

## **Health and Social Services Committee**

**HSS(2)-03-05(p.4)**

**Date: 2 February 2005**

**Venue: Committee Room 3, National Assembly for Wales**

**Title: The National Health Service (Pharmaceutical Services) (Wales) Regulations 2005**

### **Purpose**

To seek approval to progress the National Health Service (Pharmaceutical Services) (Wales) Regulations 2005 to implement the new Community Pharmacy Contract on the 1 April 2005.

### **Summary/Recommendation**

The draft regulations need to be approved immediately in order to maintain the current restrictive legislative timescale. As the regulations are an early draft they will be subject to amendments and shared out of Committee as appropriate.

### **Background**

On 1 April 2005 community pharmacists in England and Wales will have a new NHS contract.

Pharmacists' current contract was agreed in 1987 and is now out of step with developments in pharmacy and the NHS. This contract focuses on throughput of a high volume of prescriptions.

The new Regulations allow for a new contract with different aims: it will reward high quality services, harness the skills of pharmacists and pharmacy staff to develop opportunities of integrated working, and provide minimum standards and less bureaucracy for both pharmacies and Local Health Boards.

The Pharmaceutical Services Negotiating Committee road shows on the new contract were held at the beginning of November 2004, and in Wales Community Pharmacy Wales (CPW) held road shows on 4, 8, 11 & 14 November 2004. On the 22nd November 2004 community pharmacy contractors voted in favour of the funding arrangements and service framework of the new Community Pharmacy Contract. In Wales, 75.4% of pharmacies voted - with 95% voting positively.

## Basic structure

### Key points

1. Community pharmacists will be working under the new contractual framework in April 2005
2. The new contract is focused on high quality services rather than dispensing large volumes of prescriptions
3. The new contract is made of three tiers: **essential, advanced and enhanced services**
4. All contractors will be expected to provide essential services and it is hoped that a majority will provide advanced services
5. Enhanced services are commissioned locally by LHBs in Wales although a national specification for each service will be drawn up

All contractors will be expected to offer essential services. Advanced services will require accreditation of the pharmacist, the pharmacy premises or both. These two tiers form the national pharmacy contract.

For the third tier of enhanced services, a service specification and value will be agreed nationally for each enhanced service, they will however, be commissioned by Local Health Boards.

The contract structure is expected to develop over time, so those services currently classified as enhanced services could be moved to either the essential or the advanced sections of the contract in order to meet the needs of patients, the NHS and the profession.

### Essential services

There are seven essential services. They must be provided by all community pharmacy contractors and are not open to local negotiation.

First is dispensing. Dispensing covers the supply of medicines and appliances, and the provision of advice about the medicines dispensed and about possible interactions with other medicines. It also includes making a record of what has been dispensed and possibly the advice given (this will be decided within the next few weeks). The dispensing service will also include the **provision of compliance aids needed by patients with disabilities**. The next essential

service is repeat dispensing. This will operate along the lines of the repeat dispensing pilots.

Clinical governance is an essential requirement for the contract. Contractors will be expected to ensure that standard operating procedures are used, that adverse incidents are reported to the National Patient Safety Agency, that continuing professional development is undertaken by pharmacists, that services are audited, that patient satisfaction questionnaires are carried out and that interventions are monitored.

Another essential service is in public health. This will include opportunistic one-to-one counselling on smoking cessation and coronary heart disease risk factors, promoting vaccination against influenza and providing education about appropriate use of antibiotics.

Signposting patients to other health care providers is also an essential service. Linked to this is support for self-care; this essential service will include receiving referrals from NHS Direct and provision of advice to patients on treatment of minor ailments, thus reducing burdens on GPs.

The final essential service is medicines waste disposal.

### **Advanced services**

The second tier of the contract is advanced services. In order to provide them, pharmacists will have to be accredited or the pharmacy premises will have to fulfil certain requirements. Although part of the national contractual framework, not all contractors are likely to provide advanced services from day one because of the additional requirements. However, it is hoped that, in time, all contractors will provide advanced services.

There are two advanced services: medicines use review and a prescription intervention service.

The medicines use review involves a pharmacist undertaking a face-to-face review with a patient. The review will be concordance-centred and identify any problems the patient has with his or her current medication and then address these problems. It will also examine the patient's knowledge of his or her medication and help the patient to develop this knowledge. Information will then be fed back to the patient's GP.

The prescription intervention service is similar to the medicines use review but is initiated differently. Instead of a planned review, the prescription intervention service will be a review triggered by a pharmacist identifying a significant issue with a patient's prescription.

## **Enhanced services**

Enhanced services will be commissioned locally by LHBs. A service specification will be agreed nationally but LHBs will be able to vary these according to local needs.

Because enhanced services are commissioned, how many of them a particular pharmacy provides will be determined by local needs so a definitive list of all the enhanced services pharmacists could offer is impossible to determine. However, some examples of enhanced services that are expected to be commonplace are:

- Minor ailments management
- Diabetes screening
- Substance misuse services
- Coronary heart disease screening
- Disease-specific medicines management
- Palliative care services
- Emergency hormonal contraception
- Full clinical medication review (ie, "Room for Review" level three)
- Concordance services
- Out-of-hours services
- Care home and intermediate care services
- Prescriber support services
- Domiciliary assessments
- Head lice management
- Smoking cessation service
- Gluten-free food supply service

## **Compliance**

The current provision of pharmaceutical services is provided under the provisions of the National Health Services (Pharmaceutical Services) Regulations 1992, as amended; this regulates the terms on which pharmaceutical services are provided. Sections 41- 43 of the National Health Service Act 1977 permits the making of regulations. Assembly functions in and under the Act have been delegated to the Minister. There are no issues of regularity or propriety. The Assembly Compliance Office has seen this and is content (ref: SR/01/05/3167).

