and Use) Regulations 2006 require SOPs to be in place for maintaining a record of Schedule 2 drugs that have been returned by patients.

The DDA publishes an SOP for the destruction of CDs for members at: http://www.dispensingdoctor.org/about.php?id=835
Chapter 4: Regulations affecting dispensing practice

The key regulations affecting dispensing practice are:

- **GMS Contract and Statement of Financial Entitlements** (consolidated SFE and GMS Contract)
- **The Dispensing Services Quality Scheme Regulations**
- **Pharmaceutical Services Regulations**
- **Controlled Drugs Regulations**
- **Wholesale Dealer’s Licence Requirements**
- Miscellaneous Regulations and updates

For more information

4.1 Key points

The dispensing fee varies on a sliding scale according to dispensed item turnover (see SFE Annex G, Part 2). Dispensing doctors should ensure that the volume of items prescribed and dispensed is commensurate with the predicted norm for the practice profile unless there are good clinical reasons for significant variance.

It has always been the case that the dispensing fee is regarded as a professional fee for the act of dispensing of the quantity of pharmaceutical product as ordered by the prescriber.

Therefore, if a patient is prescribed and dispensed monthly repeat medication, eg, furosemide 40mg one tab daily x 28 tabs, then one prescription form for this item should be sent to the pricing authority each month.

However, if the patient is supplied with, for example, six months’ supply of oral contraceptives on a repeat basis, then one prescription should be issued every six months and six months’ worth of items dispensed. It would be considered fraudulent to dispense a six-month quantity but to claim a monthly dispensing fee for six months.

**Excessive or inappropriate prescribing**

Annex 8 of the revisions of the SFE for 2006–2007 provides guidance as to what might be regarded excessive or inappropriate prescribing by health professionals involved in primary care. Guidance is given with regard to:

- Prescribing cost-effectively for the NHS and making changes to patients’ repeat prescribed medicines.
- Drug purchasing
- Sponsorship/financial arrangements with pharmaceutical companies
- PCO incentive schemes
- Generic prescribing/endorsement of prescriptions.
- Profligate prescribing.
GPs must always use their clinical judgement and prescribe what they feel appropriate for an individual patient. Statements by PCOs indemnifying individual practices against possible future action by patients who believe they have been damaged by treatment restrictions have no legal force and do not provide any protection.

**VAT registration**

In England and Wales, the provisions for dispensing practices changed in April, 2006 and in Scotland, from July, 2011. Following the changes, a dispensed prescription does not receive a VAT allowance from NHSBSA unless it relates to a personally administered item as listed in paragraph 17.4 of the SFE. HMRC will, however, reimburse all input tax paid on NHS dispensed pharmaceutical products except those that are personally administered because they are regarded as a GMS-exempt supply.

All dispensing practices should, therefore, be registered for VAT. It is worth noting that the definition of a personally administered item under Paragraph 17.4 is NOT the same as that defined by HMRC. For VAT return purposes, any item that is personally administered or applied to a patient by the doctor or his staff should be treated as VAT exempt.

### 4.2 The Dispensing Services Quality Scheme (England & Wales)

In summary, £2.58 will be payable for each patient on the practice dispensing list provided the practice signs up to and achieves the quality standards as specified in the SFE. The key SFE specifications are:

- There must be a nominated dispensing GP who will be accountable for dispensing service and standards
- Dispensing staff must have training appropriate to their role
- The practice must have a written record of all dispensing staff training and must ensure that they undertake continuing professional development and annual appraisal
- All dispensers should have training equivalent to pharmacy services NVQ level 2 or have signed up to such courses within three months of the practice signing up to the scheme
- For those with a limited dispensing role or where the residual term of employment is not commensurate with committing to a formal training course, such staff must have a certificate signed by the accountable GP and practice manager (if any) to confirm that a competency assessment has been made
- All dispensers who work independently must have a minimum of 1,000 hours of dispensing work experience over the preceding five years
- The practice must ensure that a minimum level of staff hours appropriate to patients’ needs is dedicated to dispensing services
- The practice must ensure that standard operating procedures (SOPs) are in place that reflect good practice in all the procedures that are actually performed in the dispensary
• The practice must commit to auditing dispensing services with significant event monitoring and reporting of untoward events to the PCO
• There must be a written policy for risk assessment and management
• Dispensary opening hours must be declared to the PCO and be on public display with information about out-of-hours services
• Practices conduct reviews of dispensing patients’ use of medicines (10 percent of dispensing list/year).

