

2012 No. 1909

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service  
(Pharmaceutical Services)  
Regulations 2012

*Made* - - - -

*18th July 2012*

*Laid before Parliament* -

*23rd July 2012*

*Coming into force* - -

*1st September 2012*



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The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 8, 22, 126, 128A, 129, 130, 132, 148, 150A, 151(5) and (7), 154, 159(9), 160, 162,

163(3), 164, 172, 182 and 272(7) and (8) of the National Health Service Act 2006(a) and section 37(1) of the Health Act 2009(b).

## PART 1

### Introductory

#### Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services) Regulations 2012 and come into force on 1st September 2012.

#### Interpretation

2.—(1) Subject to paragraph (5), in these Regulations—

“100 hours condition” is to be construed in accordance with regulation 65(1);

“the 1968 Act” means the Medicines Act 1968(c);

“the 1992 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 1992(d), as in force on 31st March 2005;

“the 2005 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005(e), as in force immediately before the appointed day;

“the 2006 Act” means the National Health Service Act 2006;

“additional opening hours” is to be construed, as the context requires, in accordance with paragraph 23(13) of Schedule 4 or paragraph 13(12) of Schedule 5, or both;

“advanced electronic signature” means an electronic signature which is—

- (a) uniquely linked to the signatory;
- (b) capable of identifying the signatory;
- (c) created using means that the signatory can maintain under their sole control; and
- (d) linked to the date to which it relates in such a manner that any subsequent change of data is detectable;

“advanced services” means the directed services for which the Secretary of State determines the remuneration under section 164 of the 2006 Act(f) (remuneration for persons providing pharmaceutical services);

“APMS contractor” means a person or partnership that provides primary medical services under contractual arrangements with a Primary Care Trust under section 83(2)(b) of the 2006 Act (primary medical services);

“APMS practice” means an APMS contractor that has a patient list;

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(a) 2006 c.41. Section 128A was inserted by the Health Act 2009 (c.21), section 25; section 129 has been amended by the Health Act 2009, sections 26 and 27 and Schedule 6, the Health and Social Care Act 2012 (c. 7), section 207(8), and by S.I. 2010/231; section 130 has been amended by the Health and Social Care Act 2012, section 207(10), and by S.I. 2010/22; section 132 has been amended by S.I. 2007/289 and 2010/22 and 231; section 148 has been amended by S.I. 2010/22; section 150A was inserted by the Health Act 2009, section 28; section 154 has been amended by S.I. 2010/22; and section 164 has been amended (although the amendments are not yet fully in force) by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4. By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England. *See also* section 275(1) of the 2006 Act, which contains definitions of “prescribed” and “regulations” that are relevant to the powers being exercised.

(b) 2009 c. 21.

(c) 1968 c. 67.

(d) 1992/662; revoked by S.I. 2005/641.

(e) 2005/641; revoked by Schedule 7 to these Regulations.

(f) The amendments made to section 164 by the Health and Social Care Act 2008 (c. 14), section 141, and Schedule 15, Part 4, are not yet fully in force.

“appliance” means an appliance included in a list approved by the Secretary of State for the purposes of section 126 of the 2006 Act<sup>(a)</sup> (arrangements for pharmaceutical services);

“appliance contractor premises” means listed chemist premises (or in the context of an applicant seeking the listing of premises, proposed listed chemist premises) of an NHS appliance contractor;

“appliance use review service” means arrangements made in accordance with directions under section 127 of the 2006 Act (arrangements for additional pharmaceutical services) for a pharmacist or a specialist nurse to review a person’s use of a specified appliance;

“appointed day” means 1st September 2012;

“armed forces of the Crown” means the forces that are “regular forces” or “reserve forces” within the meanings given in section 374 of the Armed Forces Act 2006<sup>(b)</sup> (definitions applying for the purposes of whole Act).

“bank holiday” means any day that is by virtue of section 1 of or Schedule 1 to the Banking and Financial Dealings Act 1971<sup>(c)</sup> (which relate to bank holidays) a bank holiday in England;

“batch issue” means a form, provided by a Primary Care Trust and in the format required by the NHS BSA, which—

- (a) is issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable an NHS chemist or dispensing doctor to receive payment for the provision of repeat dispensing services;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is generated by a computer and not signed by a repeatable prescriber;
- (d) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and
- (e) has included on it a number denoting its place in the sequence referred to in subparagraph (d);

“best estimate”, in the context of the location of proposed appliance contractor premises or pharmacy premises mentioned in a routine application, is to be construed in accordance with paragraph 1(10) of Schedule 2;

“breach notice” is to be construed in accordance with regulation 71(1);

“change of ownership application” means an application pursuant to regulation 26;

“Charges Regulations” means the National Health Service (Charges for Drugs and Appliances) Regulations 2000<sup>(d)</sup>;

“child” means a person who has not attained the age of 16 years;

“controlled locality” means an area that is a controlled locality by virtue of regulation 36(1) or is determined to be so in accordance with regulation 36(2);

“core opening hours” is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 4 or paragraph 13(2) of Schedule 5, or both;

“directed services” means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act;

“dispensing contractor”, except in the context of Schedule 7, means an NHS chemist or a dispensing doctor whom or which a patient wishes to dispense their electronic prescriptions;

“dispensing doctor” is to be construed in accordance with regulation 46(1);

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(a) See section 126(9) of that Act, which provides a definition of “listed” that includes the power for the Secretary of State to approve lists for the purposes of section 126.  
(b) 2006 c. 52.  
(c) 1971 c.80.  
(d) S.I. 2000/620.



“dispensing doctor list” is to be construed in accordance with regulation 46(1);

“distance selling premises” are listed chemist premises, or potential pharmacy premises, at which essential services are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises;

“drugs” includes medicines;

“Drug Tariff” is to be construed in accordance with regulation 89(1);

“electronic communication” has the meaning given in section 15(1) of the Electronic Communications Act 2000(a) (general interpretation);

“electronic prescription” means an electronic prescription form or an electronic repeatable prescription;

“electronic prescription form” means data created in an electronic form for the purpose of ordering a drug or appliance, which—

- (a) is signed with a prescriber’s advanced electronic signature;
- (b) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and
- (c) does not indicate that the drug or appliance ordered may be provided more than once;

“electronic repeatable prescription” means data created in an electronic form, which—

- (a) is signed with a repeatable prescriber’s advanced electronic signature;
- (b) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service;
- (c) indicates that the drugs or appliances ordered may be provided more than once; and
- (d) specifies the number of occasions on which they may be provided;

“emergency requiring the flexible provision of pharmaceutical services” has the meaning given in regulation 29(4);

“employment” includes unpaid employment and employment under a contract for services, and “employed”, “employer” and “employs” are to be construed accordingly;

“enhanced services” means the directed services that are not advanced services;

“essential services”, except in the context of the definition of “distance selling premises”, is to be construed in accordance with paragraph 3 of Schedule 4;

“EPS list” is to be construed in accordance with regulation 10(4)(a);

“Electronic Prescription Service” means the service of that name which is operated under the auspices of the Informatics Division of the Department of Health;

“excepted application” means an application to which section 129(2A) and (2B) of the 2006 Act(b) (regulations as to pharmaceutical services) do not apply by virtue of any provision of Part 4;

“general practitioner” means a medical practitioner who is on a medical performers list;

“GMS contract” means a general medical services contract;

“GMS practice” means a party (which may be a partnership) to a GMS contract other than a Primary Care Trust;

“GMS Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004(c), but in the context of Schedule 7 means those Regulations as in force immediately before the appointed day;

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(a) 2000 c.7. The definition of “electronic communication” has been amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

(b) Inserted by the Health Act 2009 (c. 21), section 26(3).

(c) S.I. 2004/291.

“GPhC register” means the register maintained under article 19 of the Pharmacy Order 2010(a) (establishment, maintenance of and access to the register);

“Health Board”, except in the context of “Local Health Board”, means a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978(b) (Health Boards);

“health care professional” means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(c) (which relates to the Council for Healthcare Regulatory Excellence);

“home Primary Care Trust”, in relation to any body corporate with a registered office in England, means the Primary Care Trust in whose area that office is situated;

“independent nurse prescriber” means a person—

- (a) who is registered in the Nursing and Midwifery Register; and
- (b) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

“Independent Prescribing Service” means a directed service commissioned as an Independent Prescribing Service by a Primary Care Trust;

“licensing body” means any body anywhere in the world that licenses or regulates any profession;

“listed chemist premises” is to be construed in accordance with regulation 10(3)(a);

“listed dispensing premises” is to be construed in accordance with regulation 46(2)(a);

“Local Health Board” means a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006(d) (Local Health Boards);

“LPS chemist” means a party to an LPS scheme other than the commissioning body;

“LPS scheme” includes a pilot scheme within the meaning given in section 134(2) of the 2006 Act(e) (pilot schemes);

“LPS Regulations” means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(f);

“medical performers list” means a list of medical practitioners prepared and published under regulation 3(1) of the National Health Service (Performers Lists) Regulations 2004(g) (performers lists);

“medical practice premises” means—

- (a) in relation to a provider of primary medical services, premises which are identified in the provider’s arrangements with a Primary Care Trust as the practice premises from which primary medical services are to be provided during core hours to patients on the provider’s patient list; or
- (b) in relation to a person on a dispensing doctor list who is not a provider of primary medical services—

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(a) S.I. 2010/231.

(b) 1978 c. 29. Section 2 has been amended by: the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990 (c.19), section 28, Schedule 9, paragraph 19(1), and Schedule 10; the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(2); the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(2); and the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5), section 2(1).

(c) Section 25 has been amended by: the Health and Social Care Act 2008 (c. 14), section 113, Schedule 10, paragraph 17, and Schedule 15, Part 2; and by S.I. 2010/231.

(d) 2006 c. 42.

(e) Section 134(2) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraph 8.

(f) S.I. 2006/552.

(g) S.I. 2004/585; regulation 3 has been amended by S.I. 2008/1187.

- (i) in the case of a general practitioner who performs services on behalf of a provider of primary medical services, the practice premises from which primary medical services are to be provided during core hours to patients on the provider’s patient list, or
- (ii) in the case of a general practitioner who performs services on behalf of a PCTMS practice, the practice premises that the Primary Care Trust has nominated as the practice premises for that practice;

“member”, in relation to a provider of primary medical services, means—

- (a) a partner in the partnership that is the provider; or
  - (b) a shareholder in the company limited by shares that is the provider,
- but no other providers of primary medical services are to be treated as having members;

“national disqualification” includes, in addition to a national disqualification as mentioned in section 159 of the 2006 Act **(a)** (national disqualification)—

- (a) a national disqualification as mentioned in section 115 of the National Health Service (Wales) Act 2006 (national disqualification);
- (b) any decision in Scotland or Northern Ireland corresponding to a national disqualification as mentioned in section 159 to the 2006 Act; and
- (c) any other decision that was a national disqualification for the purposes of the 2005 Regulations;

“National Health Service Commissioning Board” means, until the end of 30th September 2012, the NHS Commissioning Board Authority established by the NHS Commissioning Board Authority (Establishment and Constitution) Order 2011 **(b)**;

“NHS appliance contractor” means a person included in a pharmaceutical list of the type referred to in regulation 10(2)(b);

“NHS BSA” means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005 **(c)**;

“NHS Care Record” means the component of the EPS which is accessed for the purposes of nominating an NHS chemist or dispensing doctor to dispense electronic prescriptions;

“NHS chemist” means an NHS appliance contractor or an NHS pharmacist;

“NHS pharmacist” means a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a);

“NHS services” means services provided as part of the health service;

“nominated dispensing contractor” means an NHS chemist or dispensing doctor who has been nominated in the NHS Care Record to dispense the electronic prescriptions of a particular patient;

“non-electronic prescription form” means a form for ordering a drug or appliance which is—

- (a) provided by a Health Board, the Regional Health and Social Care Board, a Local Health Board, a Primary Care Trust, an NHS Trust or an NHS Foundation Trust for use by a prescriber;
- (b) issued by a prescriber; and
- (c) does not indicate that the drug or appliance ordered may be provided more than once;

“non-proprietary name” means a name which is, or which is a permitted variation of—

- (a) an International Nonproprietary Name (INN);
- (b) an International Nonproprietary Name Modified (INN.M);
- (c) a British Approved Name (BAN);

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**(a)** Section 159 has been amended by S.I. 2010/22.  
**(b)** S.I. 2011/2237.  
**(c)** S.I. 2005/2414.

- (d) a British Approved Name Modified (BANM); or
- (e) an approved name,

and for this purpose these names (and their permitted variations) have the same meanings as in a list of names which has been prepared and caused to be published by the British Pharmacopoeia Commission<sup>(a)</sup> and which has not been superseded;

“notice” or “notification”, except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and “notify” is to be construed accordingly;

“notice of commencement” means a notice given, or to be given, under paragraph 34(2) of Schedule 2;

“notifiable application” is to be construed in accordance with paragraph 18 of Schedule 2;

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001<sup>(b)</sup> (establishment and maintenance of register);

“optometrist independent prescriber” means an optometrist against whose name in the register of optometrists maintained under section 7 of the Opticians Act 1989<sup>(c)</sup> (which relates to the register of optometrists and the register of dispensing opticians) is recorded an annotation signifying that the optometrist is qualified to order drugs and appliances as an optometrist independent prescriber;

“other primary care organisation” or “another primary care organisation” means—

- (a) as regards Wales—
  - (i) a Local Health Board, or
  - (ii) in relation to any time prior to 1st April 2003 a Health Authority;
- (b) as regards Scotland, a Health Board; and
- (c) as regards Northern Ireland—
  - (i) the Regional Health and Social Care Board, or
  - (ii) in relation to any time prior to 1st April 2010, a Health and Social Services Board;

“outline consent”, in the context of—

- (a) an application for outline consent, is to be construed in accordance with regulation 51(1)(a); or
- (b) a subsisting outline consent, means outline consent—
  - (i) granted under these Regulations, or
  - (ii) which was outline consent for the purposes of the 2005 Regulations;

“outstanding pharmacy application” has the meaning given in regulation 53(8);

“partner PCT” has the meaning given in section 116(9) of the Local Government and Public Involvement in Health Act 2007<sup>(d)</sup> (health and social care: joint strategic needs assessments);

“patient list” means a list of patients that is a registered patient list for the purposes of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004<sup>(e)</sup>;

“PCTMS practice” means a medical practice established by a Primary Care Trust in order to provide primary medical services under section 83(2)(a) of the 2006 Act;

“pharmaceutical needs assessment” is to be construed in accordance with regulation 3(1);

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(a) The British Pharmacopoeia Commission was originally established by S.I. 1970/1256 and is at 151 Buckingham Palace Road, London SW1 9SZ.  
(b) S.I. 2002/253; amended by S.I. 2009/1182.  
(c) 1989 c.44; amended by S.I. 2005/848.  
(d) 2007 c.28.  
(e) S.I. 2004/906. See regulation 2(2) of those Regulations.