## **Financial Implications**

The Director of Resources (CB1775) has noted that there are no financial implications for the Assembly at this point in time.

**Dr Brian Gibbons**  
**Minister for Health and Social Services**

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STATUTORY INSTRUMENTS

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**2005 No.**

**NATIONAL HEALTH SERVICE, WALES**

**The National Health Service (Pharmaceutical Services)  
(Amendment) (Wales) Regulations 2005**

*Made* - - - - 2005

*Coming into force* - - 1 April 2005

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations further amend the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I.1992/662) (“the principal Regulations”) which govern the arrangements the provision of pharmaceutical services under the National Health Service Act 1977.

The amendments made by these Regulations introduce a contractual framework for the provision of pharmaceutical services which will enable pharmacies to provide a greater range of services and to be rewarded for the range and quality of those services.

Regulation 8 of these Regulations replaces Part II of the Terms of Service for Chemists which are contained within Schedule 2 to the principal Regulations with new terms of service for Chemists which are contained within Part 2 to 5 of the substituted provision. The new terms of service introduce three tiers of pharmaceutical services: firstly, nationally set essential services, which include dispensing, repeat dispensing, clinical governance requirements and disposal of medication; secondly, advanced services, which are also nationally set and which currently comprise medicines use review and prescription intervention services; and finally, locally enhanced services, which can be commissioned by Local Health Boards and the terms of which can be agreed locally.

Regulation 9 substitutes a new Part 6 into Schedule 2 to the principal Regulations. This replaces without change the terms of services for doctors who provide pharmaceutical services.

These Regulations make other amendments consequential upon the introduction of the new contractual framework for chemists.

**2005 No.**

**NATIONAL HEALTH SERVICE, WALES**

**The National Health Service (Pharmaceutical Services)  
(Amendment) (Wales) Regulations 2005**

*Made* - - - - 2005

*Coming into force* - - 1 April 2005

The National Assembly for Wales in exercise of the powers conferred by sections 41, 42, 43 and 126(4) of the National Health Service Act 1977(1) hereby makes the following Regulations:

**Citation, commencement, interpretation and application**

1.—(1) These Regulations are called the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2005 and will come into force on 1 April 2005.

(2) In these Regulations—

“the principal Regulations” (“*y prif Reoliadau*”) means the National Health Service (Pharmaceutical Services) Regulations 1992(2);

(3) These Regulations apply in relation to Wales only.

**Amendment of Regulation 2 of the principal Regulations**

2.—(1) Regulation 2(1) of the principal Regulations is amended in accordance with the following provisions of this regulation.

(2) For the definition of “supplementary prescriber” substitute—

“supplementary prescriber” means a person—

(a) whose name is registered in—

(i) the Nursing and Midwifery Register,

(ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of (the registers and registration) of the Pharmacy Act 1954(3), or

(iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(4), or

(iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(1) relating to —

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(1) Footnotes to do – NB check powers AND may need to refer to the section 43ZA and section 49F, I, N, O, P and Q

(2) SI 1992/662

(3) c.61

(4) SI 1976/1213 (NI 22)

- (aa) chiropodists and podiatrists,
  - (bb) physiotherapists,
  - (v) radiographers: diagnostic or therapeutic; and
  - (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber;”.
- (3) For the definition of “terms of service” substitute—
- “ “terms of service” means the terms of service contained in or referred to—
- (a) in relation to chemists, in Parts 1 to 5 of Schedule 2,
  - (b) in relation to doctors who provide pharmaceutical services, in Parts 1 and 6 of Schedule 2.”.
- (4) In the appropriate places in the alphabetical order, insert the following definitions—
- “ “essential services” has the meaning given in paragraph 3 of Schedule 2;
- “NHS services” means services provided as part of the health service continued under section 1(1) of the Act;”.
- (5) Omit the following definition—
- “ “repeat dispensing chemist”;

#### **Amendment of regulation 4 of the principal Regulations**

**3.**—(1) Regulation 4 of the principal Regulations is amended in accordance with the following provisions of this regulation.

(2) In paragraph (1), for “additional professional services under regulation 16A or repeat dispensing services under regulation 16B” substitute “directed services, and if he has, which services.”.

(3) In paragraph (2)(b)(iii) omit the words “other than repeat dispensing services”.

(4) For paragraph (6) substitute the following paragraph—

“(6) A Local Health Board shall refuse an application in which a chemist does not offer to provide all of the essential services, but may grant an application either in respect of all, or in respect of some only, of the directed services specified in it.”.

#### **Omission of regulation 16A of the principal Regulations.**

**4.** Regulation 16A is omitted.

#### **Omission of regulation 16B of the principal Regulations**

**5.** Regulation 16B is omitted.

#### **Amendment of regulation 18 of the principal Regulations**

**6.** In regulation 18(1), for sub-paragraph (g) substitute the following sub-paragraph—

“(g) the dispensing or other fees or allowances payable in respect of the provision of pharmaceutical services.”.

#### **Amendment of Part I of Schedule 2 to the principal Regulations**

**7.** In paragraph 2 of Part 1 to Schedule 2 to the principal Regulations (incorporation of provisions) after sub-paragraph (c) insert the following sub-paragraph—

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(1) The register is maintained by the Health Professions Council in accordance with Article 6 of the Health Professions Order 2002 (SI 2002/254)

“ and

(d) so much of regulation 20 of the Community Health Councils Regulations 2004<sup>(1)</sup> as relate to the entry and inspection of premises either owned or controlled by the chemist or doctor or where pharmaceutical services are provided.”.

### **Substitution of Part II of Schedule 2 to the principal Regulations**

8. For Part II of Schedule 2 to the principal Regulations (Terms of Service for Chemists) substitute the following Parts—

## **“PART 2 ESSENTIAL SERVICES**

### **Essential Services**

3. For the purposes of these Regulations, “essential services” means—
- (a) the services described in this Part; and
  - (b) the activities described in this Part to be carried out in connection with those services.

