

## SCHEDULE 5

Regulation 12

Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provisions of drugs

### PART 1

#### General

##### Interpretation

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the NHS pharmacist has that prescription in their possession, and
- (b) that person presents, or the NHS pharmacist has in their possession, an associated batch issue.

##### Incorporation of provisions

2. Any provisions of the following affecting the rights and obligations of NHS pharmacists who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations,
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services),
- (c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
  - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and,
  - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board, and
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010<sup>(1)</sup> (entry and inspection of premises) as relate to the entry and inspection of premises either owned or controlled by the NHS pharmacist or where pharmaceutical services are provided by that NHS pharmacist.

### PART 2

#### Essential services

##### Essential services

3. For the purposes of this Schedule, “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.

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(1) [S.I. 2010/288 \(W. 37\)](#).

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### Dispensing services

4. An NHS pharmacist must, 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 prescriber in pursuance of their functions in the health service in Wales, England, Scotland or Northern Ireland.

### 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 (drugs or medicines to be ordered only in certain circumstances), 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,

an NHS pharmacist must, 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 they supply in the normal course of business.

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

- (a) presents a non-electronic 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<sup>(2)</sup>, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001<sup>(3)</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a repeatable prescriber,
  - (ii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
  - (iii) 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 an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iii),

an NHS pharmacist must, 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 they supply in the normal course of their business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances is to 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 NHS pharmacist has that prescription in their possession, and
- (b) that person presents, or the NHS pharmacist has in their possession, an associated batch issue.

<sup>(2)</sup> 1971 c. 38. See section 2(1)(a) of that Act which defines “controlled drug” for the purposes of that Act.

<sup>(3)</sup> S.I. 2001/3998.

## **Supply in accordance with a SSP**

6.—(1) This sub-paragraph applies where—

- (a) a person requests a drug or appliance from an NHS pharmacist in accordance with a prescription form or repeatable prescription, and
- (b) a SSP has effect in respect of—
  - (i) the requested drug or appliance, or
  - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, the NHS pharmacist must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, the NHS pharmacist may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

- (a) the NHS pharmacist is able to do so with reasonable promptness,
- (b) to do so is in accordance with the SSP, and
- (c) the supply of a different product or quantity of product to that ordered by the prescriber is by or under the direct supervision of a registered pharmacist who is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where an NHS pharmacist, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

- (a) the registered pharmacist mentioned in sub-paragraph (3)(c) must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as so endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription), and
- (b) if the patient to or for whom the product is provided is on a patient list, and the supply—
  - (i) by virtue of regulation 226A(5)(c)(iii) of the Human Medicines Regulations 2012 (sale etc. by a pharmacist in accordance with a serious shortage protocol), is of a prescription only medicine that is different to but has a similar therapeutic effect to the product ordered by the prescriber, or
  - (ii) is of any other type, and the Welsh Ministers and the person who is, for the time being, the person consulted under section 89(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

the NHS pharmacist must notify the provider of primary medical services on whose patient list the patient is, of the supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(5) Where—

- (a) sub-paragraph (1) applies,

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- (b) a registered pharmacist is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS pharmacist is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 5(1) and (2) are to be read as requirements to act within a reasonable timescale.

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

7.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist to provide a drug or appliance.

(2) The NHS pharmacist may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that—

- (a) in the case of a request for a drug, the drug is neither—
  - (i) a Scheduled drug, nor
  - (ii) 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, and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to—
  - (i) give the NHS pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or
  - (ii) give the NHS pharmacist an electronic prescription form or electronic repeatable prescription complying with the ETP service within 72 hours of the request being made.

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

8.—(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 NHS pharmacist to do so—

- (a) the NHS pharmacist must give an estimate of the time when the drugs or appliances will be ready, and
- (b) if they are not ready by then, the NHS pharmacist must 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 NHS pharmacist must 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) of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
  - (i) entitlement to exemption under regulation 8(1) (exemptions) of the Charges Regulations, or
  - (ii) entitlement to remission of such charges under regulation 5 of the Remission of Charges Regulations (remissible NHS charges),

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 (a) to (f) of regulation 5(2) of the Remission of Charges Regulations, and at the time of the declaration such evidence is already available to the NHS pharmacist, and

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

(3) Sub-paragraph (2) applies to the provision of a drug or appliance in accordance with a SSP as it does to the provision of a drug or appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes, the prescription for product reimbursement purposes, as mentioned in paragraph 6(4)(a), is treated as being the prescription in accordance with which the drug or appliance is provided (even though the supply is not in pursuance of that prescription).