The DSQS is a quality framework, which has patient safety at its centre. Widely adopted by dispensing practices, it will add to a practice’s defence in the event of a significant dispensing error. The DDA, therefore, encourages dispensing practices to sign up to the scheme as soon as possible.

Any practice that encounters genuine difficulty with any aspect of the scheme should contact the DDA. If consensus emerges about specific logistical problems with the scheme, the DDA will take them up with the GPC and relevant health authorities, and seek appropriate amendment.

For more information
DSQS information is available from the GPC and the Department of Health, and from the DDA [online] at: http://www.dispensingdoctor.org/content.php?id=1406

### 4.3 Pharmaceutical Services Regulations

**Key points: The NHS Regulations (Pharmaceutical Services) 2012 (England)**

The long-awaited 2012 NHS (Pharmaceutical Services) Regulations came into effect in England on September 1, 2012, reinforcing the place of dispensing practice in rural areas, clarifying doctors’ terms of service and ending the controversies caused by 100-hour pharmacy openings.

The new regulations, the NHS (Pharmaceutical Services) Regulations Statutory Instrument SI 2012/1909 transfer the 2005 Pharmaceutical Services regulations and amendments relating to rural dispensing without any significant change, albeit with certain clarifications and minor modifications to the regulations.

Those dispensing practices existing immediately prior to the laying of the 2005 Regulations retain the same dispensing rights as they did under the terms of the 1992 Regulations.


**Dispensing registration [Reg. 48(1)] [=2005 Regs: Reg. 60 (1)]**

Regulation 48 of the NHS Pharmaceutical Services Regulations 2012 makes it clear that a patient living in a controlled area on the list of a dispensing doctor may AT ANY TIME request that he or she receive pharmaceutical services from that doctor. If such a patient chooses to use the services provided by a pharmacy that does not, of itself, prevent them from reapplying at a later date to go back on to the dispensing list.
The situation is different if a change of practice is involved: to prevent “unfair”
competition, a patient of a prescribing practice cannot become a dispensing
patient of another practice even if all other requirements are met, unless he
has moved house (changed his registered address).

**New applications to dispense by doctors** [Reg. 51] [2005: Regs. 18, 61]
This will not be permitted if there is a pharmacy within 1.6km/1 mile of the
premises from which the practice wishes to start dispensing. Note: This only
applies to new applications. Existing dispensing practices retain their dispensing
rights. However, non-dispensing practices that have patients in a rural area can
apply to dispense from premises that are more than 1.6km from any pharmacy.
Small villages may expand to a point where it becomes viable for a practice to build
premises given a successful application to dispense. The village would be
designated a reserved location until such time (if ever) that the population exceeds
2,750 within a 1.6km/1-mile radius of any would-be pharmacy.

**Additional premises and relocation of premises** [Reg. 55] [2005: Reg.65]
If existing dispensing practices apply to relocate premises or open additional
premises then approval will only be given if the premises are more than 1.6km/
1 mile from any pharmacy. Approval will not take effect until one year post-
application to prevent manipulative moves by dispensing doctors by allowing time
for a pharmacy to relocate in such circumstance. There is a provision for temporary
premises approval during the 12-month interval, which may be extended to a
maximum of 15 months in total.

**Minor relocations** [Reg. 55(2)] [2005: Reg.65]
A minor relocation can only be considered for a pharmacy if there has not been a
relocation in the previous 12 months. A similar provision allows dispensing
practices to relocate without formally reapplying for outline consent to dispense
or for premises re-registration approval provided it is considered to be a minor
relocation with no adverse effects on existing pharmaceutical services.

