
WELSH STATUTORY INSTRUMENTS

2005 No. 1013

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

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 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 chemist has that prescription in his possession; and
- (b) that person presents, or the chemist 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.—(1) 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—

- (a) the chemist shall give an estimate of the time when the drugs or appliances will be ready; and
- (b) 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).

(2) 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(2) 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(1) 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 pharmacist referred to in sub-paragraph (2) is employed by a chemist, the pharmacist 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 the 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 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 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;
- (c) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs; or
- (d) 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 to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by a chemist 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) he has no record of that prescription;
- (b) he does not have any associate batch issue and it is not presented to him;
- (c) it is not signed by a repeatable prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) 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;

- (f) if the repeatable prescription was signed more than one year previously;
 - (g) the expiry date on the repeatable prescription has passed; or
 - (h) where he has been informed by the repeatable prescriber that the prescription is no longer required.
- (4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that he makes such a request), a chemist shall only provide the drugs and appliances so ordered 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;
 - (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; and
 - (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) 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);
- (i) destroy any surplus batch issues relating to drugs or appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused the drugs or appliances pursuant to paragraph 9;
- (j) ensure that where a person is refused drugs or appliances pursuant to paragraphs 9(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice;
- (k) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification; and
- (l) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4).

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 chemist for the collection and disposal of drugs of that description.

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

- (a) where required to do so by the Local Health Board or by a waste disposal contractor retained by the Local Health Board, 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 co-operate with any suitable arrangements that the Local Health Board has in place 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 diabetes,
 - (ii) is at risk of coronary heart disease or high blood pressure, or
 - (iii) 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 chemist; 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 his Local Health Board, ensure that—
- (a) 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; and
 - (b) where requested to do so by the Local Health Board, record the number of people to whom he or his staff have provided information as part of one of those campaigns.

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 chemist 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.

PART 3

PHARMACY OPENING HOURS

Pharmacy opening hours: general

21.—(1) A chemist shall ensure that pharmaceutical services are provided at each of the 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 on or before 31 March 2005) that 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, at the times and on the days so set;
- (c) if his Local Health Board, or on appeal the National Assembly for Wales, has directed on or before 31 March 2005 that he must provide pharmaceutical services at the premises for more than 40 hours per week, at set times and on set days, at the times and on the days so set; or
- (d) if his Local Health Board, or on appeal the National Assembly for Wales, has directed under this Part that he must provide pharmaceutical services at the premises for more than 40 hours per week—
 - (i) for the total number of hours each week required by virtue of that direction, and
 - (ii) as regards the additional hours for which he is required to provide pharmaceutical services by virtue of that direction, at the days on which and the times at which he is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received three months notice of the proposed suspension.

(2) 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 (including the times at which he is providing pharmaceutical services when he is not obliged to do so by virtue of sub-paragraph (1)); and
 - (b) the pharmaceutical services which he ordinarily provides at each of those premises,

but all chemists, if they are on a pharmaceutical list on 1 April 2005, shall supply such a return to the Local Health Board by 1 July 2005 and shall state in that return if the days

and times submitted represent a change to the days on which and the times at which they provided pharmaceutical services at those premises prior to 1 April 2005.

(4) Where a chemist changes—

- (a) the days on which or the times at which pharmaceutical services are to be provided at premises from which he has undertaken to provide pharmaceutical services; or
- (b) the pharmaceutical services which he is ordinarily to provide at those premises,

he shall supply the Local Health Board with a return informing it of the change.

(5) Where a chemist has submitted a return under sub-paragraph (3) or (4) in respect of any premises, or where he has set out in an application under these Regulations for inclusion in the pharmaceutical list the days on which and the times at which pharmaceutical services will be provided at the premises to which the application relates if the application is granted—

- (a) he shall ensure that pharmaceutical services are provided at the premises to which the return or application relates on the days and at the times set out in return or application (unless the return or application has been superseded by a return, or a further return, under sub-paragraph (4)); and
- (b) he shall not change—
 - (i) the days on which or the times at which pharmaceutical services are to be provided at those premises; or
 - (ii) the pharmaceutical services which he is ordinarily to provide at those premises,

as set out in that return or application, for a period of at least three months after that return or application was received by the Local Health Board.

(6) 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.