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

**9.—(1)** Where an NHS pharmacist is presented with a prescription form or a repeatable prescription, the NHS pharmacist must 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<sup>(4)</sup> and the following provisions of this Part.

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

(3) Where the pharmacist referred to in sub-paragraph (2) is employed by an NHS pharmacist, the registered pharmacist must not be someone—

- (a) who is disqualified from inclusion in a relevant list, or
- (b) who is suspended from the General Pharmaceutical Council Register.

(4) If the order is for, or a product to be provided in accordance with a SSP is, an appliance of a type requiring measuring and fitting (for example a truss), the NHS pharmacist must make all necessary arrangements—

- (a) for measuring the person named on the prescription form or repeatable prescription for the appliance, and
- (b) for fitting the appliance.

(5) If the order is for, or a product to be provided in accordance with a SSP is, 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 must 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 Schedule 4 or 5 to the Misuse of Drugs Regulations 2001,

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(4) 1985 c. 72.

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and does not prescribe its quantity, strength or dosage, an NHS pharmacist may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care they consider to be appropriate and, subject to sub-paragraph (7), in such quantity as they consider to be appropriate for a course of treatment for a period not exceeding 5 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 NHS pharmacist 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 Schedule 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 an NHS 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 NHS pharmacist must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) In this paragraph, “special container” means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(10) Where a drug is ordered by a prescriber, or is to be provided in accordance with a SSP is, in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a marketing authorisation holder for the drug, the NHS pharmacist must provide the drug in an original pack (or in original packs) of that size which have been assembled by a manufacturer of the drug for such a marketing authorisation holder, unless—

- (a) it is not possible for the NHS pharmacist to obtain such a pack (or packs) with reasonable promptness in the normal course of business, or
- (b) it is not practicable for the NHS pharmacist to provide such a pack (or packs) in response to the order (for example because of patient needs or the method of administration of the drug).

(11) Except as provided in sub-paragraph (12), an NHS pharmacist must 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, an NHS pharmacist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is in 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 must apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(14) An NHS pharmacist must provide any drug which they are required to provide under paragraph 5, or provides under paragraph 6, in a suitable container.

(15) Where an NHS pharmacist provides a drug or appliance under paragraph 6, the NHS pharmacist must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.

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

**10.—(1)** An NHS pharmacist may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the NHS pharmacist reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because they reasonably believe the form has been stolen or forged),
- (b) it appears to the NHS pharmacist 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 NHS pharmacist's clinical judgement,
- (c) the NHS pharmacist 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) An NHS pharmacist must 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) An NHS pharmacist must refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
  - (i) the requested drug or appliance, or
  - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description, and
- (b) alternative provision has already taken place in accordance with the SSP.

(4) An NHS pharmacist may refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
  - (i) the requested drug or appliance, or
  - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description,
- (b) a registered pharmacist is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS pharmacist is unable to provide the drug or appliance within a reasonable timescale,

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but if the NHS pharmacist does refuse to do so, they must provide the patient or the person requesting the drug or appliance on behalf of the patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.

(5) An NHS pharmacist must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the NHS pharmacist has no record of that prescription,
- (b) the NHS pharmacist does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and such batch issue is not presented to them,
- (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 6 months previously,
- (f) the repeatable prescription was signed more than 1 year previously,
- (g) the expiry date on the repeatable prescription has passed, or
- (h) the NHS pharmacist has been informed by the repeatable prescriber that the prescription is no longer required.