### **Dispensing services**

4. A chemist shall, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting a prescription for that drug or appliance signed by a health care professional in pursuance of his functions in the health service, the Scottish health service or the Northern Ireland health service.

### **Dispensing of drugs and appliances**

5.—(1) Subject to the following provisions of this Part, where a person presents on a prescription form—

- (a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber;
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, signed by, and endorsed on its face with the reference “SLS” by a prescriber; or
- (c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference “SLS” by a prescriber,

a chemist shall, with reasonable promptness and in accordance with any directions given by the prescriber in the prescription form, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.

(2) Subject to the following provisions of this Part, where any person—

- (a) presents a repeatable prescription which contains—
  - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a repeatable prescriber,
  - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the

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<sup>(1)</sup> SI 2004/905 (W.89)



Misuse of Drugs Regulations 2001, signed by and endorsed on its face with the reference “SLS” by a repeatable prescriber,

(iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or

(iv) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference “SLS” by a repeatable prescriber,

and also presents an associated batch issue; or

(b) requests the provision of drugs or appliances in accordance with a repeatable prescription of a kind specified in paragraph (a),

a chemist shall, with reasonable promptness and in accordance with any directions given by the repeatable prescriber in the repeatable prescription, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.

(3) For the purposes of this paragraph, a repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

(a) the pharmacist has that prescription in his possession; and

(b) that person presents, or the pharmacist has in his possession, an associated batch issue.

### **Urgent supply without a prescription**

6. Where, in a case of urgency, a prescriber personally known to a chemist requests him to provide a drug, the chemist may provide that drug before receiving a prescription form or repeatable prescription, provided that—

(a) that drug is not a Scheduled drug;

(b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001; and

the prescriber undertakes to give the chemist a prescription form or repeatable prescription in respect of the drug within 72 hours.

### **Preliminary matters before providing ordered drugs or appliances**

7. If the person presenting the prescription form or repeatable prescription, or requesting the provision of drugs or appliances in accordance with a repeatable prescription, asks the chemist to do so—

(c) the chemist shall give an estimate of the time when the drugs or appliances will be ready; and

(d) if they are not ready by then, the chemist shall give a revised estimate of the time when they will be ready (and so on).

(4) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription—

(a) the chemist shall ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations by virtue of either—

(i) entitlement to exemption under regulation 8(1) of the Charges Regulations, or

(ii) entitlement to remission of such charges under regulation 4 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by regulation 8(1) of the Charges Regulations or in respect of entitlement to remission by virtue of sub-paragraphs (e) to (k) of regulation 4(1) of the

Remission of Charges Regulations, and at the time of the declaration the chemist already has such evidence available to him; and

- (b) if no satisfactory evidence, as required by paragraph (a), is produced to the chemist, the chemist shall endorse the form on which the declaration is made to that effect.

### **Providing ordered drugs or appliances**

**8.—(1)** Where a chemist is presented with a prescription form or a repeatable prescription, the chemist shall only provide the drugs or appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and endorsed as described in paragraph 5(1) or (2); and

(b) in accordance with the order and any directions given by the prescriber on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985 and the following provisions of this Part.

(2) Drugs or appliances so ordered shall be provided either by or under the direct supervision of a pharmacist.

(3) Where the chemist referred to in sub-paragraph (2) is employed by a chemist, the chemist must not be someone—

(a) who—

(i) has been disqualified under section 46(2)(b) of the Act (or under any corresponding provision in force in Scotland or Northern Ireland) from inclusion in the pharmaceutical list of a Primary Care Trust (or, in Scotland, of a Health Board or, in Northern Ireland, of a Health and Social Services Board), and

(ii) is the subject of a declaration under section 46(2)(c) of the Act (or any corresponding provision in force in Scotland or Northern Ireland) that he is not fit to be engaged in any capacity in the provision of pharmaceutical services; or

(b) who is suspended.

(4) If the order is for an appliance of a type requiring measuring and fitting by the chemist (for example a truss), the chemist shall make all necessary arrangements—

(a) for measuring the person named in a prescription form or repeatable prescription for the appliance; and

(b) for fitting the appliance.

(5) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided shall comply with the standard or formula specified therein.

(6) If the order—

(a) is an order for a drug; but

(b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Regulations 2001 other than a drug which is for the time being specified in Schedules 4 or 5 to those Regulations,

and does not prescribe its quantity, strength or dosage, a chemist may provide the drug in such strength and dosage as in the exercise of his professional skill, knowledge and care he considers to be appropriate and, subject to sub-paragraph (7), in such quantity as he considers to be appropriate for a course of treatment for a period not exceeding five days.

(7) Where an order to which sub-paragraph(6) applies is for—

(a) an oral contraceptive substance;

(b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs; or

- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, the chemist may provide the minimum size available package.

(8) Where any drug, not being one to which the Misuse of Drugs Regulations 2001 apply, ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by a pharmacist in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile;
- (b) effervescent or hygroscopic;
- (c) a liquid preparation for addition to bath water;
- (d) a coal tar preparation;
- (e) a viscous preparation; or
- (f) packed at the time of its manufacture in a calendar pack or special container;

the chemist shall, subject to sub-paragraph (9), provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) A chemist shall not provide, pursuant to sub-paragraph (8), a drug in a calendar pack where, in his opinion, it was the intention of the prescriber who ordered the drug that it should be provided only in the exact quantity ordered.

(10) In this paragraph—

- (a) “calendar pack” means a blister or strip pack showing the days of the week or month against each of the several units in the pack; and
- (b) “special container” means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(11) Except as provided in sub-paragraph (12), a chemist shall not provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription.

