SCHEDULE 4 Regulation 11(1)(a)(i)

Terms of service of NHS pharmacists

PART 1

General

Responsibilities of NHS pharmacists and pharmacy staff

1.—(1) To the extent that this Schedule imposes a requirement on an NHS pharmacist in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) if the NHS pharmacist is a registered pharmacist—

(i) that NHS pharmacist must comply with that requirement, or

(ii) if the NHS pharmacist employs or engages natural persons in connection with the provision of pharmaceutical services, the NHS pharmacist must either comply with that requirement or secure compliance with that requirement by—

(aa) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or

(bb) in other cases, by the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services; or

(b) if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—

(i) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or

(ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.

(2) Where in this Schedule reference is made to an NHS pharmacist—

(a) being the subject of any activity, and it is an activity to which a natural person could only, or would normally, be subject; or

(b) forming a view,

that reference is to be construed as a referring, as appropriate, to the NHS pharmacist (if a natural person) or to the NHS pharmacist's staff.

(3) References in this Schedule to an NHS pharmacist are to be construed in accordance with sub-paragraphs (1) and (2).

Breaches by directors and superintendents

2. Where this Schedule imposes a requirement on the director or superintendent of a body corporate that is on a pharmaceutical list, a breach of that requirement is to be deemed to be a breach by the body corporate of its terms of service.

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. 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 prescriptions for drugs or appliances ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of drugs and appliances

5.—(1) In this Part, "signed" includes signature with a prescriber's advanced electronic signature.

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

(a) any person presents to an NHS Pharmacist (P) a non-electronic prescription form which contains—

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

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**1**) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference "SLS", or

(iii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; or

(b) subject to sub-paragraph (4), P receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—

(i) any person requests the provision of drugs or appliances in accordance with that prescription, or

(ii) P has previously arranged with the patient that P will dispense that prescription on receipt,

P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.

(3) Subject to the following provisions of this Part, where—

(a) any person presents to P 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(**2**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**3**) (which

(**1**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.
(**2**) 1971 c.38; *see* section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.
(**3**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a 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 a prescriber and including the reference "SLS",

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

(iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference "SLS",

and also presents an associated batch issue; or

(b) P receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—

(i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or

(ii) P has previously arranged with the patient that P will dispense that repeatable prescription on receipt,

P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.

(4) P must not provide under an electronic prescription form 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.

(5) For the purposes of this paragraph, a non-electronic 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) P has that prescription in P's possession; and

(b) that person presents, or P has in P's possession, an associated batch issue.

Urgent supply without a prescription

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

(2) P 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 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and

(b) in the case of a request for a drug or an appliance, the prescriber undertakes to—

(i) give P 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) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

Preliminary matters before providing ordered drugs or appliances

7.—(1) If a person specified in sub-paragraph (2) asks an NHS pharmacist (P) to do so—

(a) P must give an estimate of the time when the drugs or appliances will be ready; and

(b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are ready).

(2) A person specified in this sub-paragraph is a person—

(a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or

(b) requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, P 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) or (1A) of the Charges Regulations(**4**) (supply of drugs and appliances by chemists) by virtue of either—

(a) entitlement to exemption under regulation 7(1) of the Charges Regulations(**5**) (exemptions); or

(b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations(**6**) (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration P already has such evidence available to P.

(4) If, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (3), is produced to P, P shall endorse the form on which the declaration is made to that effect.

(5) In the case of an electronic prescription, P must transmit to the Electronic Prescription Service—

(a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—

(i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and

(ii) whether or not satisfactory evidence was produced to P as required by sub-paragraph (3);

(b) in any case where a charge is due, confirmation that the relevant charge was paid; and

(c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

(**4**) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.
(**5**) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.
(**6**) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

Providing ordered drugs or appliances

8.—(1) Where an NHS pharmacist (P) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, P must only provide the drugs or appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 5(2) or (3); and

(b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(**7**) 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 registered pharmacist.

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

(a) who is disqualified from inclusion in a relevant list; or

(b) who is suspended from the GPhC register.