(6) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that they make such a request), an NHS pharmacist must only provide the drugs and appliances so ordered if they are 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, or manner of utilisation of the appliance by, the patient in respect of whom the prescription was written has not 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**

**11.—**(1) In connection with the services provided under paragraph 4, an NHS pharmacist must—

- (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, or
  - (ii) returning unwanted drugs or appliances to the pharmacy for safe destruction,
- (c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need,

- (d) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
    - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
    - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question,
  - (e) 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,
  - (f) 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 paragraph (e),
  - (g) undertake appropriate training in respect of repeat prescribing, having regard to any recommendations in respect of such training set out in the Drug Tariff,
  - (h) if they take possession of a repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue,
  - (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) 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 10,
  - (k) ensure that where a person is refused drugs or appliances pursuant to paragraph 10(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice,
  - (l) 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,
  - (m) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 10(4),
  - (n) when providing appliances, provide a patient with a written note of the NHS pharmacist's name, address and telephone number, and
  - (o) when providing specified appliances, comply with the additional requirements set out in paragraph 12.
- (2) Where, on presentation of a prescription form or repeatable prescription in connection with dispensing services under paragraph 4, an NHS pharmacist is unable (having regard to any relevant SSP) to provide an appliance, or stoma appliance customisation is required and the NHS pharmacist is unable to provide that, the NHS pharmacist must—
- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor, or
  - (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

**Additional requirements in relation to specified appliances**

12.—(1) This paragraph sets out the additional requirements referred to in paragraph 11(1)(o) relating to the provision of specified appliances.

(2) An NHS pharmacist who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS pharmacist must offer to deliver the specified appliance to the patient's home,
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient,
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content, and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS pharmacist must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance, or
- (b) if the NHS pharmacist believes it is appropriate to do so, must—
  - (i) refer the patient to a prescriber, or
  - (ii) offer the patient an appliance use review service.

(4) If the NHS pharmacist is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the NHS pharmacist must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to the NHS pharmacist.

(5) Where an NHS pharmacist provides a telephone care line in respect of the dispensing of any specified appliance, the NHS pharmacist must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line, or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales<sup>(5)</sup>, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

“expert clinical advice” (*“cyngor clinigol arbenigol”*), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

“out of hours periods” (*“cyfnodau y tu allan i oriau”*), in relation to a pharmacy, means the periods outside the periods during which the NHS pharmacist—

- (a) is obliged to provide pharmaceutical services at the pharmacy by virtue of paragraph 22(1) or 26(1), or
- (b) does provide pharmaceutical services at the pharmacy in accordance with a notification under paragraph 22(2).

**Disposal service in respect of unwanted drugs**

13. An NHS pharmacist must, to the extent paragraph 14 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs provided to the NHS pharmacist for disposal.

(5) NHS Direct Wales telephone number 0845 46 47, website address [www.nhsdirect.wales.nhs.uk](http://www.nhsdirect.wales.nhs.uk).

### **Basic procedure in respect of unwanted drugs**

14.—(1) Subject to sub-paragraph (2), where a person presents to an NHS pharmacist or any of the NHS pharmacist's 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 NHS pharmacist must accept the drugs and dispose of them in accordance with sub-paragraph (3).

(2) An NHS pharmacist must not be required to accept any drugs for disposal unless the Local Health Board in whose pharmaceutical list the NHS pharmacist is included has made arrangements with the NHS pharmacist for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, the NHS pharmacist must—

- (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, and
- (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 must co-operate with any suitable arrangements that the Local Health Board has in place for regular collection of the drugs from the NHS pharmacist's premises by or on behalf of the Local Health Board.

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

15. In connection with the services provided under paragraph 13, an NHS pharmacist must—

- (a) ensure that they and any of their staff, 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 they and any of their staff 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**

16. An NHS pharmacist must, to the extent paragraphs 17 and 18 require, and in the manner set out in those paragraphs, promote public health messages to members of the public.

### **Prescription linked intervention**

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

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

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the NHS pharmacist must, 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) An NHS pharmacist must, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record must be in a form that facilitates—

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

### **Public health campaigns**

**18.** An NHS pharmacist must, at the request of the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, ensure that—

- (a) they, and any of their staff, participate, in the manner reasonably requested by the Local Health Board, in up to six campaigns in each calendar year to promote public health messages to users of the NHS pharmacist's pharmacy, and
- (b) where requested to do so by the Local Health Board, record the number of people that have been provided information as part of one of those campaigns.