To Qualify as a “minor relocation” the Primary Care Trust must be satisfied that:

(a) for the patient groups that are accustomed to accessing pharmaceutical
services at the existing premises, the location of the new premises is not
significantly less accessible

(b) granting the application would not result in a significant change to the
arrangements that are in place for the provision of pharmaceutical services
(including by a person on a dispensing doctor list) or of local pharmaceutical
services:
(i) in any part of its area, or
(ii) in a controlled locality of a neighbouring Primary Care Trust, where that
controlled locality is within 1.6 kilometres of the premises to which the
applicant is seeking to relocate; and

(c) the Primary Care Trust is satisfied that granting the application would not
cause significant detriment to proper planning in respect of the provision of
pharmaceutical services in its area. This is important for practices that outgrow their premises or where premises become condemned.

**Practice amalgamations** [Reg. 59] [2005: Reg.66]

This regulation has proved to be problematical. As part of the national accord with the pharmacists, it was intended that the amalgamation of a dispensing practice with a non-dispensing practice would trigger a new application for outline consent to dispense, and an application for premises approval. It was also intended that putative applications could be made before an amalgamation formally took place.

If outline consent or premises approval was not granted then the practices involved could reconsider their amalgamation plans with no detriment to patient dispensing services, provided the amalgamation did not take place. If the amalgamation were to go ahead despite a failed application to dispense for the enlarged ‘new practice’, then residual dispensing rights would apply to the existing dispensing patients and residual premises approval would be given to the existing dispensing premises only.

In the case of amalgamations where each practice is a dispensing practice and where there is no change of dispensing premises there would be no requirement to apply for outline consent or for premises approval.

However, the regulations, as written, do not actually reflect the agreement principles. At the time of writing, the DDA, GPC, PSNC and DH are in consultation with a view to amending the regulations.

It is strongly advised that when dispensing practices are considering amalgamation they should contact the DDA for advice before any formal amalgamation takes place.

**Inspection Paragraph 9 of Schedule 6, Terms of Service for dispensing doctors**

Primary Care Trusts in England maintain a list of dispensing contractors, and a list of premises from which those doctors are authorised to dispense. All premises from which dispensing by doctors takes place will be open to inspection by the PCO to ensure terms of service are being complied with.

**Control of Entry**

**England**

In terms of pharmacy market entry (‘control of entry’), the 2012 Regulations:

- remove three of the four current exemptions to the “necessary or expedient” test: 100-hour pharmacies, large out-of-town shopping centres and large one-stop primary care centres
- introduce additional provisions for the remaining exemption, distance-selling pharmacy applications
- introduce a performance management regime, including the sanction of removal, for under-performing pharmacies
- replace the necessary or expedient “control of entry” test with determinations
based on needs or improvements identified in the relevant PCT’s local Pharmaceutical Needs Assessment (PNA)

- introduce the concept of “unforeseen benefits” to the overall provision of services allowing applicants to demonstrate innovative ways of providing services or of delivering better health outcomes not anticipated in the PNA.

In the Impact Assessment accompanying the Regulations, the Department of Health forecasted that rural areas will see the most new pharmacy applications as a result of the 2012 regulations. Its view is that: “The major expected impact of this policy is to encourage new pharmacy provision away from well-served areas of high demand to areas with lower current levels of provision.”

According to the DDA, dispensing practices operating in communities with more than 2,750 people will be most at risk. More information and advice is available on DDA Online at: [http://www.dispensingdoctor.org/comments.php?id=2184](http://www.dispensingdoctor.org/comments.php?id=2184)

Wales

A consultation into the Control of Entry regulations in Wales was launched by the Welsh Assembly Government during 2012.