(4) If the order is for an appliance of a type requiring measuring and fitting (for example a truss), P must make all necessary arrangements for a registered pharmacist—

(a) to measure the person named on the prescription form or repeatable prescription for the appliance; and

(b) to fit 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 must comply with any relevant 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(**8**) (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

and does not prescribe its quantity, strength or dosage, P (in this context, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care P considers to be appropriate and, subject to sub-paragraph (7), in such quantity as P considers 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,

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(**7**) 1985 c.72.

(**8**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

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, P 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 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by P 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 special container,

P 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) Subject to sub-paragraph (11), where a drug is ordered by a prescriber on a prescription form or a repeatable prescription 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, P must provide the drug in an original pack (or in original packs) of that size which has been assembled by a manufacturer of the drug for such a marketing authorisation holder, unless—

(a) it is not possible for P to obtain such a pack (or packs) with reasonable promptness in the normal course of business; or

(b) it is not practicable for P 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) In the case of oral liquid methadone, P (in practice, a registered pharmacist) must decide whether it would be most appropriate to provide—

(a) each dose in a separate container;

(b) an original pack (or original packs); or

(c) the oral liquid methadone in some other way,

and P must then provide it in packaging that accords with that decision.

(12) P must only provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription if—

(a) it is ordered as specified in sub-paragraph (13); or

(b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**9**) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

(13) A Scheduled drug that is a drug with an appropriate non-proprietary name may be provided in response to an order on a prescription form or repeatable prescription for a drug ("the prescribed drug") that is not a Scheduled drug but which has the same non-proprietary name as the Scheduled drug if—

(a) the prescribed drug is ordered by that non-proprietary name or by its formula;

(**9**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

(b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically); and

(c) the Scheduled drug is not in a pack which consists of a drug in more than one strength, and providing it would involve the supply of part only of the pack.

(14) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (13) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(15) P must provide any drug which P is required to provide under paragraph 5 in a suitable container.

Refusal to provide drugs or appliances ordered

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

(a) P reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because P reasonably believes it has been stolen or forged);

(b) it appears to P that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, 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 P's (in practice, a registered pharmacist's) clinical judgement;

(c) P or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person;

(d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence; or

(e) the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—

(i) the remuneration of persons providing pharmaceutical services, and

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless P (or the person who employs or engages P) is to receive no pharmaceutical remuneration of any kind in respect of the drug or appliance.

(2) P 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) P must refuse to provide drugs or appliances ordered on a repeatable prescription where—

(a) P has no record of that prescription (other than on the first occasion on which the prescription is presented);

(b) P does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to P;

(c) it is not signed by a 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 (whether electronically or otherwise) more than 6 months previously;

(f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) P has been informed by the 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 the patient makes such a request), P must only provide the drugs or appliances ordered if P is satisfied—

(a) that the patient to whom the prescription relates—

(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 to whom the prescription relates 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 to whom the prescription relates 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.—(1) In connection with the services provided under paragraph 4, an NHS pharmacist (P) 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 patients 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 premises 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 it is expected that the drug or appliance will become available;

(f) keep and maintain records—

(i) of drugs and appliances provided, in order to facilitate the continued care of the patient;

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and

(iii) of notes provided under sub-paragraph (e);

(g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;

(h) if P takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;

(i) if P provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;

(j) 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);

(k) 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;

(l) 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;

(m) 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;

(n) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4);

(o) when providing appliances, provide a patient with a written note of P's name, address and telephone number; and

(p) 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 the dispensing services under paragraph 4, P is unable to provide an appliance, or stoma appliance customisation is required and P is unable to provide that, P shall—

(a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 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 P.

Additional requirements in relation to electronic prescribing

11.—(1) An NHS pharmacist (P) must, if requested to do so by any person—

(a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through P's pharmacy premises; and

(b) where the Electronic Prescription Service is not available through P's pharmacy premises, provide that person with contact details of at least 2 NHS pharmacists in the area at whose premises the service is available, if these details are known to P.

(2) Where the Electronic Prescription Service is available through P's pharmacy premises, P must, if requested to do so by any person, enter in that person's PDS patient details—

(a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; or

(b) where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person.

(3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(4) Regulation 116(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

(5) If P is a nominated dispensing contractor for a person (X) but the nomination was made before P became the person listed in a pharmaceutical list in relation to the pharmacy premises nominated in X's PDS patient details, P must within 6 months of P becoming the person so listed—

(a) explain to X that the ownership of the pharmacy premises has changed; and

(b) ask X whether X wishes to maintain the nomination in respect of those pharmacy premises.