(12) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, a chemist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(13) Where a drug which is ordered as specified in sub-paragraph (12) combines more than one drug, that sub-paragraph shall apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(14) A chemist shall provide any drug which he is required to provide under this paragraph in a suitable container.

### **Refusal to provide drugs or appliance ordered**

**9.**—(1) A chemist may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the chemist reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because he reasonably believes the form has been stolen or forged);
- (b) it appears to the chemist that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to the chemist’s clinical judgement;

- (c) the chemist or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription, or by any person accompanying that person; or
  - (d) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.
- (2) A chemist shall refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.
- (3) A chemist shall refuse to provide drugs or appliances ordered on a repeatable prescription where—
- (a) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than six months previously;
  - (b) if the repeatable prescription was signed more than one year previously; or
  - (c) the expiry date on the repeatable prescription has passed.
- (4) If presented with a repeatable prescription, a chemist shall only provide the drugs or appliances order if he is satisfied—
- (a) that the patient in respect of whom the prescription was written—
    - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
    - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment,
 but this paragraph does not apply in respect of the first occasion when the prescription is presented;
  - (b) that the medication regimen of the patient in respect of whom the prescription was written has altered in a way which indicates the need or desirability of reviewing the patient's treatment;
  - (c) there have been no changes to the health of the patient in respect of whom the prescription was written which indicate the need or desirability of reviewing the patient's treatment.

**Further activities to be carried out in connection with the provision of dispensing services**

- 10.** In connection with the services provided under paragraph 4, a chemist shall—
- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—
    - (i) to enable them to utilise the drugs or appliances appropriately, and
    - (ii) to meet the patient's reasonable needs for general information about the drugs or appliances;
  - (b) provide appropriate advice to persons to whom they provide drugs or appliances on—
    - (i) the safe keeping of the drugs or appliances, and
    - (ii) returning unwanted drugs or appliances to the pharmacy for safe destruction;
  - (c) provide appropriate advice to persons to whom they provide drugs or appliances in accordance with a repeatable prescription in particular on the importance of only requesting those items which they actually need;
  - (d) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when the drug or appliance becomes available;
  - (e) keep and maintain records—
    - (i) of drugs and appliances provided, where it is necessary or desirable to do so in order to facilitate the continued care of the patient;

- (ii) in appropriate cases, of advice given and any interventions or referrals made (in particular of clinically significant interventions in cases involving repeatable prescriptions), and
- (iii) of notes provided under sub-paragraph (d);
- (f) undertake appropriate training in respect of repeat prescribing, having regard to any recommendations in respect of such training set out in the Drug Tariff;
- (g) if he takes possession of a repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (h) after providing drugs or appliances under a repeatable prescription—
  - (i) endorse an associated batch issue, as required by the Drug Tariff, and
  - (ii) forward that batch issue to **Health Solutions Wales**;
- (i) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
- (j) where a patient is provided with drugs or appliances under a repeatable prescription, notify the person responsible for the prescription of any clinically significant issues arising in connection with the prescription and keep a record of that notification.

**Disposal service in respect of unwanted drugs**

11. A chemist shall, to the extent paragraph 12 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs presented to him for disposal.

**Basic procedures in respect of unwanted drugs**

12. —(1) Subject to paragraph (2), where a person presents to a chemist or any of his staff any drugs provided for a patient in, and which have been kept in—

- (a) a private household; or
- (b) a residential care home,

the chemist shall accept the drugs and dispose of them in accordance with sub-paragraph (3).

(2) A chemist shall not be required to accept any drugs for disposal unless the Local Health Board with which he is listed has made arrangements with the pharmacist for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, the chemist shall—

- (a) separate solid drugs or ampoules, liquids and aerosols from each other;
- (b) store the drugs in containers provided by the Local Health Board, or by a waste disposal contractor retained by the Local Health Board for the purpose of storing drugs of that description;
- (c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

and shall have in place suitable arrangements for regular collection of the drugs from his premises by or on behalf of the Local Health Board.

**Further activities to be carried out in connection with the disposal of unwanted drugs**

13. In connection with the services provided under paragraph 11, a chemist shall—

- (a) ensure that he and any staff he has, are aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks; and

- (b) ensure that he and any staff he has have readily available and close to any place where waste drugs are stored appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

### **Promotion of healthy lifestyles**

14. A chemist shall, to the extent paragraphs 15 and 16 require, and in the manner set out those paragraphs, promote public health messages to members of the public.

### **Prescription linked intervention**

15.—(1) Where a person using a pharmacy—

- (a) presents a prescription form or repeatable prescription to a chemist; and
- (b) it appears to the chemist that the person—
  - (i) has or is at risk of diabetes, coronary heart disease or high blood pressure, or
  - (ii) smokes or is overweight,

the chemist shall, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

- (a) by the provision of written material (for example leaflets); and
- (b) by referring the person to other sources of information or advice.

(3) A chemist shall, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the pharmacist; and
- (b) follow-up care for the person who has been given the advice.

### **Public health campaigns**

16. A chemist shall, at the request of its Local Health Board, ensure that he and any staff he has participate, in the manner reasonably requested by his Local Health Board, in up to six campaigns in each calendar year to promote public health messages to users of his pharmacy.

### **Signposting**

17. A chemist shall, to the extent paragraph 18 requires and in the manner set out in that paragraph, provide information to users of his pharmacy about other health and social care providers and support organisations.

### **Service outline in respect of signposting**

18.—(1) Where it appears to a chemist or his staff, having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using his pharmacy—

- (a) requires advice, treatment or support that the chemist cannot provide; but
- (b) another provider, of which the chemist is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

the chemist shall provide contact details of that provider to that person and shall, in appropriate cases, refer that person to that provider.