“pharmaceutical needs assessment map” means the map which a Primary Care Trust includes in its pharmaceutical needs assessment pursuant to paragraph 7 of Schedule 1;

“pharmacist independent prescriber” means a registered pharmacist (P)—

- (a) against whose name in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(a) (which relate to the registers and the registrar) is recorded an annotation signifying that P is qualified to order drugs and appliances as a pharmacist independent prescriber; and
- (b) who—
  - (i) is an NHS pharmacist with whom, or is employed or engaged by an NHS pharmacist with which, a Primary Care Trust has made an arrangement for the provision of an Independent Prescribing Service,
  - (ii) is (where it is possible to be) or who is employed or engaged by, an APMS contractor, a GMS contractor, an LPS chemist or a PMS contractor, and in the course of being so P provides services under arrangements that have been made with a Primary Care Trust that are equivalent to those provided under an Independent Prescribing Service, or
  - (iii) is employed or engaged by a Primary Care Trust, an NHS trust or NHS foundation trust to perform NHS services and is prescribing in that capacity;

“pharmacy premises” means listed chemist premises (or in the context of an applicant seeking the listing of premises, proposed listed chemist premises) of an NHS pharmacist;

“pharmacy procedures” are the procedures required by section 72A(3) of the 1968 Act(b) (the responsible pharmacist);

“PMS contractor” means—

- (a) a person with whom arrangements have been made under section 92 of the 2006 Act (which relates to arrangements for the provision of primary medical services), unless that person is in a partnership and the other members of the partnership have also made parallel arrangements under that section;
- (b) a partnership, the members of which have made arrangements in parallel under section 92 of the 2006 Act;

“PMS practice” means a PMS contractor that has, or each of whose members (in the case of a partnership) has, a patient list;

“the PMS Regulations” means National Health Service (Personal Medical Services Agreements) Regulations 2004(c), but in the context of Schedule 7 means those Regulations as in force immediately before the appointed day;

“practice amalgamation” is to be construed in accordance with regulation 59(1);

“premises approval”, in the context of—

- (a) an application for premises approval, is to be construed in accordance with regulation 51(1)(b); or
- (b) a subsisting premises approval, means premises approval—
  - (i) granted under these Regulations, or
  - (ii) which was a premises approval for the purposes of the 2005 Regulations;

“prescriber”, unless the context otherwise requires, means a medical practitioner, a dental practitioner, a pharmacist independent prescriber, a supplementary prescriber, an independent nurse prescriber or an optometrist independent prescriber;

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(a) S.I. 1976/1213 (N.I. 22).

(b) Section 72A was inserted by the Health Act 2006 (c. 28), section 30, and has been amended by S.I. 2006/2407.

(c) S.I. 2004/627.

“prescription form”, except in the context of the expression “electronic prescription form” or “non-electronic prescription form”, means an electronic prescription form or a non-electronic prescription form;

“Prescription of Drugs Regulations” means the National Health Service (General Medical Services) (Prescription of Drugs etc.) Regulations 2004(a);

“product with an appropriate non-proprietary name” means a product with a non-proprietary name which is not mentioned in—

- (a) Schedule 1 to the Prescription of Drugs Regulations (drugs and other substances not to be ordered under a general medical services contract); or
- (b) except where the conditions set out in paragraph 42(2)(a) and (b) of Schedule 6 to the GMS Regulations(b) (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations(c) (drugs, medicines and other substances that may be ordered only in certain circumstances);

“protected characteristic” means a characteristic listed in section 149(7) of the Equality Act 2010(d) (public sector equality duty), and references to people sharing a protected characteristic are to be understood by referral to the provisions of Chapter 1 of Part 2 of that Act (protected characteristics);

“provider of primary medical services” means a GMS practice, a PMS practice or an APMS practice, and “provides” in the context of primary medical services, is to be construed accordingly;

“provisional date” is to be construed in accordance with regulation 53(9)(b);

“Regional Health and Social Care Board” means the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009(e) (Regional Health and Social Care Board);

“registered pharmacist” means a person who is registered in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

“relevant list” means—

- (a) a pharmaceutical list or an equivalent list maintained by another primary care organisation; or
- (b) a list maintained by a Primary Care Trust or another primary care organisation of approved performers or providers of primary medical, dental or ophthalmic services;

“registered pharmacy technician” means a person registered as a pharmacy technician in Part 2 or 5 of the GPhC register;

“relevant local authority”, in relation to a Primary Care Trust, means a local authority whose area falls wholly or partly in the area of the Primary Care Trust;

“relevant local involvement network” means a person who in pursuance of arrangements made by a relevant local authority under section 221(1) of the Local Government and Public Involvement in Health Act 2007 (health services and social services: local involvement networks) is to carry on activities specified in section 221(2) of that Act;

“relevant NHS services” means pharmaceutical services, local pharmaceutical services and primary medical services;

“remedial notice” is to be construed in accordance with regulation 70(1);

“Remission of Charges Regulations” means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003(f);

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(a) S.I. 2004/629.

(b) Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.

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

(d) 2010 c. 15.

(e) 2009 c. 1 (N.I.).

(f) S.I. 2003/2382.



“repeatable prescriber” means—

- (a) a pharmacist independent prescriber who is issuing or creating repeatable prescriptions as part of an arrangement with a Primary Care Trust for the provision of an Independent Prescribing Service;
- (b) a pharmacist independent prescriber who—
  - (i) is, or who is employed or engaged by, an LPS chemist, and
  - (ii) is issuing repeatable prescriptions as part of an arrangement with a Primary Care Trust under which services are provided that are equivalent to those provided under an Independent Prescribing Service; or
- (c) a prescriber—
  - (i) who is (where it is possible for them to be so), or who is employed or engaged by, a provider of primary medical services or a PMS practice, and
  - (ii) who is issuing repeatable prescriptions under arrangements for the provision of repeatable prescribing services that are part of the practice’s or the provider’s GMS contract, section 92 arrangements or arrangements under section 83(2) of the 2006 Act;

“repeatable prescription” means—

- (a) a form for ordering drugs or appliances which is—
  - (i) provided by a Health Board, the Regional Health and Social Care Board, a Local Health Board, a Primary Care Trust, an NHS Trust or an NHS Foundation Trust for use by a prescriber,
  - (ii) issued by a prescriber,
  - (iii) indicates that the drugs or appliances ordered may be provided more than once, and
  - (iv) specifies the number of occasions on which they may be provided; or
- (b) an electronic repeatable prescription;

“reserved location” means, except in the context of making a determination that an area is a reserved location under these Regulations, an area determined as such under—

- (a) regulation 41(2) or 42(1); or
- (b) regulation 35 of the 2005 Regulations(a) (pharmaceutical services in reserved locations);

“restricted availability appliance” means an appliance which is approved for particular categories of person or particular purposes only;

“routine application” is to be construed in accordance with regulation 12;

“the SCAT Regulations” means the National Health Service (Service Committees and Tribunal) Regulations 1992(b), as in force immediately before the appointed day;

“Scheduled drug” means a drug specified in Schedule 1 or 2 to the Prescription of Drugs Regulations(c) (which relate to drugs, medicines and other substances not to be ordered under a general medical services contract or that may be ordered only in certain circumstances);

“specified appliance” means—

- (a) any of the following appliances listed in Part IXA of the Drug Tariff—
  - (i) a catheter appliance (including a catheter accessory and maintenance solution),
  - (ii) a laryngectomy or tracheostomy appliance,
  - (iii) an anal irrigation system,
  - (iv) a vacuum pump or constrictor ring for erectile dysfunction, or
  - (v) a drainage wound pouch;

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(a) Prior to its repeal, regulation 35 was amended by S.I. 2005/1501.

(b) S.I. 1992/664. These Regulations, together with the amendments to them, are revoked by paragraph 1 of Schedule 8.

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

- (b) an incontinence appliance listed in Part IXB of the Drug Tariff; or
- (c) a stoma appliance listed in Part IXC of the Drug Tariff;

“stoma appliance customisation” means the customisation of a quantity of more than one stoma appliance, where—

- (a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;
- (b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and
- (c) that modification is based on the patient’s measurements or a record of those measurements and, if applicable, a template;

“superintendent” has the same meaning as in section 71 of the 1968 Act<sup>(a)</sup> (bodies corporate);

“staff” includes locums and other persons engaged on contracts for services who act as staff;

“supplementary opening hours” is to be construed, as the context requires, in accordance with paragraph 23(3) of Schedule 4 or paragraph 13(4)(a) of Schedule 5, or both;

“supplementary prescriber” means—

- (a) a registered pharmacist against whose name in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs and appliances as a supplementary prescriber;
- (b) a person—
  - (i) who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001<sup>(b)</sup> (establishment and maintenance of register) which relates to chiropodists and podiatrists, physiotherapists or radiographers, and
  - (ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs and appliances as a supplementary prescriber; or
- (c) an optometrist against whose name in the register of optometrists maintained under section 7 of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs and appliances as a supplementary prescriber.

(2) In these Regulations, “pharmaceutical services”, in the context of—

- (a) Part 2 and Schedule 1, means the pharmaceutical services to which a pharmaceutical needs assessment must relate by virtue of regulation 3(2); or
- (b) arrangements made or to be made for the provision of pharmaceutical services by a medical practitioner, means the dispensing of drugs and appliances but not pharmaceutical services as mentioned in section 132(7)(a) or (b) of the 2006 Act (persons authorised to provide pharmaceutical services),

but otherwise has the meaning given in section 126(8) of the 2006 Act (arrangements for pharmaceutical services).

(3) Where reference is made in these Regulations to proceedings (but not investigations) reaching their final outcome—

- (a) in relation to any proceedings where there are rights of appeal under these Regulations either to the Secretary of State or the First-tier Tribunal, means the outcome of the proceedings—
  - (i) once the period for bringing an appeal has expired without an appeal being brought, or
  - (ii) if an appeal is brought in accordance with those rights, once the Secretary of State or the First-tier Tribunal has determined the appeal,

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(a) Section 71 was substituted by the Health Act 2006 (c. 28), section 28, and has been subsequently amended by S.I. 2007/3101 and 2010/231.

(b) S.I. 2002/254; article 5 has been amended by S.I. 2009/1182. This Order was so renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).



whether or not the matter is thereafter appealed through the courts; or

- (b) in relation to any other proceedings where there are rights of appeal (but not including appeals through the courts against decisions referred to in sub-paragraph (a)(ii)), means the outcome of the proceedings—
- (i) once the period for bringing an appeal has expired without an appeal being brought, or
  - (ii) if an appeal is brought in accordance with those rights, once those rights have been exhausted.

(4) Where reference is made in these Regulations to a decision of a Primary Care Trust and that decision is changed on appeal (whether by the Secretary of State, the First-Tier Tribunal or a court), unless the context otherwise requires, the reference to that decision is to be construed as a reference to the decision as changed on appeal.

(5) Where a word or expression used in Schedule 7 has a different meaning in the 2005 Regulations from that given in paragraphs (1) to (3), that word or expression bears the meaning that it bears in the 2005 Regulations, or is given in paragraphs (1) to (3), as the context requires.

## PART 2

### Pharmaceutical needs assessments

#### **Pharmaceutical needs assessments**

3.—(1) The statement of the needs for pharmaceutical services which each Primary Care Trust is required to publish by virtue of section 128A of the 2006 Act<sup>(a)</sup> (pharmaceutical needs assessments), whether it is the statement of its first assessment or of any revised assessment, is referred to in these Regulations as a “pharmaceutical needs assessment”.

(2) The pharmaceutical services to which each pharmaceutical needs assessment must relate are all the pharmaceutical services that may be provided under arrangements made by a Primary Care Trust for—

- (a) the provision of pharmaceutical services (including directed services) by a person on a pharmaceutical list;
- (b) the provision of local pharmaceutical services under an LPS scheme (but not LP services which are not local pharmaceutical services); or
- (c) the dispensing of drugs and appliances by a person on a dispensing doctors list (but not other NHS services that may be provided under arrangements made by a Primary Care Trust with a dispensing doctor).

#### **Information to be contained in pharmaceutical needs assessments**

4.—(1) Each pharmaceutical needs assessment must contain the information set out in Schedule 1.

(2) Each Primary Care Trust must, in so far as is practicable, keep up to date the map which it includes in its pharmaceutical needs assessment pursuant to paragraph 7 of Schedule 1 (without needing to republish the whole of the assessment or publish a supplementary statement).

#### **Date by which the first pharmaceutical needs assessment is to be published**

5. Each Primary Care Trust established—

- (a) on or after the appointed day; or

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(a) Inserted by the Health Act 2009 (c. 21), section 25.

(b) on a day that is less than 10 months before the appointed day, must publish its first pharmaceutical needs assessment within 10 months of the date on which its PCT order comes into force (if it has not already done so).

### **Subsequent assessments**

**6.**—(1) After it has published its first pharmaceutical needs assessment, each Primary Care Trust must publish a statement of its revised assessment—

- (a) within 10 months of the coming into force of any order under section 18 of the 2006 Act (Primary Care Trusts) varying its area that—
  - (i) comes into force on or after the appointed day, or
  - (ii) came into force on a day that is less than 10 months before the appointed day (if it has not already done so); or
- (b) within 3 years of its previous publication of a pharmaceutical needs assessment (whether under these Regulations or the 2005 Regulations).

(2) A Primary Care Trust must make a revised assessment as soon as is reasonably practicable after identifying changes since the publication of its pharmaceutical needs assessment which are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services), unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

(3) Pending the publication of a statement of a revised assessment, a Primary Care Trust may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its pharmaceutical needs assessment (and any such supplementary statement becomes part of that assessment), where—

- (a) the changes are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the 2006 Act; and
- (b) the Primary Care Trust—
  - (i) is satisfied that making a revised assessment would be a disproportionate response to those changes, or
  - (ii) is in the course of making a revised assessment and is satisfied that immediate modification of its pharmaceutical needs assessment is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area.

### **Temporary extension of pharmaceutical needs assessments**

**7.** As regards any locality, if—

- (a) the Primary Care Trust for that locality—
  - (i) has changed as a result of the coming into force of a PCT order (whether that Order establishes a new Primary Care Trust or varies the area of a Primary Care Trust), and
  - (ii) has not published a pharmaceutical needs assessment that relates to that locality; and
- (b) a pharmaceutical needs assessment which relates to that locality was published by a Primary Care Trust that was the Primary Care Trust for that locality before the coming into force of that PCT order,

pending the publication of a pharmaceutical needs assessment that relates to that locality by its (new) Primary Care Trust, the pharmaceutical needs assessment that relates to that locality is the pharmaceutical needs assessment mentioned in paragraph (b) (read with any supplementary statement relating to that assessment published under regulation 6(3)).

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<sup>(a)</sup> Section 129(2) has been amended by the Health Act 2009 (c. 21), section 26(2).

## Consultation on pharmaceutical needs assessments

8.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Primary Care Trust (PCT1) must consult the following about the contents of the assessment it is making—

- (a) any Local Pharmaceutical Committee for its area (including a Local Pharmaceutical Committee for its area and that of one or more other Primary Care Trusts);
- (b) any Local Medical Committee for its area (including a Local Medical Committee for its area and that of one or more other Primary Care Trusts);
- (c) the persons on its pharmaceutical lists and its dispensing doctors list (if it has one);
- (d) any LPS chemist with whom PCT1 has made arrangements for the provision of any local pharmaceutical services;
- (e) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT1 has an interest in the provision of pharmaceutical services in its area;
- (f) any local authority with which PCT1 is or has been a partner PCT;
- (g) any NHS trust or NHS foundation trust in its area; and
- (h) any neighbouring Primary Care Trust.

(2) The persons mentioned in paragraph (1) must together be consulted at least once during the process of making the assessment on a draft of the proposed pharmaceutical needs assessment.

(3) Where a Primary Care Trust is consulted on a draft under paragraph (2), if there is a Local Pharmaceutical Committee or Local Medical Committee for its area that is different to the Local Pharmaceutical Committee or Local Medical Committee consulted under paragraph (1)(a) or (b), the Primary Care Trust—

- (a) must consult that Committee before making its response to the consultation; and
- (b) must have regard to any representations received from the Committee when making its response to the consultation.

(4) The persons consulted on the draft under paragraph (2) must be given a minimum period of 60 days for making their response to the consultation, beginning with the day by which all those persons have been served with the draft.

(5) For the purposes of paragraph (4), a person is to be treated as served with a draft if that person is notified by PCT1 of the address of a website on which the draft is available and is to remain available (except due to accident or unforeseen circumstances) throughout the period for making responses to the consultation.

(6) If a person consulted on a draft under paragraph (2)—

- (a) is treated as served with the draft by virtue of paragraph (5); or
- (b) has been served with copy of the draft in an electronic form,

but requests a copy of the draft in hard copy form, PCT1 must as soon as is practicable and in any event within 14 days supply a hard copy of the draft to that person (free of charge).

## Matters for consideration when making assessments

9.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Primary Care Trust must have regard, in so far as it is practicable to do so, to the following matters—

- (a) any assessment or further assessment of relevant needs prepared under section 116 of the Local Government and Public Involvement in Health Act 2007<sup>(a)</sup> (health and social care: joint strategic needs assessments)—

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(a) 2007 c.28.