Additional requirements in relation to specified appliances

12.—(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(p) relating to the provision of specified appliances.

(2) An NHS pharmacist (P) 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) P 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), P 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 P 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 P is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), P must give the patient the contact details of at least 2 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 P.

(5) Where P provides a telephone care line in respect of the dispensing of any specified appliance, P 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 National Health Service Trust(**10**), or the website address of NHS Direct National Health Service Trust on line, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

"expert clinical advice", 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", in relation to pharmacy premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

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 presented to the NHS pharmacist for disposal.

Basic procedure in respect of unwanted drugs

14.—(1) Subject to paragraph (2), where a person presents to an NHS pharmacist (P) any drugs provided for a patient in, and which have been kept in—

(a) a private household; or

(b) a children's home; or

(c) a residential care home, that is to say an establishment which exists wholly or mainly for the provision of residential accommodation, together with board and personal care, for persons in need of personal care because of—

(i) old age,

(ii) mental or physical disability,

(iii) past or present dependence on alcohol or drugs,

(iv) any past illnesses, or

(v) past or present mental disorder,

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

(2) P is not required to accept any drugs for disposal unless the NHSCB has made arrangements for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, P must—

(a) where required to do so by the NHSCB or by a waste disposal contractor retained by the NHSCB, separate solid drugs or ampoules, liquids and aerosols from each other;

(b) store the drugs in containers provided by the NHSCB, or by a waste disposal contractor retained by the NHSCB, 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),

(**10**) Established by S.I. 2007/478.

and shall co-operate with any suitable arrangements that the NHSCB has in place for regular collection of the drugs from P's pharmacy premises by or on behalf of the NHSCB.

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 (P) must—

(a) ensure that P (including P's staff) is 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 P (including P's staff) has 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 non-electronic prescription form or non-electronic repeatable prescription to an NHS pharmacist (P) or requests the provision of drugs or appliances in accordance with an electronic prescription; and

(b) it appears to P that the person—

(i) has diabetes,

(ii) is at risk of coronary heart disease, especially those with high blood pressure, or

(iii) smokes or is overweight,

P 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) P 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 P; and

(b) follow-up care for the person who has been given the advice.

Public health campaigns

18. An NHS pharmacist (P) must, at the request of the NHSCB, ensure that—

(a) P (including P's staff) participates, in the manner reasonably requested by the NHSCB, in up to 6 campaigns in each calendar year to promote public health messages to users of P's pharmacy;

(b) where requested to do so by the NHSCB, P records the number of people to whom P (including P's staff) has 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 (P), having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using P's pharmacy—

(a) requires advice, treatment or support that P cannot provide; but

(b) another provider, of which P is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

P 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, P is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within P's normal course of business, P must—

(a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 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 P.

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

(4) P 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 P; 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 (P), having regard to the need to minimise the inappropriate use of health and social care services, that a person (X) using P's pharmacy would benefit from advice from P to help X manage a medical condition (including, in the case of a carer, to help X in assisting in the management of another person's medical condition), P must provide advice to X 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) P must, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1), and of any drugs supplied when the advice was given, and that record shall be in a form that facilitates—

(a) auditing of the provision of pharmaceutical services by P; and

(b) follow-up care for the person to whom or in respect of whom the advice has been given.

PART 3

Hours of opening

Pharmacy opening hours: general

23.—(1) An NHS pharmacist (P) must ensure that pharmaceutical services are provided at P's pharmacy premises—

(a) for 40 hours each week;

(b) for not less than 100 hours each week, in the case of premises in respect of which a 100 hours condition applies;

(c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 40 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;

(d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for more than 40 hours per week, and at set times and on set days, at the times and on the days so set; or

(e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 40 hours each week, but only on set times and on set days as regards the additional opening hours—

(i) for the total number of hours each week required by virtue of that direction, and

(ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction,

but the NHSCB may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension.

(2) The hours during which pharmacy premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as "core opening hours".

(3) P must notify the NHSCB of other hours during which P's pharmacy premises are to be open, which are hours in addition to P's core opening hours (and which are referred to in these Regulations as "supplementary opening hours").