(2) Where appropriate, a referral under sub-paragraph (1) may be made by means of a written referral note.

(3) The chemist shall, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the chemist; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

### **Support for self-care**

**19.** A chemist shall, to the extent paragraph 20 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

### **Service outline in respect of self-care**

**20.—**(1) Where it appears to a chemist or his staff, having regard to the need to minimise the inappropriate use of health and social care services, that a person using his pharmacy would benefit from advice from the pharmacist to help him manage a medical condition (including, in the case of a carer, to help the carer in assisting in the management of another person's medical condition), the chemist shall provide advice to the person using the pharmacy as regards managing the medical condition, including as appropriate advice—

- (a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and
- (b) on changes to the patient's lifestyle.

(2) The chemist shall, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1) and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the chemist; and
- (b) follow-up care for the person to whom or in respect of whom the advice has been given.

### **Support for people with disabilities**

**21.** A chemist shall, to the extent paragraph 22 requires and in the manner set out in that paragraph, provide assistance to disabled people to enable them to utilise appropriately the drugs that they have been prescribed.

### **Service outline in respect of support for people with disabilities**

**22.—**(1) A chemist shall, on request, assess the need of a disabled person for assistance in enabling them to utilise drugs that have been prescribed to them appropriately.

(2) For the purposes of carrying out an assessment under sub-paragraph (1), the chemist shall—

- (a) provide the disabled person with an assessment form, which is in the form determined for these purposes by the National Assembly for Wales;
- (b) on request, provide the disabled person with assistance in completing the form.

(3) Once the assessment form has been completed, the chemist shall determine whether or not, in his opinion, the disabled person does require assistance to enable him to utilise appropriately the drugs that he has been prescribed.

(4) If the chemist determines that, in his opinion, the disabled person does require assistance to enable him to utilise appropriately the drugs that he has been prescribed, the chemist shall, subject to sub-paragraph (6), provide that assistance in one of the following ways—

- (a) by providing level one support, which entails assistance by means of any or a combination of the following—
  - (i) labelling the disabled person's drugs in a way that takes account of an impairment of vision,

(ii) removing solid dosage forms of a drug from blister strips and repackaging them in a suitable tablet container, but the chemist shall only provide this service in respect of a maximum of one month's supply of the drug at any one time,

(iii) providing reminder charts,

(iv) by providing drugs administration records;

(b) by providing level two support, which entails providing medication in a multi-compartment compliance aid, which is on the list of approved multi-compartment compliance aids established and maintained by the National Assembly for Wales;

(c) in a case where the disabled person needs greater assistance than available under level one or level two support, by referring his case to his Local Health Board,

and in making a determination under sub-paragraph (3), a chemist shall have regard to the types of assistance available under this sub-paragraph.

(5) A chemist shall forward all completed assessment forms in respect of assessments carried out under this paragraph to his Local Health Board.

(6) If a Local Health Board, having reviewed an assessment form forwarded to it under sub-paragraph (5), determines that, in its opinion, a person to whom a chemist is providing assistance under sub-paragraph (4) does not require that assistance—

(a) the Local Health Board shall notify the chemist in writing that he must cease providing that assistance under sub-paragraph (4) (although he may provide it, where appropriate, not as an essential service); and

(b) the chemist shall cease to provide that assistance under that sub-paragraph (although he may provide it, where appropriate, not as an essential service).

## PART 3

### PHARMACY OPENING HOURS

#### **Pharmacy opening hours: general**

**23.**—(1) A chemist shall ensure that pharmaceutical services are provided at each of premises from which he has undertaken to provide pharmaceutical services—

(a) for not less than 40 hours each week; or

(b) if his Local Health Board, or on appeal the National Assembly for Wales, has directed **(either under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations)** that—

(i) he may provide pharmaceutical services at the premises for fewer than 40 hours per week, provided that he provides those services at set times and on set days, or

(ii) he must provide pharmaceutical services at the premises for more than 40 hours per week, and at set times and on set days,

at the times and on the days so set.

(2) Subject to sub-paragraph (3), at each of the premises from which a chemist has undertaken to provide pharmaceutical services, he shall exhibit—

(a) a notice specifying the times at which the premises are open for the provision of drugs and appliances; and

(b) at times when the premises are not open, a notice based on information provided by the Local Health Board, legible from outside the premises, specifying the addresses of other chemists, included in the pharmaceutical list and the times at which drugs and appliances may be obtained from those addresses.

(3) A chemist shall, on request, submit a return to the Local Health Board setting out—

(a) the times at which pharmaceutical services are provided at each of the premises from which he has undertaken to provide pharmaceutical services; and



- (b) the pharmaceutical services which he ordinarily provides at each of those premises.
- (4) Where a chemist is prevented by illness or other reasonable cause from complying with his obligations under sub-paragraph (1), he shall, where practicable, make arrangements with one or more chemists whose premises are situated in the neighbourhood for the provision of pharmaceutical services during that time.
- (5) Where there is a temporary suspension in the provision of pharmaceutical services by a chemist for a reason beyond the control of the chemist, the chemist shall not be in breach of sub-paragraphs (1) and (2), provided that—
  - (a) he notifies the Local Health Board of that suspension as soon as practical; and
  - (b) he uses all reasonable endeavours to resume provision of pharmaceutical services as soon as practicable;
- (6) Planned refurbishment of a pharmacy is neither a “reasonable cause” for the purposes of sub-paragraph (4) nor a “reason beyond the control of the pharmacist” for the purposes of sub-paragraph (5).

### **Matters to be considered when issuing directions in respect of pharmacy opening hours**

**24.**—(1) Where a Local Health Board issues a direction setting any times or days under this Part, it shall in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are allocated in such a manner as to ensure that the pharmaceutical services are provided at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services on working days.