### **Signposting**

**19.** An NHS pharmacist must, to the extent paragraph 20 requires and in the manner set out in that paragraph, provide information to users of the NHS pharmacist's pharmacy about other health and social care providers and support organisations.

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

**20.—(1)** Where it appears to an NHS pharmacist or their staff, having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the NHS pharmacist's pharmacy—

- (a) requires advice, treatment or support that the NHS pharmacist cannot provide, but
- (b) another provider, of which the NHS pharmacist 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 NHS pharmacist must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

(2) Where, on presentation of a prescription form or repeatable prescription, an NHS pharmacist is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the NHS pharmacist's normal course of business, the NHS pharmacist must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor, or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

(3) Where appropriate, a referral under this paragraph may be made by means of a written referral note.

(4) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any information given or referral made under this paragraph and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, 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**

**21.** An NHS pharmacist must, to the extent paragraph 22 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 support for self-care**

**22.**—(1) Where it appears to an NHS pharmacist or their staff, having regard to the need to minimise the inappropriate use of health and social care services, that a person using the NHS pharmacist's pharmacy would benefit from advice from the NHS pharmacist to help the person 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 NHS pharmacist must 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 NHS pharmacist must, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, 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**

**23.**—(1) An NHS pharmacist must ensure that pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services—

- (a) for not less than 40 hours each week, or
- (b) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist may provide pharmaceutical services at the premises for fewer than 40 hours per week, provided that the NHS pharmacist provides those services at set times and on set days, at the times and on the days so set, or
- (c) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist 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

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- (d) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist 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 the NHS pharmacist is required to provide pharmaceutical services by virtue of that direction, at the days on which and the times at which the NHS pharmacist 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 pharmaceutical services for a set period, where it has received 3 months' notice of the proposed suspension from the NHS pharmacist.

(2) An NHS pharmacist must notify the Local Health Board in whose pharmaceutical list the NHS pharmacist is included of other hours during which the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open by virtue of sub-paragraph (1) (and which are referred to in these Regulations as “supplementary opening hours”).

(3) At each of the premises from which an NHS pharmacist has undertaken to provide pharmaceutical services, the NHS pharmacist must 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 NHS pharmacists included in the pharmaceutical list and the times at which drugs and appliances may be obtained from those addresses.

(4) An NHS pharmacist must, on request, submit a return to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included setting out—

- (a) the times at which pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services (including the times at which the NHS pharmacist is providing pharmaceutical services when they are not obliged to do so by virtue of sub-paragraph (1)), and
- (b) the pharmaceutical services which the NHS pharmacist ordinarily provides at each of those premises.

(5) Where an NHS pharmacist changes—

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

the NHS pharmacist must supply the Local Health Board on whose pharmaceutical list the NHS pharmacist is included with a return informing it of the change.

(6) Where an NHS pharmacist has submitted a return under sub-paragraph (4) or (5) in respect of any premises, or where the NHS pharmacist 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) the NHS pharmacist must 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 the return or

application (unless the return or application has been superseded by a return, or a further return, under sub-paragraph (5)), and

- (b) the NHS pharmacist must 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 the NHS pharmacist is ordinarily to provide at those premises,

as set out in that return or application, for a period of at least 3 months after that return or application was received by the Local Health Board.

(7) Where an NHS pharmacist is prevented by illness or other reasonable cause from complying with their obligations under sub-paragraph (1), they must, where practicable, make arrangements with one or more other NHS pharmacists whose premises are situated in the neighbourhood for the provision of pharmaceutical services during that time.

(8) Where there is a temporary suspension in the provision of pharmaceutical services for a reason beyond the control of the NHS pharmacist, the NHS pharmacist will not be in breach of sub-paragraphs (1), (2) and (3) provided that—

- (a) the NHS pharmacist notifies the Local Health Board on whose pharmaceutical list the NHS pharmacist is included of that suspension as soon as practicable, and
- (b) the NHS pharmacist uses all reasonable endeavours to resume provision of pharmaceutical services as soon as practicable.

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

(10) For the purposes of calculating the number of hours that a pharmacy is open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it must 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.