The proposals make it harder to open new practice dispensaries. In return, existing practice dispensaries will receive full recognition as providers of pharmaceutical services contractors. It is proposed that all applicants to provide pharmaceutical services in Wales should be subject to the prejudice, and necessary and expedient tests. Currently, applications from dispensing practices are only subject to the prejudice test. By creating a level playing field in rural areas, the changes aim to ensure:

- that doctors provide pharmaceutical services where it is necessary or expedient
- that the contribution made by dispensing doctors to securing the adequacy of pharmaceutical services in an area is properly recognised when determining future applications. The draft regulations proposes to give local health boards in Wales powers to refuse an application to provide pharmaceutical services if its grant would prejudice the proper provision of general medical services, dispensing services or pharmaceutical services. It is possible that this provision may allow a dispensing practice rendered unviable by a pharmacy application to argue prejudice.

In addition to synchronising the criteria for determining applications from pharmacy and dispensing practices, the Welsh market entry proposals aim to:

- Introduce measures to assess and manage the fitness to practise of new applicants to the pharmaceutical list and existing contractors
- Enable Local Health Boards to reject new pharmacy applications where current pharmaceutical services are determined adequate to address the assessed local need
- Introduce fees for applicants, to discourage speculative applications
- Simplify the process for relocation of community pharmacies over short distances.
The consultation does not propose to change the circumstances in which doctors can provide pharmaceutical services (i.e. the ‘one mile’ rule).

The consultation on the draft Welsh control of entry regulations in Wales (Draft regulations under the National Health Service (Wales) Act 2006) will be open for comments until November 22nd, 2012. Information is available [online] at: http://wales.gov.uk/consultations/healthsocialcare/pharmregs/?lang=en&status=open

Scotland

Control of Entry in Scotland is determined by the National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2011, which came into force on April 1, 2011. Dispensing doctors have stated that the regulations prejudice dispensing services provided by practices, due to the Regulations’ definition of pharmaceutical services, the lack of meaningful consultation with patients, and the lack of acceptance by Government of the need for cross subsidy. Since introduction, the regulations have led to several contentious pharmacy openings, and for the affected practice, the subsequent total loss of dispensing rights.

Scottish control of entry regulations make no provision for a ‘one-mile rule’. However, NHS Boards have delegated powers that enable them to allow dispensing GP practices to continue dispensing after a local pharmacy application is accepted in a neighbourhood in certain circumstances. To determine whether practice NHS dispensing may co-exist with an NHS pharmacy, the NHS Board must determine whether a person will have serious difficulty in obtaining from a pharmacist any drugs, medicines or applications, other than scheduled drugs, required for that person’s treatment due to the following reasons:

- Distance
- Inadequacy of means of communication or
- Other exceptional circumstances.

Practices in Scotland may wish to note that the DDA is unaware of any practices that have retained dispensing rights in a neighbourhood following a successful pharmacy application.


4.4 Working with pharmacies

The theme of the 2011 Dispensing Doctors’ Association annual conference was “Pharmacy and Dispensing Doctors - Collaboration and Co-operation”. The DDA believes that joint working between pharmacists and doctors has the potential to benefit patients, and make better use of doctors’ and pharmacists’ skills.

Models of joint working may include:

- Increased contact within existing business models
- Co-location of practice and pharmacy as separate entities
- Partnership working (Integrated Primary Care Pharmacy).
GMC Good Practice Guidelines and the GMS/PMS Regulations concerning electronic prescription transmission set out the following principles underpinning any joint working between pharmacists and GPs:

- Prescribing patients should always have a free choice as to where they have their NHS prescriptions dispensed and practices should refrain from directing their patients to a particular pharmacy
- Patients should have access to information about any doctors’ interests (financial or commercial) in any pharmacy they are likely to use
- Practices must not allow any financial or commercial interests in a pharmacy to influence the way patients are advised
- Practices should not accept any inducement which may affect or be seen to affect the advice given to patients
- Patients must not be pressurised to use a particular pharmacy in any event, either directly or indirectly, nor should a doctor disparage or otherwise undermine patients’ trust in a pharmacy or pharmacist by making malicious or unfounded criticisms.