(2) The Local Health Board may only direct that a chemist may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in the neighbourhood is likely to be adequate to meet the need for such services at times when the pharmacist is not providing pharmaceutical services.

(3) In this Part, “working days” means Monday to Saturday excluding a Good Friday, Christmas Day and any bank holiday.

### **Determination of pharmacy opening hours instigated by the Local Health Board**

**25.**—(1) Where it appears to the Local Health Board, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the times at which a pharmacy is or will be open for the provision of pharmaceutical services will not, or no longer meet, the needs of—

- (a) people in the neighbourhood; or
- (b) other likely users of his pharmacy,

for pharmaceutical services on working days, it may carry out an assessment as to whether to issue a direction requiring the pharmacist whose pharmacy it is to provide pharmaceutical services at the pharmacy at set times and on set days.

(2) Before concluding the assessment under sub-paragraph (1) the Local Health Board shall—

- (a) give notice to the chemist of any proposed changes to the times at which or the days on which the pharmacy is to be open; and
- (b) allow him 60 days within which to make written representations to the Primary Care Trust about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board shall—

- (a) issue a direction (which will replace any existing direction) setting the days on which and the times at which the chemist must provide pharmaceutical services at the pharmacy;

(b) confirm any existing direction setting the days on which and the times at which the chemist must provide pharmaceutical services at the pharmacy, whether issued under this Part or **paragraph 4 of Schedule 2 to the 1992 Regulations**;

(c) either—

(i) revoke (without replacing it) any existing direction setting the times at which or the days on which the chemist must provide pharmaceutical services at the pharmacy, **whether issued under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations**, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 23(1)(a), the pharmacy will need to be open for not less than 40 hours each week..

(4) The Local Health Board shall notify the chemist writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the chemist is to provide pharmaceutical services at the pharmacy, it shall include with the notification a statement in writing of—

(a) the reasons for the change; and

(b) the chemist's right of appeal under paragraph (6).

(5) A chemist may, within 30 days of receiving notification under sub-paragraph (4) appeal in writing to the National Assembly for Wales against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the chemist is to provide pharmaceutical services.

(6) The National Assembly for Wales may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(7) The National Assembly for Wales shall notify the chemist in writing of its determination and shall in every case include with the notification a written statement of the reasons for the determination.

(8) If the times at which or the days on which a chemist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the chemist shall introduce the changes—

(a) if he has not appealed under sub-paragraph (5), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (4); or

(b) if he has appealed under sub-paragraph (5), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (7).

#### **Determination of pharmacy opening hours instigated by the pharmacist**

**26.**—(1) A chemist may apply to a Local Health Board for it to change the times at which or days on which pharmaceutical services are to be provided at his pharmacy.

(2) The Local Health Board shall determine an application within 60 days of receiving it.

(3) In determining the application, the Local Health Board shall—

(a) issue a direction (which will replace any existing direction)—

(i) setting the days on which and the times at which the chemist must provide pharmaceutical services at the pharmacy, and

(ii) which has the effect of either granting the application under this paragraph or granting it only in part;

(b) confirm any existing direction setting the days on which and the times at which the chemist must provide pharmaceutical services at the pharmacy, whether issued under this Part or **paragraph 4 of Schedule 2 to the 1992 Regulations**;

(c) either—

(i) revoke (without replacing it) any existing direction setting the times at which or the days on which the chemist must provide pharmaceutical services at the pharmacy, whether issued under this Part or **paragraph 4 of Schedule 2 to the 1992 Regulations**, where this has the effect of granting the application under this paragraph or granting it only in part, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 23(1)(a), the pharmacy will need to be open for not less than 40 hours each week..

(4) Where the Local Health Board is considering taking action under sub-paragraph (3)(a) or sub-paragraph 3(c)(i), it shall consult the Local Pharmaceutical Committee before determining the application.

(5) A Local Health Board shall notify the chemist in writing of any direction issued or any other action taken under sub-paragraph (3), and where this has the effect of refusing an application under this paragraph or granting it in part, it shall send the chemist a statement in writing setting out—

(a) the reasons for the refusal or, as the case may be, for granting the application only in part; and

(b) the chemist's right of appeal under sub-paragraph (6).

(6) A chemist may, within 30 days of receiving a notification pursuant to sub-paragraph (5), appeal in writing to the National Assembly for Wales against any action under sub-paragraph (3) which has the effect of refusing an application under this paragraph or granting it only in part.

(7) The National Assembly for Wales may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(8) The National Assembly for Wales shall notify the chemist in writing of its determination and shall in every case include with the notification a written statement of the reasons for the determination.

## PART 4

### CLINICAL GOVERNANCE AND COMPLAINTS

#### Clinical governance

27.—(1) A chemist shall, in connection with all the pharmaceutical services provided by him, participate, in the manner reasonably required by his Local Health Board, in an approved system of clinical governance.

(2) For these purposes a system of clinical governance is “approved” if it is approved by the National Assembly for Wales and comprises the following components—

(a) a patient and public involvement programme, which includes—

(i) a requirement that the chemist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of his pharmacy,

(ii) a requirement that the chemist publicises the NHS services that are available at or from his pharmacy,

(iii) a requirement that the chemist should undertake an approved patient satisfaction survey annually, in an approved manner,

(iv) monitoring arrangements for drugs or appliances owed to patients but which are out of stock,