(11) In this Part—

“additional hours” (“*oriau ychwanegol*”) for which an NHS pharmacist is to be required to provide pharmaceutical services are those hours during which the NHS pharmacist would not be providing pharmaceutical services, were the NHS pharmacist subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d);

“existing direction” (“*cyfarwyddyd presennol*”) means one that has been made in accordance with this Part or one that was in existence on the date that these Regulations come into force.

### **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 must 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 NHS pharmacist is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS pharmacist 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 NHS pharmacist is not providing pharmaceutical services.

(4) The Local Health Board may only direct that an NHS pharmacist must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that the NHS pharmacist will receive reasonable remuneration in respect of the additional hours for which they are required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as a consequence of regulation 42 in respect of those hours is “reasonable remuneration” for these purposes).

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

**25.—**(1) Where it appears to the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, 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 that pharmacy,

for pharmaceutical services, it may carry out an assessment as to whether to issue a direction requiring the NHS pharmacist 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, Easter Sunday and bank holidays).

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

- (a) give notice to the NHS pharmacist of any proposed changes to the times at which or the days on which the pharmacy is to be open, and
- (b) allow the NHS pharmacist 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 must—

- (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 NHS pharmacist 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 NHS pharmacist 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 23(1)(a), the pharmacy must 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 must set out in that direction—
  - (i) the total number of hours each week for which the NHS pharmacist must provide pharmaceutical services at the pharmacy, and

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

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 40 hours each week, it must 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 must 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 must notify the NHS pharmacist 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 NHS pharmacist is to provide pharmaceutical services at the pharmacy, it must include with the notification a statement in writing of—

- (a) the reasons for the change, and
- (b) the NHS pharmacist's right of appeal under sub-paragraph (7).

(7) An NHS pharmacist may, within 30 days of receiving notification under sub-paragraph (6) appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services.

(8) The Welsh Ministers 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 Welsh Ministers must notify the NHS pharmacist in writing of their determination and must 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 an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if they have not appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive notification under sub-paragraph (6), or
- (b) if they have appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive notification under sub-paragraph (9).

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

**26.**—(1) An NHS pharmacist may apply to a Local Health Board on whose pharmaceutical list the NHS pharmacist is included for it to change the days on which or the times at which the NHS pharmacist is obliged to provide pharmaceutical services at the NHS pharmacist's pharmacy in a way that—

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

(2) Where an NHS pharmacist makes an application under sub-paragraph (1), as part of that application the NHS pharmacist must 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

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in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The Local Health Board must 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 must—

- (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 NHS pharmacist must provide pharmaceutical services at the pharmacy provided that the existing direction would meet the requirements of sub-paragraphs (5) and (6), or
- (c) either—
  - (i) revoke (without replacing it) any existing direction in respect of the times at which or the days on which the NHS pharmacist 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 23(1)(a), the pharmacy must 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 must set out in that direction—
  - (i) the total number of hours each week for which the NHS pharmacist is required to provide pharmaceutical services at the pharmacy, and
  - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and the times at which the NHS pharmacist is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 40 hours each week, it must 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 must 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 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).

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

(8) A Local Health Board must notify the NHS pharmacist 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 must send the NHS pharmacist 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 NHS pharmacist's right of appeal under sub-paragraph (9).

(9) An NHS pharmacist may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Welsh Ministers 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 Welsh Ministers 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 Welsh Ministers must notify the NHS pharmacist in writing of their determination and must 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 an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if they have not appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive notification under sub-paragraph (8), or
- (b) if they have appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive notification under sub-paragraph (11).

### **Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services**

27.—(1) Notwithstanding the provisions of this Schedule, during an emergency requiring the flexible provision of pharmaceutical services, the Local Health Board in whose pharmaceutical list the NHS pharmacist is included may, on application from the NHS pharmacist, permit the NHS pharmacist a temporary change to the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS pharmacist gives at least 24 hours' notice of the change or closure, and
- (b) the reasons given by the NHS pharmacist for the request are, in the opinion of the Local Health Board, adequate reasons.

(2) The Local Health Board need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that the NHS pharmacist's reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to the NHS pharmacist.