- (i) in the preparation of which the Primary Care Trust—
    - (aa) was a partner PCT, or
    - (bb) was not a partner PCT but the assessment nevertheless related to its area, and
  - (ii) which has not been superseded by a further assessment under that section;
  - (b) the outcome, in relation to the making of the assessment, of its compliance with its duties under Chapter 1 of Part 11 of the Equality Act 2010<sup>(a)</sup> (public sector equality duty);
  - (c) the demography of its area;
  - (d) the benefits from having a reasonable choice with regard to obtaining pharmaceutical services;
  - (e) any different needs of different localities within its area;
  - (f) the pharmaceutical services provided under arrangements with any neighbouring Primary Care Trust which affect—
    - (i) the need for pharmaceutical services in its area, or
    - (ii) whether further provision of pharmaceutical services in its area would secure improvements to or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
  - (g) any other NHS services provided in or outside its area (which are not covered by subparagraph (f)) which affect—
    - (i) the need for pharmaceutical services in its area, or
    - (ii) whether further provision of pharmaceutical services in its area would secure improvements to or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.
- (2) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Primary Care Trust must take account of likely future needs—
- (a) to the extent necessary to make a proper assessment of the matters mentioned in paragraphs 2 and 4 of Schedule 1; and
  - (b) having regard to likely changes to—
    - (i) the number of people in its area who require pharmaceutical services,
    - (ii) the demography of its area with regard to the people who share a protected characteristic, and
    - (iii) the risks to the health or well-being of people in its area, including particular risks to the health or well-being of people in its area who share a protected characteristic.

## PART 3

General matters relating to pharmaceutical lists and applications in respect of them

### Pharmaceutical lists and EPS lists

**10.**—(1) Each Primary Care Trust must prepare, maintain and publish 2 lists of persons, other than medical practitioners or dental practitioners, who undertake to provide pharmaceutical services from premises in the area of the Primary Care Trust.

(2) Those lists (which are pharmaceutical lists) are—

- (a) a list of persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs; and

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

- (b) a list of persons who undertake to provide pharmaceutical services only by way of the provision of appliances.
- (3) Each pharmaceutical list must be available for public inspection and must include—
- (a) the address of the premises in the area of the Primary Care Trust at which the listed person has undertaken to provide pharmaceutical services (“the listed chemist premises”);
  - (b) the days on which and times at which, at those premises, the listed person is to provide those services during the core opening hours and any supplementary opening hours of the premises.
- (4) Subject to paragraph (5), each Primary Care Trust must—
- (a) prepare, maintain, publish and make available for public inspection a list (to be called an “EPS list”) of all the NHS chemists in its area who participate in the Electronic Prescription Service; and
  - (b) include on its EPS list the address of any premises at which the Electronic Prescription Service is provided.
- (5) A Primary Care Trust need not prepare, maintain, publish and make available for public inspection an EPS list if it is clear from its pharmaceutical lists which NHS chemists in its area participate in the Electronic Prescription Service and where in its area the Electronic Prescription Service is provided.
- (6) Schedule 2, which has effect, contains provisions with regard to—
- (a) the information to be supplied by a person—
    - (i) seeking inclusion in a pharmaceutical list who is not already included in it, or
    - (ii) who is included in a pharmaceutical list and who is seeking—
      - (aa) to open, within the area of the Primary Care Trust whose list it is, additional premises from which to provide the same or different pharmaceutical services,
      - (bb) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services, or
      - (cc) to provide, from the person’s listed chemist premises, services that are in addition to those already listed in relation to that person; and
  - (b) the procedure to be followed by persons as mentioned in sub-paragraph (a) when making a routine application or an excepted application; and
  - (c) other related matters.
- (7) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under Parts 2 to 5 and Schedule 2 (as it does in relation to appeals against decisions under Parts 7, 8, 10 and 12).

**Terms of service of NHS chemists: general**

11.—(1) The arrangements under which an NHS pharmacist undertakes to provide pharmaceutical services (and so their terms of service) are to include any provisions affecting their rights and obligations—

- (a) that are included in these Regulations, including—
  - (i) the terms of service set out in Schedule 4 (which accordingly has effect), and
  - (ii) any obligation that is only applicable in prescribed cases, if the NHS pharmacist is a person to whom the obligation is applicable;
- (b) that are included in the Drug Tariff, in so far as those rights and obligations relate to NHS pharmacists and are applicable in the case of the NHS pharmacist;
- (c) where a Primary Care Trust makes an arrangement with the NHS pharmacist for the provision of any directed services, that are included in that arrangement; and

(d) that are included in regulation 3 of the Local Involvement Networks (Duty of Services-Providers to Allow Entry) Regulations 2008(a) (duty of services-providers to allow entry by local involvement networks), in so far as it applies to NHS pharmacists, as varied, where applicable, in accordance with regulation 35 or Chapter 6 of Part 7 of the 2006 Act.

(2) The arrangements under which an NHS appliance contractor undertakes to provide pharmaceutical services (and so their terms of service) are to include any provisions affecting their rights and obligations—

- (a) that are included in these Regulations, including—
  - (i) the terms of service set out in Schedule 5 (which accordingly has effect), and
  - (ii) any obligation that is only applicable in prescribed cases, if the NHS appliance contractor is a person to whom the obligation is applicable;
- (b) that are included in the Drug Tariff, in so far as those rights and obligations relate to NHS appliance contractors and are applicable in the case of the NHS appliance contractor;
- (c) where a Primary Care Trust makes an arrangement with the NHS appliance contractor for the provision of any directed services, that are included in that arrangement; and
- (d) that are included in regulation 3 of the Local Involvement Networks (Duty of Services-Providers to Allow Entry) Regulations 2008, in so far as it applies to NHS appliance contractors,

as varied, where applicable, in accordance with regulation 35 or Chapter 6 of Part 7 of the 2006 Act.

#### **Routine applications for inclusion in or amendment to a pharmaceutical list**

**12.** In these Regulations, a “routine application” is any application, other than an excepted application, by a person—

- (a) for inclusion in a pharmaceutical list who is not already included in it; or
- (b) who is included in a pharmaceutical list and who is seeking—
  - (i) to open, within the area of the Primary Care Trust whose list it is, additional premises from which to provide the same or different pharmaceutical services;
  - (ii) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services;
  - (iii) to provide, from the person’s listed chemist premises, services that are in addition to those already listed in relation to that person.

#### **Current needs: additional matters to which the Primary Care Trust must have regard**

**13.—(1)** If a Primary Care Trust receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would meet a current need—

- (a) for pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
- (b) that has been included in its pharmaceutical needs assessment in accordance with paragraph 2(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act(b) (regulations as to pharmaceutical services), the Primary Care Trust must have regard to the matters set out in paragraph (2).

(2) Those matters are—

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(a) S.I. 2008/915.

(b) Section 129(2A) was inserted by the Health Act 2009 (c. 21), section 26(3).



- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to meet the current need mentioned in paragraph (1) that the applicant is offering to meet;
  - (b) whether it is satisfied that another application offering to meet the current need mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
  - (c) whether it is satisfied that an appeal relating to another application offering to meet the current need mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
  - (d) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the needs for pharmaceutical services in the area of the Primary Care Trust that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;
  - (e) whether it is satisfied that—
    - (i) granting the application would only meet the current need mentioned in paragraph (1) in part, and
    - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
  - (f) whether—
    - (i) it is satisfied that granting the application would only meet the current need mentioned in paragraph (1) in part, but
    - (ii) it considers that, if the application were granted, it would not be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
  - (g) whether it is satisfied that—
    - (i) the current need mentioned in paragraph (1) was for services other than essential services, and
    - (ii) granting the application would result in an increase in the availability of essential services in the area of the Primary Care Trust;
  - (h) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, the current need mentioned in paragraph (1) has been met by another person who is providing, or is due to be met by another person who has undertaken to provide, either in its area or in the area of another Primary Care Trust—
    - (i) pharmaceutical services from listed chemist premises, or
    - (ii) local pharmaceutical services from LPS premises;
  - (i) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.
- (3) For the purposes of paragraph (2)(h), a need is to be treated as due to be met if—
- (a) the person (P) undertaking to meet that need is entitled to give the Primary Care Trust a notice of commencement, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet given that notice; or
  - (b) P has entered into an LPS scheme with the Primary Care Trust, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet commenced the provision of those services.

**Current needs: consequences of additional matters**

- 14.—(1) If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(a), it may—
- (a) defer determination of the application;

- (b) invite applications from other persons to offer to meet the current need mentioned in regulation 13(1) that the applicant is offering to meet; and
- (c) consider, at the same time as the applicant's application, any application it receives—
  - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
  - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to meet the current need mentioned in regulation 13(1) that the applicant is offering to meet,

but it must not defer consideration of the application for longer than 6 months.

(2) If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(b), it may defer consideration of the application until it can be considered at the same time as the other application.

(3) If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(c), it may defer consideration of the application until after the appeal has reached its final outcome.

(4) If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(d) or (e), it must refuse the application.

(5) If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(f) to (h), it must only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in its area.

**Future needs: additional matters to which the Primary Care Trust must have regard**

**15.**—(1) If a Primary Care Trust receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would meet a future need—

- (a) for pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
- (b) that has been included in its pharmaceutical needs assessment in accordance with paragraph 2(b) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services), the Primary Care Trust must have regard to the matters set out in paragraph (2).

(2) Those matters are—

- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to meet the future need mentioned in paragraph (1) that the applicant is offering to meet;
- (b) whether it is satisfied that it would be desirable to defer consideration of the application until some or all of the future circumstances specified in accordance with paragraph 2(b) of Schedule 1 have arisen (should they arise);
- (c) whether it is satisfied that another application offering to meet the future need mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (d) whether it is satisfied that an appeal relating to another application offering to meet the future need mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before determining the applicant's application;
- (e) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the needs, or future needs, for pharmaceutical services in the area of the Primary Care Trust that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;

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<sup>(a)</sup> Section 129(2A) was inserted by the Health Act 2009 (c. 21), section 26(3).



- (f) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the needs, or future needs, for pharmaceutical services in the area of the Primary Care Trust that are such that—
    - (i) the future circumstances specified in accordance with paragraph 2(b) of Schedule 1 will not, or are now unlikely to, arise (in whole or in part), and
    - (ii) granting the application would not secure improvements to, or better access to, pharmaceutical services in the area of the Primary Care Trust;
  - (g) whether it is satisfied that—
    - (i) granting the application would only meet the future need mentioned in paragraph (1) in part, and
    - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
  - (h) whether —
    - (i) it is satisfied that granting the application would only meet the future need mentioned in paragraph (1) in part, but
    - (ii) it considers that, if the application were granted, it would not be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
  - (i) whether it is satisfied that—
    - (i) the future need mentioned in paragraph (1) was for services other than essential services, and
    - (ii) granting the application would result in an increase in the availability of essential services in the area of the Primary Care Trust;
  - (j) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, the future need mentioned in paragraph (1) has been met by another person who is providing, or is due to be met by another person who has undertaken to provide, either in its area or in the area of another Primary Care Trust—
    - (i) pharmaceutical services from listed chemist premises, or
    - (ii) local pharmaceutical services from LPS premises;
  - (k) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.
- (3) For the purposes of paragraph (2)(j), a future need is to be treated as due to be met if—
- (a) the person (P) undertaking to meet that need is entitled to give the Primary Care Trust a notice of commencement, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet given that notice;
  - (b) the grant of P's application to meet that need is subject to a condition imposed by virtue of paragraph 33(2) of Schedule 2; or
  - (c) P has entered into an LPS scheme with the Primary Care Trust, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet commenced the provision of those services.

**Future needs: consequences of additional matters**

- 16.—(1) If the Primary Care Trust is satisfied as mentioned in regulation 15(2)(a), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to meet the future need mentioned in regulation 15(1) that the applicant is offering to meet; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or

- (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to meet the future need mentioned in regulation 15(1) that the applicant is offering to meet,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(2) If the Primary Care Trust is satisfied as mentioned in regulation 15(2)(b), it may defer consideration of the application for such period as is reasonable in the circumstances, having regard to when the future circumstances specified in accordance with paragraph 2(b) of Schedule 1 are likely to arise.

(3) If the Primary Care Trust is satisfied as mentioned in regulation 15(2)(c), it may defer consideration of the application until it can be considered at the same time as the other application.

(4) If the Primary Care Trust is satisfied as mentioned in regulation 15(2)(d), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the Primary Care Trust is satisfied as mentioned in regulation 15(2)(e) to (g), it must refuse the application.

(6) If the Primary Care Trust is satisfied as mentioned in regulation 15(2)(h) to (j), it must only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in its area.

**Improvements or better access in the pharmaceutical needs assessment: additional matters to which the Primary Care Trust must have regard**

17.—(1) If a Primary Care Trust receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would secure improvements, or better access—

- (a) to pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
- (b) that have or has been included in its pharmaceutical needs assessment in accordance with paragraph 4(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2B) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services), the Primary Care Trust must have regard to the matters set out in paragraph (2).

(2) Those matters are—

- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;
- (b) whether it is satisfied that another application offering to secure the improvements or better access mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (c) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
- (d) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the Primary Care Trust that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;

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<sup>(a)</sup> Section 129(2B) was inserted by the Health Act 2009 (c. 21), section 26(3).

- (e) whether it is satisfied that—
  - (i) granting the application would only secure the improvements or better access mentioned in paragraph (1) in part, and
  - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of those improvements or that better access would be secured;
- (f) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, the improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in its area or in the area of another Primary Care Trust—
  - (i) pharmaceutical services from listed chemist premises, or
  - (ii) local pharmaceutical services from LPS premises;
- (g) whether it is satisfied that—
  - (i) the improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and
  - (ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the Primary Care Trust;
- (h) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.

(3) For the purposes of paragraph (2)(f), the improvements or better access is to be treated as due to be secured by another person who has undertaken to provide services if—

- (a) the person (P) undertaking to secure the improvements or better access is entitled to give the Primary Care Trust a notice of commencement, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet given that notice;
- (b) P has entered into an LPS scheme with the Primary Care Trust, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet commenced the provision of those services.

**Unforeseen benefits applications: additional matters to which the Primary Care Trust must have regard**

**18.—(1)** If a Primary Care Trust receives a routine application and is required to determine whether the Primary Care Trust is satisfied that granting it, or granting it in respect of some only of the services specified in it, would secure improvements, or better access—

- (a) to pharmaceutical services, or pharmaceutical services of a specified type, in its area; but
- (b) the improvements or better access that would be secured were or was not included in its pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2B) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services), the Primary Care Trust must have regard to the matters set out in paragraph (2).

(2) Those matters are—

- (a) whether it is satisfied that granting the application would cause significant detriment to—
  - (i) proper planning in respect of the provision of pharmaceutical services in its area, or
  - (ii) the arrangements it has in place for the provision of pharmaceutical services in its area;

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<sup>(a)</sup> Section 129(2B) was inserted by the Health Act 2009 (c. 21), section 26(3).

- (b) whether, notwithstanding that the improvements or better access were not included in its pharmaceutical needs assessment, it is satisfied that, having regard to the desirability of—
  - (i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the Primary Care Trust,
  - (ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the Primary Care Trust, are difficult for them to access, or
  - (iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services,
 granting the application would confer significant benefits on persons in its area which were not foreseen when it published its pharmaceutical needs assessment;
- (c) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access that the applicant is offering to secure;
- (d) whether it is satisfied that another application offering to secure the improvements or better access has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (e) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
- (f) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.

(3) The Primary Care Trust need only consider whether it is satisfied in accordance with paragraphs (2)(c) to (e) if it has reached at least a preliminary view (although this may change) that it is satisfied in accordance with paragraph (2)(b).

**Applications to which regulation 17 or 18 applies: consequences of additional matters**

- 19.—(1) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(a), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
    - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

- (2) If the Primary Care Trust is satisfied as mentioned in regulation 18(2)(c), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to secure the improvements or better access that the applicant is offering to secure; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
    - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access that the applicant is offering to secure,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(3) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(b) or 18(2)(d), it may defer consideration of the application until it can be considered at the same time as the other application.

(4) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(c) or 18(2)(e), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(d) to (g) or 18(2)(a), it must refuse the application.