(v) an approved complaints system (which meets the requirements of this Part),

- (vi) a requirement that the chemist co-operates appropriately with local Community Health Council visits and takes appropriate action following the outcome of such visits,
  - (vii) a requirement that the chemist co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
  - (viii) monitoring arrangements for compliance with the Disability Discrimination Act 1995;
- (b) a clinical audit programme, which includes at least one pharmacy-based audit and one multi-disciplinary audit by his Local Health Board in each financial year;
- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock are handled in an appropriate way,
  - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
  - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,
  - (iv) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
  - (v) appropriate waste disposal arrangements (in addition to those required under Part 2) for clinical and confidential waste,
  - (vi) a clinical governance lead person in respect of each pharmacy,
  - (vii) appropriate child protection procedures, and
  - (viii) monitoring arrangements for compliance with the Health and Safety Act 1974;
- (d) a clinical effectiveness programme, which includes arrangements for monitoring the effectiveness of the advice given by a pharmacist in respect of repeatable prescriptions or to people caring for themselves or their families;
- (e) a staffing and staff management programme, which includes—
- (i) arrangement for appropriate induction training for staff and locums,
  - (ii) appropriate training for all staff in respect of any role they are asked to perform,
  - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
  - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of health service services (apart from chemists, whose development needs are covered under paragraph (f)),
  - (v) arrangements for addressing poor performance (in conjunction with a Local Health Board as appropriate);
- (f) an education, training, continuing professional and personal development of chemists programme, which includes appropriate arrangements in respect of continuing professional development and any necessary accreditation in respect of the provision of directed services; and
- (g) a use of information programme, which includes appropriate arrangements (having regard to issues both of rights of access to information and of confidentiality) to support both health care delivery and clinical governance.

### **Professional standards**

**28.** A chemist shall provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

## **Inducements**

**29.**—(1) A chemist or his staff shall not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his presenting an order for drugs or appliances on a prescription form or repeatable prescription.

## **Complaints**

**30.** A chemist shall have in place arrangements for the handling and consideration of complaints about any matter connected with his provision of pharmaceutical services as if the National Health Service (Complaints) Regulations 2004<sup>(1)</sup>.

# **PART 5**

## **OTHER TERMS OF SERVICE**

### **Directed services**

**31.** A chemist with whom a Local Health Board makes an arrangement for the provision of any directed services shall comply with the terms and conditions of the arrangement.

### **Information to be supplied**

**32.**—(1) A chemist shall give notice to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of any occurrence requiring a change in the information recorded about him in the pharmaceutical list and of any change of his private address.

(2) A chemist shall give the Local Health Board, if it so requests, the name of any chemist employed by him for the provision of drugs for persons from whom he has accepted a prescription form or a repeatable prescription.

(3) Subject to sub-paragraph (7), a chemist that is a body corporate shall (if it is on a pharmaceutical list on 1st April 2005, by 2005) supply to its Local Health Board in writing the name and address of each of its directors, and any changes to the names and addresses of each of its directors.

(4) Subject to sub-paragraph (7), if a chemist or the director of a chemist that is a body corporate is himself on, or is a director of a body corporate body which is on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Local Health Board —

- (a) if he is a director of a body corporate, the name and registered office of the body corporate on the other NHS performers or providers list; and
- (b) particulars of the other NHS performers or providers list.

(5) Subject to sub-paragraph (7), if a chemist or the director of a chemist that is a body corporate has himself in the five years prior to 1st April 2005 been on, or has in the five years prior to 1st April 2005 been the director of a corporate body that which was when he was a director on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Local Health Board—

- (a) the name and registered office of the body corporate on the other NHS performers or providers list; and
- (b) particulars of the NHS performers or providers list.

unless that information has already been supplied pursuant to sub-paragraph (4).

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<sup>(1)</sup> SI 2004/1768

(6) Subject to sub-paragraph (7), if a chemist or the director of a chemist that is a body corporate shall inform the Local Health Board—

(a) if he, or a body corporate of which he is a director, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application; and

(b) if he becomes a director of a body corporate which is on any of another Local Health Board's NHS performers or providers list, or which applies to be included in such a list, and the outcome of any such application.

(7) Where a chemist is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (6) may be provided only to the Local Health Board in which that registered office is located, if the chemist also provides that Local Health Board with details of all the other Local Health Board on whose pharmaceutical lists it is, and in these circumstances that Local Health Board shall pass the information on to any other Local Health Board —

(a) on whose pharmaceutical list the chemist is; or

(b) to whom the chemist makes an application to be on its pharmaceutical list,

that requests it.

(8) In this paragraph, "NHS performers or providers list" means—

(a) a pharmaceutical list; or

(b) any other list.

### **Withdrawal from pharmaceutical list**

**33.** Where a chemist intends to withdraw from the pharmaceutical list, he shall notify the Local Health Board of this at least three months in advance of that date, unless it is impracticable for him to do so in which case he shall notify the Local Health Board as soon as it is practicable for him to do so.

### **Charges for drugs**

**34.—**(1) Subject to regulations made under section 77 of the Act, all drugs, containers and appliances provided under these terms of service shall be provided free of charge.

(2) Where a chemist supplies a container in response to an order for drugs signed by a prescriber, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the pharmacist, the container and equipment shall remain the property of the pharmacist.

### **Inspections and access to information**

**35.—**(1) A chemist shall allow persons authorised in writing by the Local Health Board to enter and inspect his pharmacy at any reasonable time, for the purposes of—

(a) ascertaining whether or not the chemist is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing—

(i) the provision made by the chemist for patient care and treatment, and

(ii) the management by the chemist of the pharmaceutical services he provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) reasonable notice of the intended entry has been given;

(b) the person authorised in writing carries written evidence of his authorisation, which he produces on request; and

(c) he does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A chemist shall, at the request of the Local Health Board or of person authorised in writing mentioned in sub-paragraph (1), allow it or him access to any information which it or he reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the Local Health Board, in connection with its functions.”.