## **PART 4**

### **Clinical governance and complaints**

#### **Clinical governance**

28.—(1) An NHS pharmacist must, in connection with all the pharmaceutical services that the NHS pharmacist provides, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in an acceptable system of clinical governance.

(2) A system of clinical governance is “acceptable” if it provides for—

- (a) compliance with the clinical governance components set out in sub-paragraph (3), and

- (b) submission of an annual self-assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.
- (3) The clinical governance components comprise of the following—
  - (a) a patient and public involvement programme, which includes—
    - (i) a requirement that the NHS pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of the NHS pharmacist’s pharmacy,
    - (ii) a requirement that the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy,
    - (iii) a requirement that where the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy (whether the NHS pharmacist is producing their own publicity material or advertising services in material published by another person), the NHS pharmacist does so in a manner which makes clear that those services are funded as part of the health service,
    - (iv) a requirement that the NHS pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS pharmacist intends to take,
    - (v) monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
    - (vi) an approved complaints system (which meets the requirements of this Part),
    - (vii) a requirement that the NHS pharmacist co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
    - (viii) a requirement that the NHS pharmacist co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
    - (ix) monitoring arrangements for compliance with the Equality Act 2010<sup>(6)</sup>,
  - (b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year,
  - (c) a risk management programme, which includes—
    - (i) arrangements for ensuring that all stock is 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, which comprises of—
      - (aa) a patient safety incident log, and
      - (bb) a near-miss log,
    - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and the National Health Service Commissioning Board,

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<sup>(6)</sup> 2010 c. 15.

- (v) 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,
  - (vi) appropriate waste disposal arrangements (in addition to those required under paragraphs 14 and 15) for clinical and confidential waste,
  - (vii) a clinical governance lead person for each pharmacy, appointed as such by the NHS pharmacist (or that is the NHS pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,
  - (viii) appropriate child protection procedures, and
  - (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974(7),
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS pharmacist—
- (i) in respect of the provision of drugs in accordance with a repeatable prescription,
  - (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
  - (iii) to people caring for themselves or their families,

and arrangements for ensuring that the NHS pharmacist, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 11(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question,

- (e) a staffing and staff management programme, which includes—
- (i) arrangements for appropriate induction training for staff, including any locum,
  - (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 pharmaceutical, or other NHS, services including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
  - (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
  - (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum, who, arising out of their employment with the NHS pharmacist—
    - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(8) (meaning of “protected disclosure”) have the rights afforded in respect of such disclosures by that Act, and
    - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe

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(7) 1974 c. 37.

(8) 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

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to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A of that Act, have the right not to be subjected to any detriment or to dismissal as a consequence of that act,

- (f) an information governance programme, which provides for—
  - (i) compliance with approved procedures for information management and security, and
  - (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment, and
- (g) a premises standards programme, which includes—
  - (i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare acquired infection is minimised, and
  - (ii) arrangements for there to be a clear separation between the areas of a pharmacy which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

### **Professional standards**

**29.** An NHS pharmacist must provide pharmaceutical services and exercise any professional judgments in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

### **Inducements**

**30.—(1)** An NHS pharmacist or their staff must 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 the person 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).

(3) In the case of the provision of appliances, neither an NHS pharmacist nor any person employed or engaged by that NHS pharmacist must accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 11(2)(b), 12(4) or 20(2)(b), or
- (b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 11(2)(a) or 20(2)(a) and providing no additional service in connection with the item on that prescription.

### **Duty to provide information about fitness to practice matters as they arise**

**31.—(1)** Subject to paragraph 32, an NHS pharmacist, and where the NHS pharmacist is part of a body corporate each of its directors, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS pharmacist or a director—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is bound over following a criminal conviction in the United Kingdom,
- (c) accepts a police caution in the United Kingdom,
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),

- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(9)</sup> (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992<sup>(10)</sup> (penalty as alternative to prosecution),
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them,
- (i) becomes the subject of any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) becomes subject to an investigation into their professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against them,
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list, or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness grounds,

and if so, the NHS pharmacist must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 32, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate,
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse,
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list, or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the

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<sup>(9)</sup> 1995 c. 46.

<sup>(10)</sup> 1992 c. 5.