(4) Unless P is a distance selling chemist, at P's pharmacy premises P must exhibit—

(a) a notice specifying the days on which and times at which the premises are open for the provision of drugs and appliances (including times at which P is providing pharmaceutical services during supplementary opening hours); and

(b) at times when the premises are not open, a notice based on information provided by the NHSCB, where practicable legible from outside the premises, specifying—

(i) the addresses of other NHS pharmacists and the days on which and times at which drugs and appliances may be obtained from those addresses, and

(ii) the addresses of LPS chemists in the area, the type of local pharmaceutical services which those LPS chemists provide, and the days on which and times at which their premises are open.

(5) P must, on request, submit a return to the NHSCB setting out—

(a) the days on which and times at which pharmaceutical services are provided at P's pharmacy premises (including times at which P is providing pharmaceutical services during supplementary opening hours); and

(b) the pharmaceutical services which P ordinarily provides at those premises.

(6) Where P changes—

(a) the supplementary opening hours of P's pharmacy premises; or

(b) the pharmaceutical services which P ordinarily provides at those premises,

P must supply the NHSCB with a return informing it of the change.

(7) Where P has notified to the NHSCB (or, before the appointed day, a Primary Care Trust) the days on which and times at which pharmaceutical services are to be provided at P's pharmacy premises (for example, in a return under sub-paragraph (5) or (6) or in an application for inclusion in a pharmaceutical list)—

(a) P must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the times set out in the notification (unless the notification has been superseded by a return, or a further return, under sub-paragraph (6)); and

(b) P must not change—

(i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours which are neither additional opening hours nor in total less than 40 (if those core opening hours are additional opening hours, or are in total less than 40, regulation 65(5) to (7) and paragraphs 25 and 26 apply),

(ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 25 and 26 apply to changes to the total number of core opening hours),

(iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or

(iv) the pharmaceutical services which P is ordinarily to provide at those premises,

for a period of at least 3 months after that notification was received by the NHSCB (or, before the appointed day, a Primary Care Trust), unless the NHSCB agrees otherwise.

(8) Subject to sub-paragraph (9), where P is prevented by illness or other reasonable cause from complying with P's obligations under sub-paragraph (1), P must, where practicable, make arrangements with one or more NHS pharmacists or LPS chemists whose premises are situated in the same area for the provision of pharmaceutical services or local pharmaceutical services during that time.

(9) P may only make an arrangement with an LPS chemist under sub-paragraph (8) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which P ordinarily provides.

(10) Where there is a temporary suspension in the provision of pharmaceutical services by P for a reason beyond the control of P, P is not in breach of sub-paragraphs (1) and (7), provided that—

(a) P notifies the NHSCB of that suspension as soon as practical; and

(b) P uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(11) Planned refurbishment of pharmacy premises is neither a "reasonable cause" for the purposes of sub-paragraph (8) nor a "reason beyond the control of P" for the purposes of sub-paragraph (10).

(12) For the purposes of calculating the number of hours that pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(13) For the purposes of this Part, "additional opening hours", where they are required, are hours during which P is required to provide pharmaceutical services pursuant to sub-paragraph (1)(e) which are in addition to the hours during which P would be required to provide pharmaceutical services, if P were subject instead to the condition set out in sub-paragraph (1)(a).

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

24.—(1) Where the NHSCB issues a direction setting any days or times for the opening hours of pharmacy premises under this Part, it must in doing so seek to ensure that the days and times at which pharmacy premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in its area or other likely users of the pharmacy premises.

(2) In considering the matters mentioned in sub-paragraph (1), the NHSCB—

(a) must treat any local pharmaceutical services being provided in its area as if they were pharmaceutical services being so provided; and

(b) may have regard to any pharmaceutical services that are being provided in its area during supplementary opening hours.

(3) The NHSCB may only direct that an NHS pharmacist (P) 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 its area is likely to be adequate to meet the need for such services at times when P is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65 or regulation 65 of the 2012 Regulations (core opening hours conditions), the NHSCB may only direct that P must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that P is to receive reasonable remuneration in respect of the additional opening hours for which P is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(6) in respect of those hours is "reasonable remuneration" for these purposes).