(6) If the Primary Care Trust is satisfied as mentioned in regulation 18(2)(b), it may grant the application notwithstanding that the improvements or better access were or was not included in its pharmaceutical needs assessment.

**Future improvements or better access: additional matters to which the Primary Care Trust must have regard**

**20.**—(1) If a Primary Care Trust receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would secure improvements or better access in the future—

- (a) to pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
- (b) that have or has been included in its pharmaceutical needs assessment in accordance with paragraph 4(b) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2B) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services), the Primary Care Trust must have regard to the matters set out in paragraph (2).

(2) Those matters are—

- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the future improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;
- (b) whether it would be desirable to defer consideration of the application until some or all of the future circumstances specified in accordance with paragraph 4(b) of Schedule 1 have arisen (should they arise);
- (c) whether it is satisfied that another application offering to secure the future improvements or better access mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (d) whether it is satisfied that an appeal relating to another application offering to secure the future improvements or better access mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
- (e) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the Primary Care Trust that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;
- (f) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the profile or future profile of pharmaceutical services in the area of the Primary Care Trust that are such that the future circumstances specified in accordance with paragraph 4(b) of Schedule 1 will not, or are now unlikely to, arise (in whole or in part);
- (g) whether it is satisfied that—

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(a) Section 129(2B) was inserted by the Health Act 2009 (c. 21), section 26(3).

- (i) granting the application would only secure the future improvements or better access mentioned in paragraph (1) in part, and
  - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of those improvements or that better access would be secured;
- (h) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, the future improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in its area or in the area of another Primary Care Trust—
- (i) pharmaceutical services from listed chemist premises, or
  - (ii) local pharmaceutical services from LPS premises;
- (i) whether it is satisfied that—
- (i) the future improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and
  - (ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the Primary Care Trust;
- (j) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.
- (3) For the purposes of paragraph (2)(h), the improvements or better access is to be treated as due to be secured by another person who has undertaken to provide services if—
- (a) the person (P) undertaking to secure the improvements or better access is entitled to give the Primary Care Trust a notice of commencement, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet given that notice;
  - (b) the grant of P's application to secure the improvements or better access is subject to a condition imposed by virtue of paragraph 33(2) of Schedule 2; or
  - (c) P has entered into an LPS scheme with the Primary Care Trust, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet commenced the provision of those services.

**Future improvements or better access: consequences of additional matters**

21.—(1) If the Primary Care Trust is satisfied as mentioned in regulation 20(2)(a), it may—

- (a) defer determination of the application;
- (b) invite applications from other persons to offer to secure the future improvements or better access mentioned in regulation 20(1) that the applicant is offering to secure; and
- (c) consider, at the same time as the applicant's application, any application it receives—
  - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
  - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the future improvements or better access mentioned in regulation 20(1) that the applicant is offering to secure,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(2) If the Primary Care Trust is satisfied as mentioned in regulation 20(2)(b), it may defer consideration of the application for such period as is reasonable in the circumstances, having regard to when the future circumstances specified in accordance with paragraph 4(b) of Schedule 1 are likely to arise.

(3) If the Primary Care Trust is satisfied as mentioned in regulation 20(2)(c), it may defer consideration of the application until it can be considered at the same time as the other application.



(4) If the Primary Care Trust is satisfied as mentioned in regulation 20(2)(d), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the Primary Care Trust is satisfied as mentioned in regulation 20(2)(e) to (i), it must refuse the application.

**Refusal of routine applications that are based on neither a pharmaceutical needs assessment nor unforeseen benefits**

**22.** If a Primary Care Trust receives a routine application to which regulation 19(6) does not apply, the Primary Care Trust must refuse it unless granting it, or granting it in respect of some only of the services specified in it, would—

- (a) meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area that has been included in its pharmaceutical needs assessment in accordance with paragraph 2 of Schedule 1; or
- (b) secure (including in the future) improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area that have or has been included in its pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.

## PART 4

### Excepted applications

**Applications from NHS chemists in respect of providing directed services**

**23.** Section 129(2A) and (2B) of the 2006 Act (a) (regulations as to pharmaceutical services) do not apply to an application by a person already included in a pharmaceutical list for inclusion in that list also in respect of services that are directed services that are not already listed in relation to that person.

**Relocations that do not result in significant change to pharmaceutical services provision**

**24.—**(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) do not apply to an application from a person already included in a pharmaceutical list to relocate to different premises in the area of the Primary Care Trust maintaining that list if—

- (a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- (b) in the opinion of the Primary Care Trust, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
  - (i) in any part of its area, or
  - (ii) in a controlled locality of a neighbouring Primary Care Trust, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;
- (c) the Primary Care Trust is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area;

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(a) Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

- (d) the services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises (whether or not, in the case of enhanced services, the Primary Care Trust chooses to commission them); and
- (e) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow).

(2) Section 129(2A) and (2B) of the 2006 Act do not apply to an application from a person already included in a pharmaceutical list of a Primary Care Trust (PCT1) for inclusion in the pharmaceutical list of a neighbouring Primary Care Trust (PCT2), or inclusion in that list of PCT2 also in respect of other premises than those already listed in relation to that person, if—

- (a) the purpose of the application is to relocate to different premises;
- (b) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises (P1), the location of the new premises (P2) is not significantly less accessible;
- (c) in the opinion of PCT2, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
  - (i) in any part of PCT2's area; or
  - (ii) in a controlled locality of a neighbouring Primary Care Trust (including PCT1), where that controlled locality is within 1.6 kilometres of P2;
- (d) PCT2 is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area;
- (e) the services the applicant undertakes to provide at P2 are the same as the services the applicant has been providing at P1 (whether or not, in the case of enhanced services, PCT2 chooses to commission them);
- (f) the provision of pharmaceutical services will not be interrupted (except for such period as PCT2 may for good cause allow); and
- (g) the applicant consents to—
  - (i) where the applicant has only one set of listed chemist premises in PCT1's pharmaceutical list, the removal of the applicant's name from PCT1's pharmaceutical list, or
  - (ii) where the applicant has more than one set of listed chemist premises in PCT1's pharmaceutical list, the removal of P1 from being listed in relation to the applicant in PCT1's pharmaceutical list,
 with effect from the date on which the applicant undertakes to provide pharmaceutical services from P2.

(3) An application pursuant to this regulation must be refused if the existing pharmacy premises from which the applicant is seeking to relocate (P3)—

- (a) were listed in relation to an NHS pharmacist as a result of an application to which regulation 13(1)(a) of the 2005 Regulations<sup>(a)</sup> (exemption from the necessary or expedient test) applied, and—
  - (i) P3 are located in an area that, immediately before these Regulations came into force, was an approved retail area (within the meaning given in regulation 15 of the 2005 Regulations (approved retail areas)), and
  - (ii) the applicant proposes to relocate from P3 to premises that are outside that area; or
- (b) were listed in relation to an NHS pharmacist as a result of an application to which regulation 13(1)(c) of the 2005 Regulations applied, unless—

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<sup>(a)</sup> Prior to its repeal, the heading of regulation 13 was amended by S.I. 2009/2205.



- (i) the provider, or where there is more than one provider all the providers, of primary medical services at the one-stop primary care centre (within the meaning given in regulation 16 of the 2005 Regulations<sup>(a)</sup> (new one-stop primary care centres)) at which P3 are located are relocating with the applicant to a new discrete site or building,
  - (ii) at that new discrete site or building primary medical services are or are to be provided by one or more providers of primary medical services with a patient list of, or patient lists with a combined total of, 18,000 patients, and
  - (iii) at that site or building the services of a broad range of health care professionals are or will be regularly and frequently provided (together, where appropriate, with other health or social services);
- (c) have been listed in relation to the applicant for a period of less than 12 months prior to the application, and—
- (i) that listing arose out of the applicant relocating to P3 from other pharmacy premises,
  - (ii) that relocation arose out of the grant of an application—
    - (aa) that was an excepted application by virtue of this regulation, or
    - (bb) to which regulation 6 or 7 of the 2005 Regulations<sup>(b)</sup> (which related to minor relocations) applied, and
  - (iii) the applicant is unable to satisfy the Primary Care Trust that relocation from P3 is necessary for reasons that the Primary Care Trust accepts are good cause.

#### **Distance selling premises applications**

**25.**—(1) Section 129(2A) and (2B) of the 2006 Act<sup>(c)</sup> (regulations as to pharmaceutical services) do not apply to an application—

- (a) for inclusion in a pharmaceutical list by a person not already included; or
- (b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

- (2) The Primary Care Trust must refuse an application to which paragraph (1) applies—
- (a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and
  - (b) unless the Primary Care Trust is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—
    - (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
    - (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

#### **Change of ownership applications**

**26.**—(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) do not apply to an application from a person who is not included in a pharmaceutical list of a Primary Care Trust for inclusion in the list, or from a person included in a pharmaceutical list for

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(a) Prior to its repeal, regulation 16 was amended by S.I. 2005/1501.

(b) Prior to their repeal, regulations 6 and 7 were both amended by S.I. 2005/1501 and 2006/3373.

(c) Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

inclusion in that list also in respect of other premises than those already listed in relation to that person, if—

- (a) the applicant (X) is undertaking to provide pharmaceutical services at premises—
  - (i) that are already listed chemist premises, and
  - (ii) at which another person (Y) is providing pharmaceutical services;
- (b) X is proposing to carry on at the listed chemist premises, in place of Y, the business in the course of which Y is providing pharmaceutical services at those premises;
- (c) X is undertaking to provide the same pharmaceutical services as those that Y is providing; and
- (d) the provision of pharmaceutical services at the premises will not be interrupted (except for such period as the Primary Care Trust may for good cause allow).

(2) Section 129(2A) and (2B) of the 2006 Act do not apply to an application from a person who is not included in a pharmaceutical list of a Primary Care Trust (PCTX) for inclusion in that list, or from a person included in a pharmaceutical list for inclusion in that list also in respect of other premises than those already listed in relation to that person, if—

- (a) the applicant (X) is undertaking to provide the pharmaceutical services that another person (Y)—
  - (i) is providing at listed chemist premises (“Y’s premises”), whether in the area of PCTX or another Primary Care Trust, or
  - (ii) has provided at Y’s premises but Y is no longer able to provide pharmaceutical services at those premises for reasons that PCTX accepts are good cause;
- (b) X is proposing to carry on, in place of Y, the business in the course of which Y is providing, or has provided, pharmaceutical services at Y’s premises;
- (c) X is undertaking to provide the same pharmaceutical services as Y is providing or has provided at Y’s premises, but at different premises (“X’s premises”);
- (d) if Y had applied to move to X’s premises, that application would have been granted under regulation 24; and
- (e) if pharmaceutical services—
  - (i) are being provided at Y’s premises, the provision of pharmaceutical services will not be interrupted (except for such period as PCTX may for good cause allow) by the move of the business from Y’s premises to X’s premises, or
  - (ii) are not being provided at Y’s premises, the provision of pharmaceutical services will commence at X’s premises within the period that PCTX considers is an acceptable period for the interruption of the provision of pharmaceutical services by the business that X is taking over.

### **Applications for temporary listings arising out of suspensions**

**27.**—(1) Section 129(2A) and (2B) of the 2006 Act (a) (regulations as to pharmaceutical services) do not apply to an application—

- (a) for temporary inclusion in a pharmaceutical list by a person not already included; or
- (b) by a person already included in a pharmaceutical list for temporary inclusion in that list in respect of services, or services and premises, other than those already listed in relation to that person,

from a person (X) who proposes to provide pharmaceutical services which are not being provided because the person listed in relation to them (Y) is suspended from the pharmaceutical list.

(2) A Primary Care Trust must refuse an application to which paragraph (1) applies—

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(a) Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

- (a) unless it is satisfied that—
    - (i) Y has nominated X as the person to provide those services for the duration of Y’s suspension and consents to X doing so,
    - (ii) X will provide the same pharmaceutical services as those that Y provided or had undertaken to provide before the suspension, and
    - (iii) there is no direct or indirect connection between X and Y (including such a connection through a third party) the nature of which makes it unlikely that X will be able to exercise an appropriate degree of autonomy;
  - (b) if Y is a body corporate and X—
    - (i) is an employee of Y,
    - (ii) is, or was at the time of the suspension or of the originating events, a director or superintendent of Y,
    - (iii) is a body corporate in which Y or an employee of Y is a majority shareholder,
    - (iv) is a body corporate in which a majority shareholder of Y is, or was at the time of the suspension or of the originating events, a director or superintendent of X,
    - (v) is a body corporate which has a director or superintendent who is an employee of Y,
    - (vi) is a body corporate which has as a director or superintendent someone who is, or was at the time of the suspension or of the originating events, a director or superintendent of Y, or
  - (c) if Y is an individual and X—
    - (i) is an employee of Y,
    - (ii) is a body corporate of which Y or an employee of Y is a director or superintendent,
    - (iii) is a body corporate in which Y or an employee of Y is a majority shareholder, or
    - (iv) is a body corporate which has a director or superintendent who is an employee of Y.
- (3) If an application to which—
- (a) paragraph (1)(a) applies is granted, the applicant must only be included in the pharmaceutical list for a fixed period;
  - (b) paragraph (1)(b) applies is granted, the premises or services must only be listed in relation to the applicant for a fixed period.
- (4) The fixed periods referred to in paragraph (3) must be no longer than—
- (a) the period of Y’s suspension; or
  - (b) until Y notifies the Primary Care Trust, with effect from a specified date (which must be at least 2 working days after the date of the notification), that Y no longer consents to X providing the services that X is providing because of Y’s suspension from the pharmaceutical list.

**Applications from persons exercising a right of return to a pharmaceutical list**

**28.**—(1) Section 129(2A) and (2B) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services) do not apply to an application—

- (a) for inclusion in a pharmaceutical list by a person not already included; or
- (b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person,

in the circumstances set out in paragraph (2).

(2) Those circumstances are—

- (a) it has been determined in accordance with—

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<sup>(a)</sup> Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

- (i) regulation 4 of the National Health Service (Local Pharmaceutical Services) (No. 2) Regulations 2002<sup>(a)</sup> (right of return to pharmaceutical lists), or
  - (ii) regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006<sup>(b)</sup> (right of return to pharmaceutical lists),
- that the applicant is to be given a right of return to a pharmaceutical list;
- (b) the applicant is seeking to exercise that right after ceasing to provide local pharmaceutical services under the LPS scheme as a consequence of entering into which, or of the variation of which, the applicant was given the right of return; and
  - (c) the granting of the right of return arose out of the provision of the local pharmaceutical services which the applicant is ceasing to provide.
- (3) The Primary Care Trust must refuse an application to which paragraph (1) applies, unless—
- (a) the change from providing local pharmaceutical services to providing pharmaceutical services will not give rise to any interruption in the receipt and dispensing of prescriptions by the applicant (except for such period as the Primary Care Trust may for good cause allow); and
  - (b) any conditions in the relevant determination of the right of return are satisfied.

### **Applications relating to emergencies requiring the flexible provision of pharmaceutical services**

**29.**—(1) Section 129(2A) and (2B) of the 2006 Act<sup>(c)</sup> (regulations as to pharmaceutical services) do not apply to an application for a temporary amendment to a pharmaceutical list which the Primary Care Trust is satisfied is necessary or expedient because of an emergency requiring the flexible provision of pharmaceutical services.

(2) In the circumstances described in paragraph (1), the Primary Care Trust may make a temporary amendment to an entry in the pharmaceutical list, but—

- (a) only for a specified period (which must not be longer than the specified period of the emergency given by the Secretary of State) which the Primary Care Trust may extend or curtail in appropriate circumstances; and
- (b) the applicant may revert to the applicant’s overridden entry in the pharmaceutical list before the end of the period specified by the Primary Care Trust, on giving the Primary Care Trust at least 24 hours notice.

(3) There is no right of appeal under these Regulations in respect of a decision to make or not to make, or to curtail the duration of, a temporary amendment to a pharmaceutical list made under this regulation.