4.5 The Electronic Prescription Service (England)

The Electronic Prescription Service (EPS) is an NHS service that will enable GP practices in England to send prescriptions electronically for dispensing by an EPS compliant dispensary.

Currently, dispensing list patients are unable to use the EPS for medicines dispensed by the practice dispensary, as there are no EPS-compliant systems for practice dispensaries on the market.

However, if they ask, all patients, including dispensing list patients, must be offered the opportunity to use the EPS, and they must be given the choice to nominate up to three EPS dispensing contractors. For dispensing list patients this will include an EPS pharmacy, an appliance contractor and the patient’s usual practice dispensary.

However, practices are reminded that an EPS nomination for a pharmacy does NOT have any effect on the dispensing status of the nominating patient – patient eligibility for dispensing services is unaffected by the nomination process.

For patients, the benefits of the EPS are said to be:

- Automatic and advance transmission of repeat prescriptions
- Choice of dispensary – up to three EPS dispensing contractors (including one pharmacy) can be nominated by the patient.

For pharmacy dispensary staff:

- Staff are freed from the work associated with re-keying prescription information
- Nominated electronic repeat prescriptions can be received prior to the patient arriving, so medications may be prepared in advance
- Easier stock control
No need to physically collect prescriptions from GP practices for patients who have nominated them
Electronic payment submission.

As of September 3rd, 2012, 6,331 dispensing contractors in England were ready to dispense using the EPS, and 613,763 patients had nominated an EPS dispensing contractor (pharmacy or dispensing appliance contractor) to receive their electronic scripts.

The EPS does not apply to Scotland and Wales, which are developing their own electronic prescribing systems.

For more information
For information on the deployment of the EPS in your local area, visit: 
http://www.connectingforhealth.nhs.uk/systemsandservices/eps

4.6 Controlled Drugs (CDs) Regulations

There are two classification systems of controlled drugs used in the UK: Classes and Schedules.

Classes
The Misuse of Drugs Act 1971 prohibits the manufacture, supply and possession of certain drugs. These are divided into classes A-C on the basis of the harmfulness attributable to a drug when it is misused. The degree of penalty, eg, for possession, is linked to the class of the drug.

Common examples
Class A: Cocaine, morphine, diamorphine, pethidine, methadone
Class B: Amphetamines, barbiturates, cannabis, codeine, pholcodine
Class C: Buprenorphine, benzodiazepines, zolpidem, anabolic steroids

Schedules
The Misuse of Drugs Act 2001 determines who is allowed to handle these drugs for their work and divides them into five schedules. The schedule determines the regulations regarding import, export, possession, prescribing and record keeping.

Schedule 1 drugs (example: cannabis) are generally not used medically, and require Home Office authority for possession and supply.

Schedule 2 drugs (examples: diamorphine, morphine, pethidine) are subject to the full requirements for prescriptions, safe custody and the need to keep registers (unless exempted in schedule 5).

Schedule 3 drugs (examples: barbiturates, buprenorphine, temazepam). These are subject to prescription requirements but not safe custody nor registration. Invoices should be kept for two years, however (the DDA recommends 11 years for product liability).

Exemptions:
• Temazepam - not subject to prescription requirements
• Buprenorphine, temazepam and diethylpropion - subject to safe custody requirements.

**Schedule 4** drugs are not subject to prescription or safe custody requirements.
• Part I Examples include benzodiazepines (not temazepam) and zolpidem
• Part II Examples: anabolic steroids.

**Schedule 5:** Drugs that on the grounds of strength are exempt of all regulations, except the retention of invoices. Examples include: 10mg/10ml morphine.

**Monitoring of CDs and premises inspection**
The supply and administration of CDs in the NHS and private sectors is the responsibility of the Care Quality Commission, whose key roles are:
• to provide external assurance of arrangements including systems set up by primary care organisations (PCOs) to ensure safe management by all healthcare providers
• to regulate the independent healthcare sector including the management of CDs.