Determination of pharmacy premises core opening hours instigated by the NHSCB

25.—(1) Where it appears to the NHSCB, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee for the area in which the premises are situated, that the days on which or times at which pharmacy premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of—

(a) people in its area; or

(b) other likely users of the pharmacy premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS pharmacist (P) whose premises they are to

provide pharmaceutical services at the pharmacy premises 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 NHSCB must—

(a) give notice to P of any proposed changes to the days on which or times at which the pharmacy premises are to be open; and

(b) allow P 30 days within which to make written representations to the NHSCB about the proposed changes.

(3) When it determines the outcome of its assessment, the NHSCB must—

(a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);

(b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5); or

(c) either—

(i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or

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

in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

(4) Where the NHSCB issues a direction under sub-paragraph (3) in respect of pharmacy premises that are to be 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 P must provide pharmaceutical services at the pharmacy, and

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

but it must not set out in that direction the days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening 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 the pharmacy premises.

(5) The NHSCB must not issue a direction under sub-paragraph (3) that has the effect simply of requiring pharmacy premises 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 pharmacy premises to be open for either more or less than 40 hours each week).

(6) The NHSCB must notify P 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 P is to provide pharmaceutical services at pharmacy premises, it must include with the notification a statement of—

(a) the reasons for the change; and

(b) P's right of appeal under paragraph (7).

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

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under paragraph (3).

(9) The Secretary of State shall notify P of the determination and shall in every case include with the notification a statement of the reasons for the determination.

(10) If the days on which or times at which P is to provide pharmaceutical services at pharmacy premises have been changed in accordance with this paragraph, P must introduce the changes—

(a) if P has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (6); or

(b) if P has appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (9).

(11) This paragraph does not apply where regulation 65(5) to (7) applies.

Determination of pharmacy premises core opening hours instigated by the NHS pharmacist

26.—(1) An NHS pharmacist (P) may apply to the NHSCB for it to change the days on which or times at which P is obliged to provide pharmaceutical services at P's pharmacy premises in a way that—

(a) reduces the total number of hours for which P is obliged to provide pharmaceutical services at those premises each week (but not those required under any 100 hours condition); or

(b) keeps that total number of hours the same.

(2) Where P makes an application under sub-paragraph (1), as part of that application P must provide the NHSCB with such information as the NHSCB may reasonably request in respect of any changes to the needs of the people in its area, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The NHSCB must determine the application within 60 days of receiving it (including any information required of P in accordance with sub-paragraph (2)).

(4) When it determines the application, the NHSCB must—

(a) issue a direction (which replaces 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 in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) 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 P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), where this has the effect of granting the application under this paragraph or granting it only in part, or

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

in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

(5) Where the NHSCB issues a direction under sub-paragraph (4) in respect of pharmacy premises that are to be 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 P must provide pharmaceutical services at the pharmacy premises, and

(ii) as regards any additional opening hours, the days on which and the times at which P is required to provide those services during those hours,

but it must not set out in that direction days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening 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 the pharmacy premises.

(6) The NHSCB must not issue a direction under sub-paragraph (4) that has the effect simply of requiring pharmacy premises 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 pharmacy premises to be open for either more or less than 40 hours each week).

(7) Where the NHSCB is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee for the area in which the pharmacy premises are situated before determining the application.

(8) The NHSCB must notify P 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 P a statement setting out—

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

(b) P's right of appeal under sub-paragraph (9).

(9) P may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State 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 Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under sub-paragraph (4).

(11) The Secretary of State must notify the pharmacist of the determination and must include with the notification a statement of the reasons for the determination.

(12) If the days on which or times at which P is to provide pharmaceutical services at pharmacy premises have been changed in accordance with this paragraph, P must introduce the changes—

(a) if P has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (4); or

(b) if P has appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (11).

(13) This paragraph does not apply where regulation 65(5) to (7) applies.

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

27.—(1) Notwithstanding the provisions of this Part, during an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from an NHS pharmacist ("P"), permit P a temporary change to the days on which or times at which P is obliged to provide pharmaceutical services at pharmacy premises, or permit temporary closure of those premises, if—

(a) P gives at least 24 hours notice of the change or closure; and

(b) the reasons given by P for the request are, in the opinion of the NHSCB, adequate reasons.