### **Substitution of Part III of Schedule 2 to the principal Regulations**

9. For Part III of Schedule 2 to the principal Regulations (Terms of Service for Doctors who Provide Pharmaceutical Services) substitute the following—

## **“PART 6**

### **TERMS OF SERVICE FOR DOCTORS WHO PROVIDE PHARMACEUTICAL SERVICES**

#### **Dispensing of drugs and appliances ordered by independent prescribers**

36.—(1) Subject to the following provisions of this Part, where a patient presents on a prescription form—

(a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by an independent prescriber;

(b) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations, signed by, and endorsed on its face with the reference “SLS” by an independent prescriber; or

(c) an order for restricted availability appliances, signed by and endorsed on its face with the reference “SLS” by an independent prescriber,

to a doctor who is authorised or required to provide by regulation 20 to provide the drugs or appliances to that patient, the doctor may provide to the patient such of the drugs or appliances so ordered as he supplies in the normal course of his practice.

(2) Drugs and listed appliances provided under this paragraph shall be provided in a suitable container.

#### **Dispensing of drugs and appliances in other cases**

37. In circumstances where paragraph 36 does not apply and subject to the following provisions of this Part, where a doctor is authorised or required by a Local Health Board under regulation 20 to provide drugs of appliances to a patient—

(a) he shall record an order for the provision of any drugs, or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with the term of a contract which gives effect to paragraph 39(3) of Schedule 6 to the GMS Regulations or an equivalent provision applying in relation to that contract;

(b) he shall provide those drugs and appliances in a suitable container;

(c) he shall provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied;

(d) he shall provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

### **Preliminary matters before providing ordered drugs or appliances**

**38.** Before providing the drugs or listed appliances recorded on a prescription form in accordance with paragraph 37(a), or the drugs or medicines or listed appliances ordered on a prescription form in accordance with paragraph 36(1), a doctor who is authorised or required by the Local Health Board under regulation 20 to provide drugs and appliances to a patient shall—

(a) ask any person who makes a declaration on the prescription form that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations by virtue of either—

- (i) entitlement to exemption under regulation 8(1) of the Charges Regulations, or
- (ii) entitlement to remission of such charges under regulation 4 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement unless the declaration in respect of entitlement to exemption by virtue of regulation 8(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 4(2)(e) to (k) of the Remission of Charges Regulations, and at the time of the declaration the doctor already has such evidence available to him; and

(b) if no satisfactory evidence, as required by sub-paragraph (a) is produced to him (and, where it is relevant, none is already available), the doctor shall endorse the form on which the declaration is made to that effect.

### **Provision of Scheduled drugs**

**39.—**(1) Subject to sub-paragraph (2), a doctor who is authorised or required by a Local Health Board under regulation 20 to provide drugs or appliances to a patient shall not provide for a patient any Scheduled drug, except that, where he has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, he may provide a drug which has the same specification notwithstanding that it is Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(2) Nothing in this paragraph or paragraph 36 shall prevent a doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

### **Fees and charges**

**40.—**(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a doctor as they apply in respect of prescriptions for drugs and appliances.

(2) Where a doctor who is authorised or required by a Local Health Board under regulation 20 to provide drugs or appliances under pharmaceutical services—

- (a) in accordance with this Part; and
- (b) had the drug or appliance been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled to a payment in respect of the drug or appliance by virtue of directions given by the National Assembly for Wales under section 28T of the Act,

the Local Health Board shall credit him with the payment.

### **Complaints procedures**

**41.—**(1) Where a doctor who is authorised or required by a Local Health Board under regulation 20 to provide drugs or appliances to a patient, or who otherwise provides pharmaceutical services, is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which gives effect to paragraph 90 of Schedule 6 to the GMS Regulations shall apply in relation to any matter



reasonably connected with his provision of pharmaceutical services as it applies as respect to services provided under that contract or agreement.

(2) Accordingly, the term of the GMS contract which gives effect to paragraph 95 of Schedule 6 to the GMS Regulations also applies in relation to complaints about such matters.”.

### **Amendment of Schedule 3 to the principal Regulations**

**10.** For paragraph 6 of Schedule 3 to the principal Regulations (Application for Inclusion in a Pharmaceutical List or Inclusion in a List in Respect of Different Services or Premises) substitute—

“ 6. (To be completed by all applicants)

#### **ESSENTIAL SERVICES FROM THIS PHARMACY**

	<i>Available</i>	<i>Proposed</i>
Clinical Governance and CPD	<input type="checkbox"/>	<input type="checkbox"/>
Dispensing (including repeat dispensing and compliance aids required under the Disability Discrimination Act)	<input type="checkbox"/>	<input type="checkbox"/>
Disposal of unwanted medicines	<input type="checkbox"/>	<input type="checkbox"/>
Promotion of healthy lifestyles	<input type="checkbox"/>	<input type="checkbox"/>
Sign-posting patients to other NHS services	<input type="checkbox"/>	<input type="checkbox"/>
Support for self-care	<input type="checkbox"/>	<input type="checkbox"/>

#### **ADVANCED SERVICES FROM THIS PHARMACY**

	<i>Available</i>	<i>Proposed</i>
Medicines Use Review	<input type="checkbox"/>	<input type="checkbox"/> ”.

#### **[Drafting notes -**

- 1.** I need to insert a transitional or saving provision in respect of the determinations made under the old paragraph 4 in respect of hours of service provision
- 2.** I have omitted references to electronic prescribing/processing – assume content, no enabling Regulations in place in Wales - please acknowledge that you are content with this approach.
- 3.** I have omitted reference to Local Enhanced service provision in the amendment to the form in Schedule 3, as instructed
- 4.** As discussed, no changes have been made to replicate the additional terms of service for dispensing doctors that are contained within the new English regulations (e.g. – re: repeatable prescriptions).
- 5.** Reference to HSW – in paragraph 10 of the inserted Schedule 2?
- 6.** Paragraph 10(k) – electronic prescribing, deleted see earlier note]