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investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

### **Home Local Health Board of bodies corporate**

**32.** Where an NHS pharmacist is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 31 and 35(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 60). When the NHS pharmacist provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS pharmacist is included.

### **Complaints**

**33.** An NHS pharmacist must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011(**11**), for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

## **PART 5**

### **Other terms of service**

#### **Directed services**

**34.** An NHS pharmacist with whom a Local Health Board on whose pharmaceutical list the NHS pharmacist is included makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

#### **Information to be supplied**

**35.—(1)** An NHS pharmacist must give notice to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included 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 them in the pharmaceutical list which they have not otherwise notified in accordance with these Regulations,
- (b) in the case of an NHS pharmacist who is an individual, any change of private address, and
- (c) in the case of an NHS pharmacist that is a body corporate, any change to the address of its registered office.

(2) An NHS pharmacist must give the Local Health Board, if it so requests, the name of any pharmacist employed by them who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (6), an NHS pharmacist that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors and superintendent.

(4) Subject to sub-paragraph (6), if an NHS pharmacist that is a body corporate appoints a director or superintendent that was not listed on the NHS pharmacist's application for inclusion in a pharmaceutical list, the NHS pharmacist must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS pharmacist or the director or superintendent of an NHS pharmacist that is a body corporate must inform the Local Health Board—

- (a) if the NHS pharmacist, or a body corporate of which they are 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 the NHS pharmacist becomes a director or superintendent of a body corporate which is in any of another Local Health Board's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS pharmacist is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS pharmacist also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

- (a) in whose pharmaceutical list the NHS pharmacist is included, or
- (b) to whom the NHS pharmacist makes an application to be included in its pharmaceutical list,

that requests it.

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

- (a) a pharmaceutical list, or
- (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

### **Withdrawal from pharmaceutical lists**

**36.** Where an NHS pharmacist intends to withdraw from the pharmaceutical list, they must notify the Local Health Board of this at least 3 months in advance of that date, unless it is impracticable to do so in which case they must notify the Local Health Board as soon as it is practicable to do so.

### **Charges for drugs and refunds**

**37.—(1)** Subject to regulations made under section 121 of the 2006 Act (charges for drugs, medicines or appliances, or pharmaceutical services) all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where an NHS pharmacist 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 NHS pharmacist, the container and equipment remains the property of the NHS pharmacist.

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

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(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if it is duly made on Form WP57 0405 within 3 months of the date on which the charge was paid.

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

**38.**—(1) An NHS pharmacist must allow persons authorised in writing by the Local Health Board in whose pharmaceutical list the NHS pharmacist is included to enter and inspect the NHS pharmacist's pharmacy at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS pharmacist is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by the NHS pharmacist for patient care and treatment, and
  - (ii) the management by the NHS pharmacist of the pharmaceutical services they provide,

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 has been invited to be present at the inspection, where this is requested by the NHS pharmacist,
- (c) the person authorised in writing carries written evidence of their authorisation, which they produce on request, and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) An NHS pharmacist must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow the Local Health Board or person authorised by it access to any information which the Local Health Board or person 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.

### **Welsh language**

**39.**—(1) Where an NHS pharmacist provides pharmaceutical services through the medium of Welsh, the NHS pharmacist must notify the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in writing.

(2) An NHS pharmacist must make available a Welsh language version of any document or form for use by patients and/or members of the public, provided by the Local Health Board.

(3) Where an NHS pharmacist displays a new sign or notice in connection with pharmaceutical services, the text on the sign or notice must be in English and Welsh, and an NHS pharmacist may utilise the translation service offered by the Local Health Board for this purpose.

(4) An NHS pharmacist must encourage the wearing of a badge, provided by the Local Health Board, by those delivering pharmaceutical services who are Welsh speaking, to convey that they are able to speak Welsh.

(5) An NHS pharmacist must encourage those delivering pharmaceutical services to utilise information and/or attend training courses and events provided by the Local Health Board, so that they can develop—

- (a) an awareness of the Welsh language (including awareness of its history and its role in Welsh culture), and

- (b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.
- (6) An NHS pharmacist must encourage those delivering pharmaceutical services to establish and record the Welsh or English language preference expressed by or on behalf of a patient.