(2) The NHSCB need not approve the request in advance of the change or closure, but if it does not do so and decides subsequently that P's reasons are not, in its opinion, adequate reasons, then the

days on which or times at which P 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 P.

PART 4

Other terms of service

Clinical governance

28.—(1) An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, 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 NHSCB and comprises the following components—

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

(i) a requirement that P produces in an approved manner, and makes available in an appropriate manner, a practice leaflet containing approved particulars in respect of P's pharmacy premises,

(ii) a requirement that the pharmacist publicises the essential services and any advanced services that are available at or from the pharmacist's pharmacy,

(iii) a requirement that where a pharmacist publicises the essential services or any directed services that are available at or from the pharmacist's pharmacy (whether the pharmacist is producing their own publicity material or advertising services in material published by another person), the pharmacist does so in a manner which makes clear that the services are funded as part of the health service,

(iv) a requirement that P undertakes an approved patient satisfaction survey annually, in an approved manner,

(v) P's monitoring arrangements for drugs or appliances owed to patients but which are out of stock,

(vi) a requirement that P co-operates appropriately with any reasonable inspection or review that the NHSCB or any relevant statutory authority wishes to undertake, and

(vii) P's monitoring arrangements in respect of P's compliance with the Equality Act 2010(**11**);

(b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one other audit agreed by the NHSCB in each financial year;

(c) a risk management programme, which includes—

(i) arrangements for ensuring that all stock is procured and 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,

(**11**) 2010 c. 15.

(iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State(**12**) and the NHSCB,

(v) appropriate standard operating procedures, including standard operating procedures in respect of dispensing drugs and appliances, 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 Part 2) for clinical and confidential waste,

(vii) a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or who is the 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 safeguarding procedures for service users,

(ix) P's monitoring arrangements in respect of P's compliance with the Health and Safety at Work etc. Act 1974(**13**);

(d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by P—

(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 P, 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 10(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 for staff (including 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 NHS services, including continuing professional development for registered pharmacists and registered pharmacy technicians, and any necessary accreditation in respect of the provision of directed services,

(v) arrangements for addressing poor performance (in conjunction with the NHSCB as appropriate), and

(vi) arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist—

(**12**) The Medicines and Healthcare Products Regulatory Agency, which is an executive agency of the Department of Health, issues safety advice, warnings, alerts and recalls in respect of medical devices on behalf of the Secretary of State, and also safety advice, warnings, alerts and recalls in respect of medicines on behalf of the Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly. The Department of Health also, separately, issues other communications concerning patient safety, on behalf of the Secretary of State.

(**13**) 1974 c. 37.

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(**14**) (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 the NHSCB which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, 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 NHSCB 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 health care acquired infection is minimised, and

(ii) arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive health care,

and for the purposes of this sub-paragraph, "approved" means approved by the NHSCB.

Professional Standards

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

Inducements etc.

30.—(1) An NHS pharmacist (P) (including P's 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 P's business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

(a) presenting an order for drugs or appliances on a prescription form or repeatable prescription, non-electronic prescription form or non-electronic repeatable prescription;

(b) nominating P as X's dispensing contractor (or one of them) in X's PDS patient details; or

(c) receiving from P any directed services.

(2) Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) Nothing in sub-paragraph (1) prohibits P from providing to a patient to whom P is providing any directed services any gift which—

(a) is supplied as part of the provision of any directed service to that patient;

(**14**) 1996 c. 18; section 43A was inserted by the Public Interest Disclosure Act 1998 (c. 23), section 1. *See also* section 43K(1)(c) (i) of the Employment Rights Act 1996 (inserted by the Public Interest Disclosure Act 1998, section 1, and amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17), Schedule 2, paragraph 63; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 177 and 178(b); and S.I. 2007/961).

(b) is directly related to that directed service;

(c) is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient's family of a healthy lifestyle; and

(d) in the case of a gift which—

(i) is not a medicine, has a monetary value not exceeding £10, or

(ii) is a medicine, is supplied as part of the provision of a minor ailments service.

(4) P (including P's staff) must not give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of P's business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—

(a) present to P an order for drugs or appliances on a prescription form or repeatable prescription;

(b) nominate P as their dispensing contractor (or one of them) in their entry in their PDS patient details; or

(c) ask P to provide them with any directed service.