(7) 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;

(8) Planned refurbishment of a pharmacy is neither a “reasonable cause” for the purposes of sub-paragraph (6) nor a “reason beyond the control of the chemist” for the purposes of sub-paragraph (7).

(9) For the purposes of calculating the number of hours that a pharmacy is open during a week that includes Christmas Day, Good Friday or a bank holiday, it shall be deemed that the pharmacy was open on that day at the times at which it would ordinarily have been open on that day of the week.

(10) In this Part —

- the “additional hours” for which a chemist is to be required to provide pharmaceutical services are those hours during which the chemist would not be providing pharmaceutical services, were he subject to the condition set out in sub-paragraph (1)
- (a) and not the condition set out in sub-paragraph (1)(e); and

“existing direction” means one that has been made in accordance with this Part, or one that was in existence on 31 March 2005.

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

22.—(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 such as to ensure that the pharmaceutical services are provided on such days and 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.

(2) In considering the matters mentioned in sub-paragraph (1) the Local Health Board may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the chemist is not obliged to provide those services.

(3) 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 chemist is not providing pharmaceutical services.

(4) The Local Health Board may only direct that a chemist must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that he will receive reasonable remuneration in respect of the additional hours for which he is required to provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is “reasonable remuneration” for these purposes”).

Determination of pharmacy opening hours instigated by the Local Health Board

23.—(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, it may carry out an assessment as to whether to issue a direction requiring the chemist whose pharmacy it is to provide pharmaceutical services at the pharmacy at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(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 30 days within which to make written representations to the Local Health Board 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) which meets the requirements of sub-paragraphs (4) and (5);
- (b) confirm any existing direction setting the days on which and the times at which the chemist must provide pharmaceutical services at the pharmacy provided that

the existing direction would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph; or

(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, or

(ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 21(1)(a), the pharmacy will need to be open for not less than 40 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of a pharmacy that is required to be open—

(a) for more than 40 hours each week, it shall set out in that direction —

(i) the total number of hours each week for which the chemist shall provide pharmaceutical services at the pharmacy, and

(ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and times at which he is required to provide those services during those additional hours,

but it shall not set out in that direction the days on which or the times at which he is to provide pharmaceutical services during hours which are not additional hours; or

(b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at that pharmacy.

(5) The Local Health Board shall not issue a direction under sub-paragraph (3) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(6) The Local Health Board shall notify the chemist in 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 sub-paragraph (7).

(7) A chemist may, within 30 days of receiving notification under sub-paragraph (6) 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.

(8) 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).

(9) 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.

(10) 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 (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (6); or
- (b) if he has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (9).

Determination of pharmacy opening hours instigated by the chemist

24.—(1) A chemist may apply to a Local Health Board for it to change the days on which or the times at which he is obliged to provide pharmaceutical services at his pharmacy in a way that—

- (a) reduces the total number of hours for which the chemist is obliged to provide pharmaceutical services each week; or
- (b) keeps the total number of hours the same.

(2) Where a chemist makes an application under paragraph (1), as part of that application he shall provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The Local Health Board shall determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

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

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and 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 provided that the existing direction would meet the requirements of sub-paragraphs (5) and (6);
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which or the days on which the chemist must provide pharmaceutical services at the pharmacy, 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 21(1)(a), the pharmacy will need to be open for not less than 40 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of a pharmacy that is required to be open—

- (a) for more than 40 hours each week, it shall set out in that direction—
 - (i) the total number of hours each week for which the chemist shall provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and the times at which he is required to provide those services during those additional hours,

but it shall not set out in that direction the days on which or the times at which he is to provide pharmaceutical services during hours which are not additional hours; or

(b) for less than 40 hours each week, it shall set out in that direction the days on which and the times at which pharmaceutical services are to be provided at that pharmacy.

(6) The Local Health Board shall not issue a direction under sub-paragraph (4) that has the effect simply of requiring a pharmacy to be open for 40 hours each week no set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

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

(8) A Local Health Board shall notify the chemist in writing of any direction issued or any other action taken under sub-paragraph (4), 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 (9).

(9) A chemist may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the National Assembly for Wales against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) 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 (4).

(11) 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.

(12) If the days on which or times at 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 (9), not earlier than 30 days after the date on which he receives his notification under sub-paragraph (8); or
- (b) if he has appealed under sub-paragraph (9), not earlier than 30 days after the date on which he receives his notification under sub-paragraph (11).