(4) For the purposes of these Regulations, “emergency requiring the flexible provision of pharmaceutical services” means an emergency declared by means of a direction to Primary Care Trusts under section 8(1) of the 2006 Act (Secretary of State’s directions to health service bodies) to the effect that, as a result of threatened or actual serious damage to human welfare caused or which may be caused by the circumstances specified in the direction, Primary Care Trusts must for a specified period—

- (a) exercise, or
- (b) where a discretion is conferred, consider exercising,

one or more of their functions under paragraph (2), regulation 61, paragraph 27 of Schedule 4 or paragraph 17 of Schedule 5, subject to any conditions or limitations set out in the direction.

(5) Where—

- (a) a direction of the type mentioned in paragraph (4) is given; and

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(a) S.I. 2002/2016.

(b) S.I. 2006/552.

(c) Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

(b) the Secretary of State issues a further direction changing the specified period of the emergency,  
the duration of the emergency is to be construed in accordance with the specified period as so changed.

## PART 5

Specific grounds for refusal or deferral of applications under Parts 3 and 4 which are not linked to fitness grounds

### **Refusal: language requirement for some NHS pharmacists**

**30.** An application for inclusion in a pharmaceutical list by a person not already included must be refused if the applicant is an individual (X) who qualified as a pharmacist in Switzerland or an EEA state other than the United Kingdom, unless X satisfies the Primary Care Trust that X has the level of knowledge of English which, in the interests of X and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the Primary Care Trust.

### **Refusal: same or adjacent premises**

**31.**—(1) An application—

- (a) for inclusion in a pharmaceutical list by a person not already included; or
- (b) by a person already included in a pharmaceutical list for inclusion also in respect of premises other than those already listed in relation to that person,

must be refused where paragraph (2) applies.

(2) This paragraph applies where—

- (a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services (“the existing services”) from—
  - (i) the premises to which the application relates, or
  - (ii) adjacent premises; and
- (b) the Primary Care Trust is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

### **Deferrals arising out of LPS designations**

**32.**—(1) An application, other than an excepted application, which is—

- (a) for inclusion in a pharmaceutical list by a person not already included;
- (b) by a person already included in a pharmaceutical list for inclusion also in respect of premises other than those already listed in relation to that person; or
- (c) to provide, from the person’s listed chemist premises, services that are in addition to those already listed in relation to him, other than additional directed services,

may be deferred where paragraph (2) applies to the relevant premises.

(2) This paragraph applies where the relevant premises are premises or part of premises, or are located within an area, designated under regulation 4 of the LPS Regulations<sup>(a)</sup> (designation of

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(a) Regulation 4 has been amended by S.I. 2009/599 and 2010/914.

priority neighbourhoods or premises), and that designation has neither been varied so that it no longer applies to the relevant premises nor been cancelled.

(3) For the purposes of this regulation, “the relevant premises” are—

- (a) the listed chemist premises or proposed listed chemist premises in the application; or
- (b) as regards an application for inclusion in a pharmaceutical list by a person not already included, if no particular premises are proposed for listing in the application, premises located at the best estimate that the Primary Care Trust is able to make as to where the proposed listed chemist premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

## PART 6

### Refusal, deferral and conditional inclusion in pharmaceutical lists of chemists on fitness grounds

#### **Refusal of applications for inclusion in a pharmaceutical list on fitness grounds**

**33.**—(1) An application for inclusion in a pharmaceutical list by a person (A) who is not already included in it must be refused if the Primary Care Trust is satisfied that—

- (a) A (or where A is a body corporate, any director or superintendent of A) has been convicted in the United Kingdom of murder;
- (b) A (or where A is a body corporate, any director or superintendent of A) has been convicted in the United Kingdom of a criminal offence, other than murder—
  - (i) which was committed after 1st April 2005, and
  - (ii) has been sentenced to a term of imprisonment of over 6 months;
- (c) A is the subject of a national disqualification; or
- (d) where, on appeal, the First-tier Tribunal determines A may be included in the pharmaceutical list subject to conditions, A has not within 30 days of that decision notified the Primary Care Trust that A agrees to the imposition of the conditions.

(2) An application for inclusion in a pharmaceutical list by a person who is not already included may be refused if the Primary Care Trust—

- (a) having contacted the referees mentioned in paragraph 3(8) of Schedule 2, is not satisfied with the references given;
- (b) considers that A is unsuitable to be included in the list;
- (c) having—
  - (i) checked with the NHS BSA for any facts that it considers relevant relating to past or current fraud investigations involving or related to A (and where A is a body corporate, any director or superintendent of A), and
  - (ii) considered these and any other facts in its possession relating to fraud involving or relating to A (and where A is a body corporate, any director or superintendent of A), considers the outcome of these enquiries justify such refusal;
- (d) having—
  - (i) checked with the Secretary of State for any facts considered by the Secretary of State to be relevant relating to past or current investigations or proceedings involving or relating to A (and where A is a body corporate, any director or superintendent of A), and
  - (ii) considered these and any other facts in its possession involving or relating to A (and where A is a body corporate, any director or superintendent of A), considers the outcome of these enquiries justify such refusal; or



- (e) considers that granting the application would be prejudicial to the efficiency of the service which A has undertaken to provide.

(3) Where the Primary Care Trust is considering refusal of an application under paragraph (2), it must consider all facts which appear to it to be relevant and must in particular take into consideration in relation to paragraph (2)(b) to (e)—

- (a) the nature of any offence, investigation or incident;
- (b) the length of time since any offence, incident, conviction or investigation;
- (c) whether there are other offences, incidents or investigations to be considered;
- (d) any action taken or penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation;
- (e) the relevance of any offence, investigation or incident to the provision by A of pharmaceutical services and any likely risk to users of pharmaceutical services or to public finances;
- (f) whether any offence was a sexual offence to which Part 1 of the Sexual Offences Act 2003<sup>(a)</sup> (sexual offences) applies, or if it had been committed in England and Wales, would have applied;
- (g) whether A (and where A is a body corporate, any director or superintendent of A) has been refused inclusion in, conditionally included in, removed, contingently removed or is currently suspended from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or other primary care organisation for such action; or
- (h) whether A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, or has in the preceding 6 months been—
  - (i) a director or superintendent of a body corporate which has been refused inclusion in, conditionally included in, removed or contingently removed from a relevant list, or
  - (ii) is currently suspended from a relevant list,for a reason relating to unsuitability, fraud or efficiency of service provision, and if so, what the facts were in each such case and the reasons given by the Primary Care Trust or other primary care organisation in each case.

(4) When the Primary Care Trust takes into consideration the matters set out in paragraph (3), it must consider the overall effect of all the matters being considered.

(5) If an application for inclusion in a pharmaceutical list by a person who is not already included in it is refused under paragraph (1) or (2), the Primary Care Trust must notify the applicant of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) the applicant's right of appeal against the decision to the First-tier Tribunal, which must be exercised within 30 days of the date on which the applicant was notified of the decision.

### **Deferral of consideration of applications for inclusion in a pharmaceutical list on fitness grounds**

**34.—**(1) An application for inclusion in a pharmaceutical list by a person (A) who is not already included in it may be deferred if the Primary Care Trust is satisfied that—

- (a) there are, in respect of A (or where A is a body corporate, in respect of A or a director or superintendent of A)—
  - (i) criminal proceedings in the United Kingdom, or

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(a) 2003 c. 42.

- (ii) proceedings elsewhere relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,

which, if they result in a conviction, or the equivalent of a conviction, would be likely to lead to A's removal from its pharmaceutical list, if A were to be included in it;
- (b) in respect of a body corporate of which A is, or has in the preceding 6 months been, or was at the time of the originating events, a director or superintendent, there are—
  - (i) criminal proceedings in the United Kingdom, or
  - (ii) proceedings elsewhere relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,

which, if they resulted in a conviction, or the equivalent of a conviction, would be likely to lead to A's removal from its pharmaceutical list, if A were to be included in it;
- (c) there is an investigation anywhere in the world—
  - (i) by A's (or where A is a body corporate, any director or superintendent of A's) licensing or regulatory body, or
  - (ii) relating to A (or where A is a body corporate, any director or superintendent of A) in A's professional capacity (including one by another Primary Care Trust or another primary care organisation),

which, if the outcome were adverse, would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
- (d) A (and where A is a body corporate, any director or superintendent of A) is suspended from a relevant list;
- (e) a body corporate of which A (or where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent, is suspended from a relevant list;
- (f) the First-tier Tribunal is considering an appeal by A (or where A is a body corporate, by A or any director or superintendent of A) against a decision of a Primary Care Trust or another primary care organisation—
  - (i) to refuse an application for inclusion in a relevant list, or
  - (ii) to include A conditionally in, or to remove or contingently remove A from, a relevant list,

and if that appeal were to be unsuccessful, the Primary Care Trust would be likely to remove A from the pharmaceutical list if A were to be included in it;
- (g) the First-tier Tribunal is considering an appeal by a body corporate of which A (or where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, or has in the preceding 6 months been, a director or superintendent, against a decision of a Primary Care Trust or another primary care organisation—
  - (i) to refuse an application by that body corporate for inclusion in its list,
  - (ii) to include A conditionally in, or to remove or contingently remove A from, a relevant list,

and if that appeal were to be unsuccessful the Primary Care Trust would be likely to remove A from the pharmaceutical list if A were to be included in it;
- (h) A (and where A is a body corporate, any director or superintendent of A) is being investigated by the NHS BSA in relation to any fraud, where the result, if adverse, would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
- (i) a body corporate, of which A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent, is being investigated by the NHS BSA in relation to any fraud, where the result if adverse would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;



- (j) the First-tier Tribunal is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of A (and where A is a body corporate, any director or superintendent of A);
- (k) the First-tier Tribunal is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of a body corporate of which A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent; or
- (l) a Primary Care Trust or other primary care organisation, for a reason relating to unsuitability, fraud or efficiency of service provision—
  - (i) is considering removal (other than voluntary removal) or contingent removal of the applicant from a relevant list, or
  - (ii) has taken a decision to remove (other than voluntary removal) or contingently remove A from a relevant list but that decision has yet to take effect.
- (2) A Primary Care Trust may only defer a decision under paragraph (1) until—
  - (a) the outcome of the cause for the deferral is known; or
  - (b) the reason for the deferral no longer exists.

**Granting applications for inclusion in a pharmaceutical list subject to efficiency conditions and conditions to combat fraud**

**35.**—(1) An application for inclusion in a pharmaceutical list by a person (P) who is not already included may be granted subject to a condition of a type mentioned in paragraph (3), which is determined by the Primary Care Trust and which the Primary Care Trust decides to impose with regard to P.

(2) The Primary Care Trust may vary the terms of service of an NHS chemist for the purpose of or in connection with the imposition of the condition.

- (3) A condition imposed under paragraph (1) must be a condition with a view to—
  - (a) preventing any prejudice to the efficiency of the services, or any of the services, which P has undertaken to provide; or
  - (b) preventing any act or omission within section 151(3)(a) of the 2006 Act (disqualification of practitioners).

(4) If a Primary Care Trust decides to grant an application subject to a condition imposed under paragraph (1), it must notify P of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) P's right of appeal against its decision to the First-tier Tribunal;
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008(a), the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (d) the effect of paragraph (5).

(5) If P issues a notice of commencement before the First-tier Tribunal has determined an appeal against a condition imposed under paragraph (1), P is to be included in the pharmaceutical list subject to the condition, but only pending the outcome of the appeal if the appeal is successful.

- (6) The appeal is to be by way of redetermination of—
  - (a) the decision of the Primary Care Trust to impose the condition; and
  - (b) if P has, at the time the appeal is determined, been included in the pharmaceutical list, any decision under paragraph (2) to vary the terms of service of P for the purpose of or in connection with the imposition of the condition.

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(a) S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.

(7) If at the time the appeal is determined, P has not been included in the pharmaceutical list, and—

- (a) the First-tier Tribunal confirms the decision of the Primary Care Trust; or
- (b) imposes a different condition,

P must, within 30 days of P being notified of the First-tier Tribunal's decision, notify the Primary Care Trust as to whether or not P wishes to withdraw P's application

(8) If P fails, in the circumstances described in paragraph (7), to notify the Primary Care Trust within that 30 days that P does not wish to withdraw P's application, the grant of P's application lapses.

## PART 7

Areas that are controlled localities and reserved locations, and new pharmacies within them

### **Determination that an area is a controlled locality**

**36.**—(1) Any area that was, or was part of, a controlled locality for the purposes of the 2005 Regulations immediately before these Regulations come into force continues to be, or to be part of, a controlled locality for the purposes of these Regulations (unless or until it is determined that the area is no longer, or no longer part of, a controlled locality).

(2) Subject to paragraph (3), a Primary Care Trust may at any time consider and determine whether or not any locality within its area, because it is rural in character, is to be, or to be part of, a controlled locality.

(3) Where the question of whether or not an area is to be, or to be part of, a controlled locality has been determined by a Primary Care Trust or on appeal (whether under these Regulations or the 2005 Regulations), that question must not be considered again in relation to that area—

- (a) for 5 years, beginning with the date of the determination of the Primary Care Trust, or if that determination was appealed, the date of the decision on appeal;
- (b) unless the Primary Care Trust is satisfied (within that 5 years) that there has been a substantial change in circumstances in relation to that area since the question was last determined.

### **Process for determining controlled localities: preliminary matters**

**37.**—(1) A Local Medical Committee or Local Pharmaceutical Committee may apply in writing to a Primary Care Trust for it to determine whether or not an area specified in the application is to be, or is to be part of, a controlled locality.

(2) Before considering the application, the Primary Care Trust must consider whether or not the application raises a question that it cannot consider by virtue of regulation 36(3).

(3) If the Primary Care Trust decides that the application does raise a question that it cannot consider by virtue of regulation 36(3), it must take no further action in relation to that application other than informing the Committee making the application of that decision and its right of appeal against that decision under regulation 45(1)(b).

### **Process for determining controlled localities: local notification and deferment of routine applications**

**38.**—(1) If a Primary Care Trust is considering making a determination that an area is or is not to be, or is or is not to be part of, a controlled locality (whether or not of its own motion), before making the proposed determination, it must give notice of the proposed determination to—

- (a) any Local Pharmaceutical Committee for its area (including a Local Pharmaceutical Committee for its area and that of one or more other Primary Care Trusts);

- (b) any Local Medical Committee for its area (including a Local Medical Committee for its area and that of one or more other Primary Care Trusts);
  - (c) any person on a pharmaceutical list or dispensing doctors list who, in the opinion of the Primary Care Trust, may be affected by the determination;
  - (d) any LPS chemist who, in the opinion of the Primary Care Trust, may be affected by the determination;
  - (e) any provider of primary medical services who, in the opinion of the Primary Care Trust, may be affected by the determination; and
  - (f) where it is considering making a determination as a consequence of a routine application, the person making that application.
- (2) The Primary Care Trust may also give notice of the proposed determination to such other persons as it considers appropriate to do so.
- (3) A notice under paragraph (1) or (2) must inform the person notified—
- (a) that they may make representations (or in the case of a Committee being notified that applied for the determination, any further representations) in writing within 30 days beginning on the day on which the notification was sent to them;
  - (b) of the date by which the Primary Care Trust expects to make its determination, which must be no later than 6 months after the day on which the Primary Care Trust first gives notice to any person in respect of the proposed determination under paragraph (1) or (2).
- (4) Once a Primary Care Trust has issued notice under paragraph (1), it must defer consideration of any routine application where the applicant is seeking the listing of pharmacy premises and the outcome of the application could (if the application is deferred) be affected as a result of the proposed determination, until—
- (a) it has determined whether the area in question is or is not to be, or is or is not to be part of, a controlled locality; and
  - (b) the proceedings relating to that determination have reached their final outcome.