(5) For the purpose of sub-paragraph (4), "relevant person" means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

(a) any NHS body or provider of primary medical services; and

(b) any person employed or engaged by any of the persons mentioned in paragraph (a).

(6) In the case of the provision of appliances, P (including P's staff) must not 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 10(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 10(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 matters as they arise

31.—(1) An NHS pharmacist (P) and, where P is a body corporate, every director and superintendent of P must, within 7 days of its occurrence, inform the NHSCB in writing if they—

(a) are convicted of any criminal offence in the United Kingdom;

(b) are bound over following a criminal conviction in the United Kingdom;

(c) accept a police caution in the United Kingdom;

(d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);

(e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(**15**) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(**16**) (penalty as alternative to prosecution);

(**15**) 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1); and the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), section 70(3).

(**16**) 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and amended by the Social Security Fraud Act 2001 (c. 11) ("the 2001 Act"), section 14. The amendments made by the 2001 Act are to be repealed by, and other amendments to section 115A are to be made by, the Welfare Reform Act 2012 (c. 5), sections 113 to 115, and Schedule 14, Part 1.

(f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

(g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;

(h) are 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) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;

(j) become the subject of any investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;

(k) become the subject of any investigation by the NHS BSA in relation to fraud;

(l) become the subject of any investigation by another primary care organisation which might lead to their removal from a relevant list; or

(m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and 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) If a person to whom paragraph (1) applies (X) is, or was at the time of the originating events, a director or superintendent of a body corporate, X must in addition inform the NHSCB within 7 days if any such body corporate—

(a) is convicted of any criminal offence in the United Kingdom;

(b) is convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

(c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;

(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 by the NHS BSA 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 primary care organisation which might lead to its removal from any relevant list; or

(h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

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

(3) P or X must consent to a request being made by the NHSCB 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.

Other information to be supplied

32.—(1) An NHS pharmacist (P) must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

(a) any occurrence requiring a change in the information recorded about P in the pharmaceutical list which P has not otherwise notified to the NHSCB in accordance with these Regulations;

(b) if P is an individual, any change to P's private address;

(c) if P is a body corporate, any change to the name, registration number, registered office or telephone number relating to that office of the body corporate; and

(d) any occurrence requiring P's addition to or removal from an EPS list or a change in the information recorded about P in that list.

(2) P must give the NHSCB, if it so requests, the name of any pharmacist employed or engaged by P who is responsible for dispensing a particular prescription.

(3) If P is a body corporate, it must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to—

(a) the names of its directors; and

(b) the name or address of its superintendent.

(4) If P is a body corporate and appoints a superintendent or director who was not listed on P's application for inclusion on a pharmaceutical list, P must, within 30 days of the person's appointment, supply to the NHSCB the information mentioned in paragraph 3 and 4 of Schedule 2 about that person.

(5) If P or a director or superintendent of P (if P is a body corporate) is on, or is a director or superintendent of a body corporate which is on, a relevant list other than a pharmaceutical list held by the NHSCB, they must supply in writing to the NHSCB—

(a) in the case of a director or superintendent of a body corporate, the name and registered office of the body corporate on the other relevant list; and

(b) particulars of the other relevant list.

(6) P or the director or superintendent of P (if P is a body corporate) must inform the NHSCB if they, or a body corporate of which they are a director or superintendent, apply to be included in a relevant list of another primary care organisation, and of the outcome of any such application.

Co-operation with Health Education England

33. An NHS pharmacist must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act(**17**) (duty as to education and training).

(**17**) Section 1F was inserted by the Health and Social Care Act 2012 (c. 7), section 7.

Complaints

34.—(1) An NHS pharmacist must have in place arrangements, which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(**18**), for the handling and consideration of any complaints.

(2) In this paragraph, "complaint" means a complaint about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

Inspections and access to information

35.—(1) An NHS pharmacist (P) must allow persons authorised in writing by the NHSCB to enter and inspect P's pharmacy premises at any reasonable time, for the purposes of—

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

(b) auditing, monitoring and analysing—

(i) the provision made by P, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and

(ii) the management by P of the pharmaceutical services P 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 premises are situated have been invited to be present at the inspection, where this is requested by P;

(c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and

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

(3) P must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

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

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

(**18**) S.I. 2009/309; amended by S.I. 2009/1768.