(13) Where an application under sub-paragraph (1)—

- (a) is received by 1 July 2005; and
- (b) is in respect of a direction that was in existence on 31 March 2005 to require the applicant to provide pharmaceutical services at a pharmacy for more than 40 hours per week, and at set times and on set days,

if the Local Health Board fails to determine the application within 60 days of receiving it, in accordance with sub-paragraph (3), that application shall be deemed to have been granted, as from three months from the date on which the application was received by the Local Health Board.

(14) Where an application under sub-paragraph (1)—

- (a) is received by 1 July 2005; and

(b) is in respect of a direction that was in existence on 31 March 2005 to require the applicant to provide pharmaceutical services at a pharmacy for more than 40 hours per week, and at set times and on set days, until that application (including any appeal) is determined or deemed to have been granted, paragraph 22(1)(a) shall apply in respect in respect of the application as if for “40” there were substituted “30”.

PART 4

CLINICAL GOVERNANCE AND COMPLAINTS

Clinical governance

25.—(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 acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is “acceptable” if it is considered acceptable 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(2);
- (b) a clinical audit programme (normally of five days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed 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 paragraphs 12 and 13) 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 chemist 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 services as part of the health service including continuing professional development for registered chemists and any necessary accreditation in respect of the provision of directed services , and
 - (v) arrangements for addressing poor performance (in conjunction with a Local Health Board as appropriate);
- (f) a use of information programme, which includes—
- (i) 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,
 - (ii) the chemist’s monitoring arrangements in respect of his compliance with the Data Protection Act 1998 and with regard to patient confidentiality, and
 - (iii) appropriate training for staff with regard to compliance with the Data Protection Act 1998 and patient confidentiality,
- and for the purposes of this sub-paragraph “approved” means approved by the National Assembly for Wales.

Professional standards

26. 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

27.—(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.

(2) Promising, offering or providing a compliance aid or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

Complaints

28. A chemist shall have in place arrangements for the handling and consideration of complaints about any matter connected with his provision of pharmaceutical services which shall—

- (a) until the coming into force of regulations in relation to complaints about pharmaceutical services made under section 113 of the Health and Social Care (Community Health and Standards) Act 2003(3?) (complaints about health care) comply with the provisions of paragraphs 10A and 10B of Schedule 2 to these Regulations as they apply on 31 March 2005; and
- (b) upon the coming into force of such regulations, comply with those regulations.

PART 5

OTHER TERMS OF SERVICE

Directed services

29. 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

30.—(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—

- (a) any occurrence requiring a change in the information recorded about him in the pharmaceutical list which he has not otherwise notified in accordance with these Regulations;
- (b) in the case of a chemist who is an individual, any change of his private address; and
- (c) in the case of a chemist that is a body corporate, any change to the address of its registered office.

(2) A chemist shall give the Local Health Board, if it so requests, the name of any pharmacist employed by him who is responsible for dispensing a particular prescription.

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

(4) Subject to sub-paragraph (7), if a chemist or the director or superintendent of a chemist that is a body corporate is himself on, or is a director or superintendent of a body corporate 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 or superintendent 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 or superintendent of a chemist that is a body corporate has himself in the five years prior to 1 April 2005 been on, or has in the five years prior to 1 April 2005 been the director or superintendent 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).

(6) Subject to sub-paragraph (7), if a chemist or the director or superintendent 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 or superintendent, 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 or superintendent 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 Boards 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 lists

31. 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 and refunds

32.—(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 chemist, the container and equipment shall remain the property of the chemist.

(3) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents a chemist with a valid claim for repayment, the chemist shall make the repayment.

(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if—

- (a) until 30 June 2005, it is duly made on Form WP57 0403 within three months of the date on which the charge was paid; or
- (b) from 1 July 2005, it is duly made on Form WP57 0405 within three months of the date on which the charge was paid.

Inspections and access to information

33.—(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 Local Pharmaceutical Committee for the area where the pharmacy is situated have been invited to be present at the inspection, where this is requested by the chemist;
- (c) the person authorised in writing carries written evidence of his authorisation, which he produces on request; and
- (d) 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 that relate to pharmaceutical services.”.