**Process of determining controlled localities: formulation of the Primary Care Trust’s decision**

- 39.**—(1) When it is determining whether or not an area is or is part of a controlled locality, a Primary Care Trust must have regard to whether the provision of—
- (a) primary medical services by a provider of primary medical services (which does not include PCTMS practices);
  - (b) pharmaceutical services by a person on a pharmaceutical list; or
  - (c) local pharmaceutical services by a provider of such services,
- is likely to be adversely affected by the consequences of the determination.
- (2) Once it has determined whether or not an area is or is part of a controlled locality, a Primary Care Trust must—
- (a) if it determines that the area is to become or become part of a controlled locality, or is to cease to be part of a controlled locality—
    - (i) delineate precisely the boundary of the resulting controlled locality on a map, and
    - (ii) either—
      - (aa) publish that map alongside its pharmaceutical needs assessment map, or
      - (bb) include that boundary in its pharmaceutical needs assessment map; and
  - (b) give notice of the determination to the persons mentioned in paragraph (3) informing them of—
    - (i) its determination and the reasons for it,

- (ii) their right of appeal, if the person has a right of appeal under regulation 45(1)(a)(i), and
  - (iii) their right of appeal under regulation 45(1)(a)(ii), in the case of a person notified who is a Local Pharmaceutical Committee, a Local Medical Committee, a provider of primary medical services, an LPS chemist or a person on a pharmaceutical or dispensing doctors list.
- (3) The persons mentioned in this paragraph are—
- (a) if the determination resulted from an application from a Local Pharmaceutical Committee or Local Medical Committee pursuant to regulation 37(1), that Committee;
  - (b) if a routine application was deferred pursuant to regulation 38(4) until the proceedings relating to the determination reached their final outcome, the person making that application; and
  - (c) the persons notified in accordance with regulation 38(1) and (2) in relation to the proposal to make the determination.

**Applications for new pharmacy premises in controlled localities: refusals because of preliminary matters**

40.—(1) This paragraph applies to all routine applications—

- (a) for inclusion in a pharmaceutical list as an NHS pharmacist; or
- (b) from an NHS pharmacist—
  - (i) to relocate to different pharmacy premises in the area of the Primary Care Trust whose list it is, or
  - (ii) to open, within the area of that Primary Care Trust, additional pharmacy premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality.

(2) If a Primary Care Trust receives an application (A1) to which paragraph (1) applies, it must refuse A1 (without needing to make any notification of that application under Part 3 of Schedule 2), where the applicant is seeking the listing of premises at a location which is—

- (a) in an area in relation to which outline consent has been granted under these Regulations or under the 2005 Regulations within the 5 year period—
  - (i) starting on the date on which the proceedings relating to the grant of outline consent reached their final outcome, and
  - (ii) ending on the date on which A1 is made; or
- (b) within 1.6 kilometres of the location of proposed pharmacy premises (other than proposed distance selling premises), in respect of which—
  - (i) a routine application under these Regulations, or
  - (ii) an application to which regulation 22(1) or (3) of the 2005 Regulations (relevant procedures for applications) applied,

was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless the Primary Care Trust is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(3) For the purposes of paragraphs (1) and (2), if no particular premises are proposed for listing in A1, the applicant is to be treated as seeking the listing of pharmacy premises at the location which is the best estimate that the Primary Care Trust is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

## Applications for new pharmacy premises in controlled localities: reserved locations

41.—(1) This paragraph applies to any routine application—

- (a) for inclusion in a pharmaceutical list as an NHS pharmacist; or
- (b) from an NHS pharmacist—
  - (i) to relocate to different pharmacy premises in the area of the Primary Care Trust whose list it is, or
  - (ii) to open, within the area of that Primary Care Trust, additional pharmacy premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality and the Primary Care Trust is required to notify the application under Part 3 of Schedule 2.

(2) If paragraph (1) applies to an application (referred to in this regulation and regulation 42 as “A1”), subject to paragraph (5), the Primary Care Trust must determine whether or not the “relevant location”, that is—

- (a) the location of the premises for which the applicant is seeking the listing; or
- (b) if no particular premises are proposed for listing in A1, the location which is the best estimate that the Primary Care Trust is able to make of where the proposed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2,

is, on basis of the circumstances that pertained on the day on which A1 was received by the Primary Care Trust, in a reserved location.

(3) Subject to regulation 43(2), the area within a 1.6 kilometre radius of a relevant location is a “reserved location” if—

- (a) the number of individuals residing in that area who are on a patient list (which may be an aggregate number of patients on more than one patient list) is less than 2,750; and
- (b) the Primary Care Trust is not satisfied that if pharmaceutical services were provided at the relevant location, the use of those services would be similar to, or greater than, the use that might be expected if the number of individuals residing in that area who are on a patient list were 2,750 or more.

(4) Before making a determination under paragraph (2) (referred to in this regulation and regulation 42 as “D1”), the Primary Care Trust must—

- (a) notify the persons notified under Part 3 of Schedule 2 about A1 that the Primary Care Trust is required to make D1 (and it may make this notification at the same time as it notifies those persons about A1); and
- (b) invite them, within a specified period of not less than 30 days, to make representations to the Primary Care Trust with regard to D1 (and the period specified must end no earlier than the date by which the person notified needs to make any representations that they have with regard to A1).

(5) The Primary Care Trust must not make a determination under paragraph (2) in respect of A1 in circumstances where an earlier application which was in respect of the relevant premises and to which either paragraph (1) or regulation 18ZA of the 2005 Regulations<sup>(a)</sup> (refusal: premises which are in a controlled locality but not a reserved location) applied was refused—

- (a) for the reasons relating to prejudice in—
  - (i) regulation 44(3), or
  - (ii) regulation 18ZA(2) of the 2005 Regulations; and
- (b) within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

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(a) Prior to its repeal, regulation 18ZA was inserted by S.I. 2005/1501.

unless the Primary Care Trust is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(6) For the purposes of paragraph (5), the “relevant premises” are—

- (a) the premises which are proposed for listing; or
- (b) if no particular premises are proposed for listing in A1, premises at the location which is the best estimate that the Primary Care Trust is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

### **Second and subsequent determinations of reserved location status**

**42.**—(1) Where a Primary Care Trust has made D1, or a determination in accordance with regulation 35 of the 2005 Regulations, and the person in relation to whose proposed listing of premises that determination was made (or that person’s successor as the owner of the relevant pharmacy business) requests a further determination (referred to in this regulation as “D2”), the Primary Care Trust may determine—

- (a) whether or not a location that has become the relevant location for the purposes of a listing application is in a reserved location, on the basis of the circumstances that pertained on the day on which the request for D2 was received by the Primary Care Trust, in circumstances where the relevant location in relation to which the earlier determination was made has changed because—
  - (i) no particular premises were proposed for listing in the application, but
  - (ii) particular premises have since been identified; or
- (b) that, on the basis of the circumstances that pertained on the day on which the request for D2 was received by the Primary Care Trust, there is no longer a reserved location with regard to the premises proposed for listing (which may have become pharmacy premises), in circumstances where—
  - (i) the Primary Care Trust determined (subject to regulation 43(2)) that the area within a 1.6 kilometre radius of a relevant location was a reserved location, but
  - (ii) the relevant location no longer meets the criteria for being a reserved location in regulation 41(3).

(2) Before making D2, the Primary Care Trust must—

- (a) notify the persons that it would notify under Part 3 of Schedule 2, if the request for a determination were an application seeking the listing of pharmacy premises at the relevant location, that the Primary Care Trust is required to make a determination under paragraph (1); and
- (b) invite them, within a specified period of up to 3 months but not less than 30 days, to make representations to the Primary Care Trust with regard to that determination.

(3) Subject to regulation 43(2), a Primary Care Trust must only determine under paragraph (1) that the area, or any part of an area, that is within a 1.6 kilometre radius of a relevant location is no longer to be classed as a reserved location if it is satisfied that the change in classification of that area, or part of an area, will not prejudice the proper provision of relevant NHS services in its area or in the area of a neighbouring Primary Care Trust.

(4) Where a Primary Care Trust makes D2—

- (a) D1 lapses as soon as D2 is made; and
- (b) the Primary Care Trust may (in accordance with regulation 50) postpone the termination of the arrangements that it has with the provider or dispensing doctor that would otherwise take place as a consequence of D2.

(5) Where—

- (a) a Primary Care Trust has made D2; and



(b) the person who sought the determination, or that person's successor as the person carrying on a pharmacy business at the relevant location, believes that the reserved location no longer meets the criteria for being a reserved location in regulation 41(3), that person may request a further determination, under paragraph (1)(b), and if that person does, paragraphs (1) to (4) apply as if the references to D1 were to the most recent determination and the references to D2 were to the new further determination.

#### **Determinations of reserved locations: supplemental matters**

**43.**—(1) Once a Primary Care Trust has determined whether or not an area is a reserved location under regulation 41(2) or 42(1), it must—

- (a) give notice of the determination to the person in relation to whose pharmacy premises or proposed pharmacy premises the determination relates, and to the persons notified in accordance with regulation 41(4) or 42(2); and
- (b) as part of that notice, inform them of—
  - (i) its determination and the reasons for it, and
  - (ii) in the case of any person notified who is a Local Pharmaceutical Committee, a Local Medical Committee, a provider of primary medical services, an LPS chemist or a person on a pharmaceutical or dispensing doctors list, their right of appeal under regulation 45(1)(c) or (d).

(2) Where—

- (a) part of the area of what would otherwise be determined under regulation 41(2) or 42(1) to be a reserved location is within 1.6 kilometres of the location of other pharmacy premises (that is, pharmacy premises other than the pharmacy premises at the relevant location); and
- (b) there is no reserved location arising out of the presence of those other pharmacy premises, that part of that area is not to be part of the reserved location.

(3) A reserved location (as opposed to the determination of a reserved location) takes effect once the pharmacy premises to which it relates are listed in the pharmaceutical list.

(4) Once a reserved location takes effect, the Primary Care Trust that determined it must delineate precisely the boundary of the reserved location on the map on which it delineates, pursuant to regulation 39(2)(a)(i), the boundary of the related controlled locality.

#### **Prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location**

**44.**—(1) This paragraph applies to all routine applications—

- (a) for inclusion in a pharmaceutical list as an NHS pharmacist; or
- (b) from an NHS pharmacist—
  - (i) to relocate to different pharmacy premises in the area of the Primary Care Trust whose list it is, or
  - (ii) to open, within the area of that Primary Care Trust, additional pharmacy premises from which to provide pharmaceutical services.

(2) As regards any application to which paragraph (1) applies, a Primary Care Trust must have regard to whether or not the applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not a reserved location.

(3) If the applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not in a reserved location, the Primary Care Trust must refuse the application if granting it would, in the opinion of the Primary Care Trust, prejudice the proper provision of relevant NHS services in its area or in the area of a neighbouring Primary Care Trust.



(4) For the purposes of paragraphs (2) and (3), if no particular premises are proposed for listing in the application, the applicant is to be treated as seeking the listing of pharmacy premises which are in a controlled locality if the best estimate that the Primary Care Trust is able to make of where the proposed pharmacy premises would be is at a location which is in a controlled locality, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

### **Appeals against decisions under Part 7**

**45.**—(1) A person with appeal rights (as provided for in this regulation) may appeal to the Secretary of State against the following decisions by a Primary Care Trust—

- (a) a determination of whether or not an area is or is part of a controlled locality as mentioned in regulation 36(2), in respect of which the only people with appeal rights are—
  - (i) a person, as mentioned in regulation 38(4), who is making a routine application to which the determination relates, and
  - (ii) a person given notice of the determination who is mentioned in regulation 39(2)(b)(iii);
- (b) a decision under regulation 37(3) that an application by a Local Pharmaceutical Committee or Local Medical Committee raises a question that it cannot consider by virtue of regulation 36(3), in respect of which only the Committee making the application to which the decision relates is a person with appeal rights;
- (c) a determination as to whether or not a relevant location is in a reserved location under regulation 41(2), in respect of which the only people with appeal rights are—
  - (i) the person making the application to which the determination relates, and
  - (ii) a person given notice of the determination who is mentioned in regulation 43(1)(b)(ii); and
- (d) a determination under regulation 42(1), in respect of which the only people with appeal rights are—
  - (i) the person making the application to which the determination relates, and
  - (ii) a person given notice of the determination who is mentioned in regulation 43(1)(b)(ii),

provided that, within 30 days of the date on which they were notified of the decision that is being appealed, they notify the Secretary of State with a valid notice of appeal.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

(3) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under this Part (as it does in relation to appeals against decisions under Parts 2 to 5, 8, 10 and 12 and Schedule 2).

## **PART 8**

### **Dispensing doctors**

#### **Dispensing doctor lists**

**46.**—(1) Each Primary Care Trust must prepare and publish a list (a “dispensing doctor list”) of the names any “dispensing doctors” in the area of the Primary Care Trust, that is to say—

- (a) providers of primary medical services who provide pharmaceutical services from medical practice premises in the area of the Primary Care Trust; and
- (b) general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in the area of the Primary Care

Trust (not including general practitioners who are listed as part of the listing of a provider by virtue of paragraph (6)(b)).

- (2) Each dispensing doctor list must be available for public inspection and must include—
  - (a) the address of any premises in the area of the Primary Care Trust for which a listed dispensing doctor has premises approval (“the listed dispensing premises”) and any other medical practice premises of the dispensing doctor in that area; and
  - (b) any area in relation to which the dispensing doctor has outline consent.
- (3) A Primary Care Trust must remove a dispensing doctor from its dispensing doctor list if—
  - (a) in the case of a listed provider of primary medical services, that person or partnership ceases to be a provider of primary medical services or ceases to be a provider of those services to the Primary Care Trust;
  - (b) in the case of a listed general practitioner, that person is no longer on a medical performers list or no longer performs primary medical services within the area of the Primary Care Trust; or
  - (c) all the arrangements that the dispensing doctor has with the Primary Care Trust to perform or provide pharmaceutical services have been discontinued, or the permissions that the dispensing doctor requires in order to have such arrangements have lapsed, in accordance with this Part.
- (4) If—
  - (a) a general practitioner who is the only partner or shareholder in a provider of primary medical services who is a dispensing doctor so elects; or
  - (b) all the general practitioners who are the members of a provider of primary medical services who are dispensing doctors so elect,

they may request that their Primary Care Trust lists that provider instead of them as the dispensing doctor (or doctors) on the Primary Care Trust’s dispensing doctors list.

- (5) In the circumstances described in paragraph (4)—
  - (a) the Primary Care Trust must agree to that request;
  - (b) the arrangements that the Primary Care Trust had with the individual dispensing doctor or doctors become arrangements with the provider of primary medical services; and
  - (c) the premises approvals and related outline consents of those general practitioners become the premises approvals and outline consents of the provider of primary medical services.
- (6) Where a provider of primary medical services is listed in a dispensing doctors list—
  - (a) the provider must notify the Primary Care Trust—
    - (i) of any general practitioner who performs primary medical services on behalf of the provider who the provider anticipates will provide pharmaceutical services on behalf of the provider, and
    - (ii) if a general practitioner who has been so notified, when the provider no longer anticipates that the general practitioner will provide pharmaceutical services on behalf of the provider; and
  - (b) as part of the listing of the provider in its dispensing doctors list, the Primary Care Trust must include the names of any general practitioner notified under sub-paragraph (a)(i), unless the Primary Care Trust has received a further notification in respect of that general practitioner under sub-paragraph (a)(ii).

#### **Terms of service of dispensing doctors: general**

47.—(1) The arrangements under which a dispensing doctor undertakes to provide pharmaceutical services (and so their terms of service) are to include any provisions affecting their rights and obligations that—

- (a) are included in these Regulations, including—

- (i) the terms of service set out in Schedule 6 (which accordingly has effect), and
  - (ii) any obligation that is only applicable in prescribed cases, if the dispensing doctor is a person to whom the obligation is applicable;
- (b) were imposed, in relation to the dispensing doctor's ability to provide pharmaceutical services, by virtue of regulation 20(2) of the 2005 Regulations<sup>(a)</sup> (imposition of conditions);
- (c) are included in the arrangements for remuneration for services provided by dispensing doctors that give effect to regulation 92, in so far as those rights and obligations are applicable in the case of the dispensing doctor; and
- (d) are included in regulation 3 of the Local Involvement Networks (Duty of Services-Providers to Allow Entry) Regulations 2008<sup>(b)</sup> (duty of services-providers to allow entry by local involvement networks), in so far as it applies to dispensing doctors.
- (2) The Primary Care Trust must ensure that those terms of service—
- (a) if the dispensing doctor has arrangements with the Primary Care Trust for the provision of primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services, are conditions of and so are enforceable under those arrangements; or
  - (b) if the dispensing doctor has no such arrangements—
    - (i) are terms of service of, and so are enforceable under, the arrangements that the Primary Care Trust has with a provider of primary medical services for the provision of primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services, or
    - (ii) are terms of service of the arrangements under which a PCTMS practice provides primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services.