Under CQC rules, all healthcare providers have to make an annual declaration as to whether they prescribe, supply or administer CDs and will be required to agree to have in place standard operating procedures (SOPs) relating to their use.

All healthcare providers will be subject to monitoring and audit of their management of CDs, using prescribing data.

All primary care organisations will have a ‘Responsible Officer’ who will be accountable for monitoring the management of CDs by all NHS healthcare providers in their geographical area. GP dispensing and non-dispensing practices will be subject to inspections by dedicated PCO staff as part of governance procedures, and following random selection. Similar inspections will be made for community pharmacies. Any healthcare provider that has a CD prescribing/supply profile that is considered abnormal may be targeted for a specific inspection. For the most part, inspections will be of an educational nature to ensure high standards in the management of CDs but the inspectors will have powers to act in the event of aberrant CD management that cannot be adequately explained or justified.

**For more information**
Amendments to the Controlled Drugs legislation are published by the Office for Public Sector [online] at: [www.opsi.gov.uk](http://www.opsi.gov.uk)

### 4.7 Wholesale Dealer’s Licences

The Medicines and Healthcare products Regulatory Agency has confirmed that dispensing doctors will require a wholesale dealer’s licence (WDL) to ‘trade’ medicines with other practices and pharmacies for patient benefit.

Since July 2, 2012, Section 10(7) of the Medicines Act 1968 has been revoked, and new provisions put in place to allow pharmacies to transact medicines without a WDL providing the transaction meets all of the following criteria:
• It takes place on an occasional basis
• The quantity of medicines supplied is small and intended to meet the needs of an individual patient
• The supply is made on a not for profit basis. The MHRA has confirmed that the new provisions are not intended to apply to dispensing doctors.

For more information

More information on registering as a wholesaler is available from the MHRA, via the DDA [online] at: http://www.dispensingdoctor.org/about.php?cid=90

4.8 Miscellaneous regulations

The Health and Safety at Work Act 1974
Dispensing practices must comply with the Health and Safety at Work Act 1974. This Act imposes a duty on employers to:
• ensure a safe system of work
• ensure safe premises for employees and visitors
• provide safe equipment
• ensure the safe handling of medicines
• provide information, instruction and supervision for employees on health and safety matters.

In the dispensing practice this means that:
• Staff must be properly trained to use equipment
• Members of the public should not have unsupervised access to drug storage areas
• A first aid box must be available and accessible, and staff should be aware of what do to in the case of needlestick injuries
• Training should be provided on first aid procedures, including CPR and anaphylaxis
• Doctors, dispensers, other staff and patients should be encouraged to promote adverse drug reporting by the Yellow card scheme.
http://yellowcard.mhra.gov.uk/

Policy statement
Practices with more than five employees must provide a policy statement on their approach to the provisions of the Act for their staff.

Risk assessments
If a potential working environment hazard is identified, a risk assessment should be undertaken. The outcome should be documented and appropriate action taken. A significant event register should be kept for the dispensary.
For more information
Information on implementing the Health and Safety at Work Act 1974 can be found [online] at: http://www.hse.gov.uk/legislation/hswa.htm

Control of Substances Hazardous to Health Regulations 2002
Under the provisions of the Control of Substances Hazardous to Health (COSHH) Regulations 2002, all employers are required to:
• identify hazardous substances at work
• assess the risks
• minimise the risks
• inform all employees of any identified risks
• train all employees on risks and precautions.

In the dispensary this means:
• compiling an accessible and up to date COSHH file containing the relevant data sheets for hazardous substances. These are available from the relevant manufacturer
• taking particular care when handling cytotoxic agents that are not protected by original packaging. The appropriate protective garments should be worn, including gloves, masks and appropriate eye protection. Staff who are pregnant or staff of either gender who are considering conception should not handle such unprotected agents.

For more information
Advice on implementing the Control of Substances Hazardous to Health [COSHH] Regulations 2002 can be found [online] at: http://www.hse.gov.uk/coshh/
Generic prescribing: reducing NHS costs

The following guidance is designed to help dispensing practices to achieve high dispensed generic rates yet maintain or improve practice income.