#### **Arrangements for the provision of pharmaceutical services by doctors: applications by patients**

48.—(1) A patient (P) may at any time request in writing that a dispensing doctor (D) provides P with pharmaceutical services if—

- (a) one or more of the Conditions specified in paragraphs (2) to (4) is satisfied in relation to P; and
- (b) P is on either D's patient list or the patient list of a provider of primary medical services or PCTMS practice (E) by whom D is employed or engaged.

(2) Condition 1 is that P satisfies the Primary Care Trust (PCT1) by which P is recorded as being on D or E's patient list that P would have serious difficulty in obtaining any necessary drugs or appliances from pharmacy premises by reason of distance or inadequacy of means of communication.

(3) Condition 2 is that P is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy premises, other than distance selling premises, and—

- (a) there is in effect—
  - (i) an outline consent that has been granted to D, and
  - (ii) a related premises approval for the premises from which D (or another general practitioner within the practice) would dispense to P; or
- (b) the following—
  - (i) immediately before these Regulations came into force, there was a right (other than outline consent) in effect under the 2005 Regulations for D, E or another general

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(a) Prior to its repeal, regulation 20 was amended by S.I. 2006/552.

(b) S.I. 2008/915.

practitioner employed or engaged by E to provide drugs or appliances to patients on D or E's patient list (a right which continues in effect under these Regulations, subject to regulation 60),

(ii) P either—

- (aa) has not previously been included in a patient list in the area of that Primary Care Trust,
- (bb) has been so included but changed address from that last notified to the Primary Care Trust, or
- (cc) has been so included and has not changed address, but immediately before P's acceptance by D or E onto their patient list, P was being provided with pharmaceutical services by another general practitioner or provider of primary medical services under arrangements with the Primary Care Trust, and

(iii) there is in effect premises approval in relation to the premises from which D would dispense to P.

(4) Condition 3 is that P is resident in a controlled locality and within a distance of 1.6 kilometres from pharmacy premises that are not distance selling premises, but—

- (a) P is resident in a reserved location; and
- (b) either paragraph (3)(a) or (b) is satisfied in relation to P.

(5) If D—

- (a) in response to the request, applies in writing to PCT1, enclosing P's request, PCT1 must make arrangements with D for the provision of pharmaceutical services to P—
  - (i) in a case to which Condition 1 applies, from D's medical practice premises, or
  - (ii) in a case to which Condition 2 or 3 applies, from D's listed dispensing premises; or
- (b) does not respond to the request as mentioned in sub-paragraph (a) within 30 days, PCT1 may, subject to paragraph (7), require D to undertake to provide pharmaceutical services to P—
  - (i) in a case to which Condition 1 applies, from D's medical practice premises, or
  - (ii) in a case to which Condition 2 or 3 applies, from D's listed dispensing premises,by a notification to that effect which gives D reasonable notice of when the requirement is to take effect.

(6) PCT1 must not, under paragraph (5)(b), require D to undertake to provide services to P, if D satisfies PCT1 that—

- (a) D does not normally provide pharmaceutical services; or
- (b) P would not have serious difficulty in obtaining any necessary drugs or appliances from pharmacy premises by reason of distance or inadequacy of means of communication.

(7) Where arrangements have been made between D and PCT1 for the provision of pharmaceutical services, those arrangements take effect—

- (a) in a case to which paragraph (5)(a) applies, from the date of the patient's request in writing; or
- (b) in a case to which paragraph (5)(b) applies, from the date which PCT1 specifies in the notice under that paragraph as the date on which the arrangements are to take effect, or if D appeals the decision under paragraph (5)(b), the date on which that appeal reaches its final outcome.

(8) Under those arrangements, at or from the relevant medical practice premises or listed dispensing premises for those arrangements, the following may provide pharmaceutical services to the patient, for as long as the arrangements remain in effect—

- (a) if the arrangements are with a provider of primary medical services (including an individual who is such a provider), any general practitioner performing primary medical services on behalf of that provider; or

- (b) if the arrangements are with an individual general practitioner who performs primary medical services on behalf of a provider of primary medical services or a PCTMS practice, the general practitioner or any other general practitioner who performs primary medical services on behalf of that provider or practice.

(9) To be valid, a notification under paragraph (5)(b) by the Primary Care Trust must include an explanation of—

- (a) the reasons for the imposition of the requirement; and
- (b) D's right of appeal under regulation 63(1)(a).

### **Necessary services for temporary patients**

**49.** A dispensing doctor who provides pharmaceutical services to patients on a patient list may provide necessary pharmaceutical services to a person who has been accepted by the dispensing doctor as a temporary patient.

### **Discontinuation of arrangements for the provision of pharmaceutical services by doctors**

**50.—(1)** In circumstances where a Primary Care Trust has arrangements (whether they were made under these Regulations or were made under or continued by virtue of the 2005 Regulations) with a dispensing doctor (D) to provide pharmaceutical services to a person (P), if—

- (a) pharmaceutical services have been provided to P because of the circumstances described in Condition 1 in regulation 48(2), but the Primary Care Trust determines that Condition 1 no longer applies in relation to P;
- (b) the area in which P is resident was but ceases to be a controlled locality, and the provision of pharmaceutical services to P arose out of P's residence in a controlled locality;
- (c) P was resident in but has moved out of a controlled locality, and the provision of pharmaceutical services to P arose out of P's residence in that controlled locality;
- (d) P is resident in a controlled locality but is not (any longer) resident at a distance of more than 1.6 kilometres from any pharmacy premises, other than distance selling premises, at or from which pharmaceutical services are being provided, and—
  - (i) the Primary Care Trust determines that Condition 3 in regulation 48(4) does not apply in respect of P, or
  - (ii) the Primary Care Trust determines that Condition 3 in regulation 48(4) does apply in respect of P, but P informs the Primary Care Trust that P wishes to be provided with pharmaceutical services by a person on its pharmaceutical list rather than by D (other than as permitted by paragraph 7 of Schedule 6);
- (e) P is resident in a reserved location, and—
  - (i) had previously informed the Primary Care Trust that P wished to be provided with pharmaceutical services by D, but
  - (ii) P has since informed the Primary Care Trust that P wishes instead to be provided with pharmaceutical services by a person on a pharmaceutical list rather than by D (other than as permitted by paragraph 7 of Schedule 6); or
- (f) P is resident in a location that ceases to be or be part of a reserved location as a consequence of a determination referred to in regulation 42 as D2,

D must terminate the provision of pharmaceutical services to P, subject to any postponement of the discontinuation by the Primary Care Trust in accordance with paragraphs (2) to (6).

(2) A Primary Care Trust may postpone the discontinuation—

- (a) until any proceedings relating to the discontinuation, including proceedings arising out of the grant of a routine or excepted application that has led to the discontinuation, have reached their final outcome; or
- (b) where paragraph (3) or (4) applies.

(3) This paragraph applies where—

- (a) a Primary Care Trust grants a routine or excepted application, the result of which is the inclusion in its pharmaceutical list of pharmacy premises that are not already listed in relation to an NHS pharmacist;
- (b) the pharmacy premises to which that application relates are not distance selling premises but—
  - (i) are in a controlled locality, or
  - (ii) are within 1.6 kilometres of a part of a controlled locality in which patients of a dispensing doctor reside and those patients are being provided with pharmaceutical services by that dispensing doctor; and
- (c) granting the routine or excepted application, in the opinion of the Primary Care Trust, results in a significant change to the arrangements that are in place for the provision of pharmaceutical services (including by a person on a dispensing doctor list) or local pharmaceutical services in any part of a controlled locality.

(4) This paragraph applies where a Primary Care Trust is required to terminate the provision of pharmaceutical services pursuant to paragraph (1)(f) but the Primary Care Trust is satisfied that the determination that led to the decision to terminate has adversely affected D.

(5) Where paragraph (3) or (4) applies, the Primary Care Trust may postpone the discontinuation for such period as it thinks fit.

(6) The Primary Care Trust must postpone the discontinuation—

- (a) while it is forming the opinion mentioned in paragraph (3)(c); or
- (b) for such period as the Primary Care Trust considers necessary in order to give the doctor reasonable notice (in any case to which paragraph (1) applies) of the discontinuation.

(7) The Primary Care Trust must notify any decision under this regulation to terminate arrangements to provide pharmaceutical services, subject to any postponement of the discontinuation, to—

- (a) D;
  - (b) if there is any postponement of the discontinuation, the NHS pharmacist listed in relation to any pharmacy premises, the presence of which, or the choice of a patient to obtain services from which, led to the determination of the Primary Care Trust;
  - (c) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts); and
  - (d) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
- (8) Each notification under paragraph (7) must include—
- (a) a statement of the reasons for the decision; and
  - (b) if the person notified is a person with rights of appeal under regulation 63(1)(b), an explanation of how those rights may be exercised.

### **Outline consent and premises approval: applications by doctors**

**51.**—(1) A person or partnership with a patient list, or a person who performs services on behalf of a provider of primary medical services or a PCTMS practice, who wishes to be granted the right to provide pharmaceutical services to patients on their own list or the provider's or practice's list (if the patients apply under regulation 48(1) on the basis of Condition 2 or 3) may apply in writing to the Primary Care Trust in whose area the premises from which the person or partnership making the application (D) wishes to dispense are located for—

- (a) consent (“outline consent”) to the provision of pharmaceutical services to patients who request those services and who reside in the area specified in the application;
- (b) approval of any medical practice premises from which D wishes to dispense (“premises approval”).



(2) Where D has outline consent that has taken effect and wishes to apply for premises approval in relation to—

- (a) additional medical practice premises from which to provide pharmaceutical services to patients who reside in the area for which D has an outline consent; or
- (b) medical practice premises from which D wishes to relocate to provide pharmaceutical services to patients who reside in the area for which D has an outline consent, but the move to new medical practice premises is not a relocation of the type provided for in regulation 55(2),

the premises approval application need not have a related outline consent application (even if the relevant outline consent was granted by a different Primary Care Trust) but in all other cases a premises approval application under paragraph (1)(b) must have a related outline consent application.

(3) An application for premises approval must include details of the address of the premises and whether those premises are already listed in relation to a different area.

(4) Except in so far as these Regulations provide to the contrary, a Primary Care Trust is to determine applications for outline consent and premises approval in such manner (including with regard to procedures) as it sees fit.

(5) A Primary Care Trust must refuse an application under paragraph (1) (but not regulation 54, 55 or 58) for premises approval if the premises in respect of which approval is sought are within 1.6 kilometres of pharmacy premises that are not distance selling premises.

(6) A Primary Care Trust must refuse an application for outline consent to the extent that any part of the area specified in the application—

- (a) is not, or is not part of, a controlled locality; or
- (b) is within 1.6 kilometres of pharmacy premises that are not distance selling premises.

(7) Where a Primary Care Trust is minded to refuse an application for outline consent pursuant to paragraph (6)(a), it may defer that decision in order to make a determination under regulation 36(2).

(8) Subject to paragraph (9), a Primary Care Trust must refuse an application under paragraph (1) (but not regulation 54, 55 or 58) if granting it would, in its opinion, prejudice the proper provision of relevant NHS services in its area or in the area of a neighbouring Primary Care Trust.

(9) If a Primary Care Trust determines that an application for outline consent would, if it had been made for a smaller area within the area specified in the application, not prejudice the proper provision of relevant NHS services in its area or in the area of a neighbouring Primary Care Trust, it may grant the application in respect of that smaller area.

(10) A Primary Care Trust must refuse an application (A1) under paragraph (1)—

- (a) for outline consent to the extent that any part of the area specified in A1 is the same as the area or any part of the area specified in an application for outline consent which was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made; or
- (b) for premises approval (but not under regulation 54, 55 or 58) if the premises specified in A1 were specified in an application for premises approval, or relate to an application for outline consent where any part of the area specified in that application is the same as the area or any part of the area specified in an earlier application for outline consent, which was refused—
  - (i) under this regulation, or
  - (ii) by virtue of regulation 18(2) of the 2005 Regulations<sup>(a)</sup> (refusal: outline consent and premises approval where patients are in a controlled locality),

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<sup>(a)</sup> Prior to its repeal, regulation 18(2) was amended by S.I. 2005/1501 and 2010/914.



within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made, unless the Primary Care Trust is satisfied that there has been a substantial and relevant change of circumstances affecting the controlled locality to which the application relates since those proceedings reached their final outcome.

### **Notification of applications for outline consent and premises approval**

**52.**—(1) Where a Primary Care Trust (PCT1) receives an application for outline consent or premises approval (including an application for premises approval to which regulation 54 or 55 applies), as soon as is practicable, it must give notice of that application to—

- (a) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (b) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (c) any person—
  - (i) included in its pharmaceutical list, or
  - (ii) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;
- (d) any LPS chemist—
  - (i) with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, and
  - (ii) whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;
- (e) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT1, has a significant interest in the outcome of the application;
- (f) any provider of primary medical services, or any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services), who in the opinion of PCT1 has a significant interest in the outcome of the application; and
- (g) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the proposed listed dispensing premises to which the application relates.

(2) PCT1 may also give notice of the application to any other person who, in the opinion of PCT1, has a significant interest in the outcome of the application;

(3) A Primary Care Trust notified under paragraph (1)(g) (PCT2) must, within 14 days of receiving the notification—

- (a) give notice of the application to—
  - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
  - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
  - (iii) any person—
    - (aa) included in its pharmaceutical list, or
    - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,

- (iv) any LPS chemist—
  - (aa) with whom PCT2 has made arrangements for the provision of any local pharmaceutical services, and
  - (bb) whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
- (v) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT2, has a significant interest in the outcome of the application, and
- (vi) any provider of primary medical services, or any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services), who in the opinion of PCT2 has a significant interest in the outcome of the application; and

(b) notify PCT1 of the action that it has taken under sub-paragraph (a).

(4) A person (P) notified under paragraphs (1) to (3)(a) may make representations in writing about the application that is the subject of the notification to PCT1 to whom the application was made, provided P does so—

- (a) within 45 days of the date on which notice of the application was given to them; or
- (b) in the case of notifications under paragraph (2) or (3), within such longer period as PCT1 may specify.

(5) If PCT1 is considering, as a consequence of an application for outline consent or premises approval, making (including revising) a determination as to whether or not an area is or is not to be part of controlled locality, it must give notice under paragraph (1) at the same time that it gives notice under regulation 38(1).

(6) A person (P) notified under paragraphs (1) to (3)(a)—

- (a) must be informed of P’s right to make representations under paragraph (4); and
- (b) need not be given the same information as other persons notified under paragraphs (1) to (3)(a) but, subject to sub-paragraphs (7) to (9), P must be provided with sufficient information, from the information supplied by the applicant, to enable P to make informed representations with regard to whether or not the application should be granted, having regard to P’s interest in the matter.

(7) P need not be provided with any information that is published as part of PCT1’s pharmaceutical needs assessment.

(8) P must not be provided with any private addresses, private telephone numbers or dates of birth supplied by the applicant (A).

(9) If A advises the Primary Care Trust that—

- (a) information supplied by A is considered by A to be confidential to A; and
- (b) A does not consent to the information being disclosed as part of the notification,

the Primary Care Trust must withhold that information from P if it considers that the full disclosure principle does not require it to provide that information to P.

(10) The “full disclosure principle” is that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application, unless it is fair and proper for that information to be withheld from that individual.

(11) If information is being withheld from P under paragraph (9), P must be informed of the nature of the information that is being withheld from P.