1) It is advisable that the practice nominates a lead GP with an interest in dispensing/prescribing. The lead GP will be responsible for formulating policy and ensuring consensus within the practice. The lead GP should be given protected time to fulfil this important role.

2) The lead GP should liaise closely with dispensers so that they can share ownership in the prescribing/dispensing policy decisions.

3) Seek agreement within the practice to use as many generics as possible and create a formulary for each MIMS or BNF section. Some PCOs run incentive schemes whereby the practice derives income for achieving specified dispensed generic targets or addressing specific prescribing quality issues.

4) Review current generic manufacturer/wholesaler supply. Some practices may use a variety of suppliers and manufacturers, switching around in order to get best deals of the moment. It is well worth considering using a main generic manufacturer who can work with and supply you through your mainstream wholesaler. Choose a manufacturer with an extensive range of generic lines.

5) Negotiate to see which company will offer the best discount rate in exchange for becoming the practice’s mainstream generic supplier. Companies will be keen to secure a high-volume customer and should be prepared to give a good discount. Ask about product line supply failure rates.

6) Dispensed generic status is only attributed to those items where the prescription is written in generic format for products that are listed in Part III of the Drug Tariff.

7) There are a few exceptions where it is good practice to prescribe by brand name. This relates to drugs where consistent bio-availability is particularly important, i.e., anticonvulsant drugs and sustained-released calcium antagonists.

8) It is desirable that dispensing practices maintain a good rapport with their prescribing colleagues within their primary care organisation. Dispensing policy should, where possible, conform to PCO prescribing policy.

Practices should take note of the GMS guidance on excessive or inappropriate prescribing (also see Section 4.1)

Guidance from the General Medical Council: GMC guidance should also inform prescribing decisions. Information is available [online] at: http://www.gmc-uk.org/guidance/index.asp

Definitions: (England and Wales)
Dispensing doctor*: A doctor who has been granted consent under the relevant regulations to provide pharmaceutical services to his patients.
* In Scotland, services provided by dispensing doctors are not considered pharmaceutical services. A dispensing doctor is defined as a contractor who is required by the NHS Board to provide dispensing services where no pharmaceutical services exist.

Controlled (rural) locality: A geographical area judged to be rural in nature by the primary care organisation. A PCO may review the rural status of an area and a Local Medical Committee or a Local Pharmaceutical Committee may ask for such a review, providing no determination has been made in the previous five years (unless has been a significant change in the population or housing provision).

One Mile Rule: Patients may only request dispensing services from their doctor:
- if the patient lives in an area which is rural in character, known as a controlled locality, at a distance of more than one mile (1.6km) from a pharmacy’s premises (but excluding any distance-selling chemist premises). The pharmacy’s premises do not have to be in a controlled locality.
- If a patient satisfies the primary care organisation that they would have serious difficulty in obtaining any necessary drugs or appliances from a chemist by reason of distance or inadequacy of means of communication (colloquially known as the serious difficulty test which can apply anywhere in England or Wales).

Reserved locations:
- If the total population living within a radius of 1.6km (1mile) of a new pharmacy in a controlled area is less than 2,750, then although the pharmacy may open, dispensing patients will be able to continue to receive dispensing services from their doctor (i.e. the 1.6km/1-mile patient rule does not apply).
- The Reserved Location provision applies whether or not the pharmacy application is subject to the Control of Entry Regulations (13–16). Once the population reaches 2,750 a pharmacy, if already open, can request a redetermination re reserved location status and, if removed, then subject to the prejudice test, the dispensing pharmacy would gain the 1.6km/1-mile protection (i.e. the doctors lose dispensing rights within a mile of the pharmacy). If an applicant thinks that the population level has reached 2,750, any new pharmacy application would trigger a redetermination of the reserved location status. If successful, reserved location status would be removed and the applicant would be subject to the prejudice test.
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