### **Decisions on outline consent and premises approval applications and the taking effect of grants**

**53.**—(1) Once a Primary Care Trust (PCT1) has determined an application for outline consent or premises approval, as soon as is practicable, it must give notice of that decision to—

- (a) the applicant; and
  - (b) any person notified by it under regulation 52(1) or (2) in relation to the application.
- (2) A Primary Care Trust notified under paragraph (1) must give notice of the decision to any person notified in relation to the application by it under regulation 52(3)(a).
- (3) Each notification under paragraph (1) or (2) must include a statement of the reasons for the decision and, if the person notified is a person with rights of appeal in relation to the decision under regulation 63(1)(c) or (d), an explanation of how those rights may be exercised.
- (4) When outline consent is granted, subject to paragraphs (12) and (14)(b), PCT1 must determine when the outline consent is to take effect.
- (5) Subject to regulation 54, premises approval takes effect, if the application for it had a related outline consent application, when the related outline consent takes effect (but otherwise it does so in accordance with regulation 56).
- (6) Outline consent takes effect on the day the proceedings relating to the grant of it have reached their final outcome, unless on the day before that day within 1.6 kilometres of the relevant practice premises there are premises which are the subject of an outstanding pharmacy application.
- (7) For the purposes of this regulation, the “relevant practice premises” are the premises—
- (a) which are the subject of a related premises approval application; or
  - (b) if there is no related premises approval application, that are the medical practice premises of the dispensing doctor from which the dispensing doctor wishes to dispense to patients in the area in relation to which outline consent is sought.
- (8) In these Regulations, “outstanding pharmacy application” means—
- (a) an application which has not yet reached its final outcome—
    - (i) for inclusion in a pharmaceutical list (not necessarily that of PCT1), or
    - (ii) from a person included in a pharmaceutical list—
      - (aa) to relocate to different premises in the area of the Primary Care Trust whose list it is, or
      - (bb) to open, within the area of that Primary Care Trust, additional premises from which to provide pharmaceutical services,
 where the applicant is seeking the listing of pharmacy premises other than distance selling premises; or
  - (b) circumstances where an application of the type mentioned in paragraph (a) has been granted, and—
    - (i) the provision of pharmaceutical services from the premises for which listing was sought has not yet commenced, and
    - (ii) the grant has not yet lapsed.
- (9) In a case where outline consent is not to take effect on the date on which it is granted, PCT1 must give the dispensing doctor to whom outline consent was granted (D) written details of—
- (a) the outstanding pharmacy application; and
  - (b) the earliest date (referred to in this Part as the “provisional date”) on which an application can be made by D for a determination of when the outline consent is to come into effect.
- (10) That provisional date, subject to paragraph (11), is the day after the end of the period of one year beginning on the day of—
- (a) the determination by PCT1 of D’s application of outline consent; or
  - (b) where that determination is the subject of an appeal, the day on which the appeal reaches its final outcome.
- (11) PCT1 may at any time before the provisional date determine that the provisional date be changed to a later date, but only to a date which is not more than 3 months after the date originally determined in accordance with paragraph (9).

(12) Outline consent lapses if, before the provisional date, pharmaceutical services are provided at the pharmacy premises to which the outstanding pharmacy application relates.

(13) On or as soon as is reasonably practicable after the provisional date, PCT1 must notify D that D may within 3 months of the provisional date request in writing that PCT1 determine whether the outline consent is to come into effect.

(14) Where PCT1 receives a request under paragraph (13), it must, as soon as is reasonably practicable determine—

- (a) unless paragraph (b) applies, that the outline consent is to come into immediate effect; or
- (b) that the outline consent has lapsed—
  - (i) where on the date of the determination (which must be a day from Monday to Friday, except Good Friday, Christmas Day or a bank holiday) primary medical services are not being provided at the relevant practice premises, or
  - (ii) by virtue of paragraph (12),

and it must inform D accordingly.

(15) A Primary Care Trust must notify the applicant for outline consent of its determination under paragraph (11) or (14) and must include with the notification of its determination an explanation of—

- (a) the reasons for the determination; and
- (b) the applicant's rights of appeal in relation to it under regulation 63(1)(e).

**Premises approval: relocations of practice premises which are not significant before outline consent takes effect**

**54.**—(1) If outline consent has been granted but has not yet taken effect, before the provisional date the person or partnership (D) to whom it was granted may apply to the Primary Care Trust that granted it to change the premises from which D wishes to dispense.

(2) The Primary Care Trust may agree to the change (and so, where appropriate, grant premises approval to the new premises) if it is satisfied that the relocation is of the type provided for in regulation 55(2).

(3) Where a Primary Care Trust agrees to a change pursuant to paragraph (2), the premises approval takes effect when the related outline consent takes effect or, if later, on the date on which the change is agreed by the Primary Care Trust.

(4) The Primary Care Trust must notify its decision in relation to the application under paragraph (1) to the persons to whom it notified the application who made representations in relation to it under regulation 52(4), and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision; and
- (b) if the person notified is a person with rights of appeal under regulation 63(1)(c) or (d), an explanation of how those rights may be exercised.

**Premises approval: relocations of practice premises which are not significant after outline consent has taken effect**

**55.**—(1) A dispensing doctor (D) who—

- (a) is providing pharmaceutical services from listed dispensing premises; and
- (b) wishes to relocate and dispense from new medical practice premises in relation to the area for which D has outline consent,

may apply in writing to the Primary Care Trust in whose area the new medical practice premises are located (whether or not it is the same Primary Care Trust as the Primary Care Trust that granted D outline consent) for premises approval for the new medical practice premises from which D wishes to dispense.

(2) Subject to paragraph (3), the Primary Care Trust must grant that application if it is of the type described in this paragraph, that is to say if the Primary Care Trust is satisfied that—

- (a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- (b) granting the application would not result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (including by a person on a dispensing doctor list) or of local pharmaceutical services—
  - (i) in any part of its area, or
  - (ii) in a controlled locality of a neighbouring Primary Care Trust, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate; and
- (c) the Primary Care Trust is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area.

(3) A Primary Care Trust must, unless it has good cause not to do so, refuse an application under paragraph (1) if an application under that paragraph or regulation 65(4)(a) of the 2005 Regulations<sup>(a)</sup> (premises approval: additional and new premises after outline consent has taken effect) has been granted to D during the 12 months before the application was submitted under paragraph (1).

(4) The Primary Care Trust must notify its decision in relation to the application under paragraph (1) to the persons to whom it notified the application who made representations in relation to it under regulation 52(4), and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision; and
- (b) if the person notified is a person with rights of appeal under regulation 63(1)(c) or (d), an explanation of how those rights may be exercised.

### **Taking effect of premises approval where there is no related application for outline consent**

**56.—**(1) Where—

- (a) premises approval is granted in relation to additional medical practice premises, or in relation to medical practice premises to which a dispensing doctor (D) is relocating; and
- (b) the application for premises approval had no related application for outline consent,

paragraph (2) applies.

(2) In the circumstances described in paragraph (1), the approval takes effect—

- (a) on the date the determination of the application takes effect, and that date is—
  - (i) if no appeal is made against the decision within the period for bringing an appeal, the date on which that period expires, or
  - (ii) if the decision is appealed within that period, the date on which the appeal reaches its final outcome; or
- (b) if on the day before that day within 1.6 kilometres of the relevant medical practice premises there are premises which are the subject of an outstanding pharmacy application, on the date which is—
  - (i) the day after the end of a period of one year from the date on which that outstanding pharmacy application reaches its final outcome, or
  - (ii) such longer period (not exceeding 3 months) as the Primary Care Trust may for good cause allow before the expiry of that year.

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<sup>(a)</sup> Prior to its repeal, regulation 65 was amended by S.I. 2006/3373.

(3) Premises approval to which paragraph (1) applies lapses if before the date on which it would otherwise take effect by virtue of paragraph (2), pharmaceutical services are provided at the pharmacy premises to which the outstanding pharmacy application relates.

### **Gradual introduction of premises approval**

**57.**—(1) Where a dispensing doctor (D) has outline consent but PCT1 considers that the provision of pharmaceutical services by any NHS pharmacist, or of LP services by any LPS chemist, is likely to be adversely affected if D provides pharmaceutical services from medical practice premises which have been subject to a related application for premises approval (whether under regulation 51, 54 or 55), PCT1 may by conditions—

- (a) postpone the taking effect of the related premises approval for such period as it thinks fit; or
- (b) limit the patients to whom D (or any successor to D) is able to provide pharmaceutical services from the medical practice premises in such manner, and for such periods, as it thinks fit.

(2) The Primary Care Trust must decide whether or not to impose conditions under paragraph (1)—

- (a) if there was a delay in the related outline consent taking effect because of an outstanding pharmacy application, when it determines that the outline consent is to come into effect; or
- (b) in any other case, when it determines the application for premises approval.

(3) The Primary Care Trust must notify any decision to impose, or not to impose, conditions under paragraph (1) to—

- (a) D;
- (b) any person with third party appeal rights in relation to the related application for premises approval;
- (c) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (d) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),

(4) A notification under paragraph (3) must include—

- (a) a statement of the reasons for the decision; and
- (b) if the person notified is a person with rights of appeal under regulation 63(1)(f), an explanation of how those rights may be exercised.

### **Temporary provision in cases of relocations or additional premises where premises approval has not taken effect**

**58.**—(1) In the circumstances described in regulation 56(1), if the premises approval has not taken effect because of an outstanding pharmacy application which has not lapsed, the Primary Care Trust may grant the applicant (D) temporary premises approval—

- (a) if it considers it is desirable to do so in order to secure the adequate provision of pharmaceutical services in the area for which D has outline consent;
- (b) for a period of not exceeding 12 months, but which may be renewed for a further period not exceeding 3 months (and if the first period granted is less than 12 months, it may be renewed more than once for up to a total aggregate period of 15 months).

(2) If a Primary Care Trust grants temporary premises approval under paragraph (1), it must notify—

- (a) D;
- (b) the applicant who made the outstanding pharmacy application;



- (c) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
  - (d) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
- (3) A notification under paragraph (2) must include—
- (a) a statement of the reasons for the decision; and
  - (b) a statement of the duration of the temporary premises approval and any circumstances in which it might be extended; and
- (4) If a Primary Care Trust refuses an application to grant temporary premises approval under paragraph (1), the Primary Care Trust must notify that decision to the applicant and include with that notification—
- (a) a statement of the reasons for the decision; and
  - (b) an explanation of how D’s rights of appeal under regulation 63(1)(c)(iii) may be exercised.

### **Practice amalgamations**

**59.**—(1) A “practice amalgamation” occurs where 2 or more patient lists are combined as a result of the coming together, as a single provider of primary medical services (SP), of 2 or more dispensing doctors.

(2) If, following a practice amalgamation, the medical practice premises of SP are all premises that immediately prior to the amalgamation were listed dispensing premises, the premises approvals for those premises and the related outline consents become the premises approvals and outline consents of SP.

(3) If, following practice amalgamation, paragraph (2) does not apply but one or more of the dispensing doctors coming together as SP had, immediately prior to amalgamation, listed dispensing premises—

- (a) if any listed dispensing premises become medical practice premises of SP—
  - (i) the premises approvals for those premises, and the related outline consents, become approvals and consents of SP, and
  - (ii) any applications for premises approval in respect of other medical practice premises of SP are to be treated under this Part as applications for additional premises;
- (b) if none of the listed dispensing premises become medical practice premises of SP—
  - (i) SP may nominate one of its medical practice premises as premises in respect of which it may apply for premises approval and have that application treated as a relocation from listed dispensing premises of a dispensing doctor who was part of the coming together to form SP, and
  - (ii) any applications for premises approval in respect of other medical practice premises of SP are to be treated under this Part as applications for additional premises.

(4) Where a practice amalgamation is proposed, a dispensing doctor who intends to be part of the practice amalgamation may make an application on the basis of paragraph (3)(b) in anticipation of circumstances that are expected to arise following the practice amalgamation, and if the dispensing doctor does so—

- (a) any premises approval granted as a consequence becomes, when the practice amalgamates, a premises approval granted to SP; or
- (b) if the proposed amalgamation does not take place, or if the dispensing doctor who makes the application does not become party to a practice amalgamation that does take place, any premises approval granted on the basis of that application lapses.

(5) If an application for premises approval arises because a practice amalgamation has taken or is due to take place, it must include the names of all the medical practitioners and any other providers of primary medical services who are participating in the amalgamation.



### **Lapse of outline consent and premises approval**

**60.**—(1) Outline consent lapses (in addition to as mentioned in regulation 53(12) and (14)(b)) if—

- (a) no arrangement has been made under regulation 48 with a patient pursuant to that outline consent within 6 months of the date on which it takes effect;
- (b) 6 months have elapsed since any drug or appliance was dispensed under the arrangements made pursuant to that outline consent; or
- (c) following a practice amalgamation, the amalgamated practice has no medical practice premises with premises approval and there are no outstanding applications to which regulation 59(3)(b) applies in respect of premises approval from the amalgamated practice.

(2) If an area, or part of an area, for which a dispensing doctor (D) has outline consent becomes a location in relation to which it is no longer possible for D to provide pharmaceutical services to patients on a patient list, D ceases to have outline consent in relation to that location.

(3) Premises approval lapses (in addition to as mentioned in regulation 56(3) and 59(4)(b)) if—

- (a) the premises are no longer medical practice premises of a dispensing doctor with outline consent;
- (b) 6 months have elapsed, or such longer period as the Primary Care Trust may for good cause allow, since any drug or appliance was dispensed under the arrangements made pursuant to regulation 48 at those premises;
- (c) the provider of primary medical services whose premises, or (if different) the dispensing doctor in relation to whom they are listed, notifies the Primary Care Trust on whose dispensing doctors list the premises are listed that all the medical practitioners with authority to dispense from those premises have ceased to do so;
- (d) the dispensing doctor in relation to whom the premises are listed in the dispensing doctors list is no longer listed in that list; or
- (e) the related outline consent lapses.

(4) A right which continues in effect by virtue of regulation 48(3)(b)(i) is to be treated as outline consent for the purposes of paragraphs (1) and (3).

(5) For the purposes of—

- (a) paragraph (1)(a), no account is to be taken of a period when D is unable to make arrangements to provide pharmaceutical services, or
- (b) paragraph (1)(b) or (3)(b), no account is to be taken of a period when D is unable to provide pharmaceutical services,

because of a condition imposed by virtue of regulation 20(2) of the 2005 Regulations<sup>(a)</sup> (imposition of conditions) or by virtue of regulation 57.

### **Temporary arrangements during an emergency requiring the flexible provision of pharmaceutical services**

**61.**—(1) During an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may require a dispensing doctor on its dispensing doctor list to provide pharmaceutical services (“temporary services”) to patients to whom the dispensing doctor is not otherwise entitled to provide pharmaceutical services—

- (a) where, as a result of the temporary closure of pharmacy premises in its area, the Primary Care Trust considers that, in order to secure continuing adequate provision of pharmaceutical services in its area during the emergency, it is necessary for it to require provision of those temporary services; and

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<sup>(a)</sup> Prior to its repeal, regulation 20 was amended by S.I. 2006/552.

- (b) for a specified period (which must not be longer than the specified period of the emergency given by the Secretary of State), which the Primary Care Trust may extend or curtail in appropriate circumstances.

(2) The Primary Care Trust must terminate arrangements to provide temporary services if the doctor notifies it that the doctor is unwilling to provide those services (and so wishes to revert to the doctor's overridden arrangements for the provision of pharmaceutical services).

(3) A Primary Care Trust may grant temporary premises approval—

- (a) in relation to additional premises that are not listed dispensing premises; or
- (b) to premises to which a doctor wishes to relocate temporarily from listed dispensing premises,

if it is satisfied that it is necessary or desirable to do so because of an emergency requiring the flexible provision of pharmaceutical services.

(4) In the circumstances described in paragraph (3)—

- (a) the temporary premises approval must be for a specified period (which must not be longer than the specified period of the emergency given by the Secretary of State), which the Primary Care Trust may extend or curtail in appropriate circumstances; and
- (b) the dispensing doctor may revert to the overridden premises approval before the end of the period specified by the Primary Care Trust, on giving the Primary Care Trust at least 24 hours notice.

(5) There is no right of appeal under these Regulations in respect of a decision under this regulation—

- (a) to require, or not to require, a dispensing doctor to provide temporary services;
- (b) to extend or curtail the duration of any requirement to provide temporary services;
- (c) to grant or refuse an application for temporary premises approval; or
- (d) to extend or curtail, or not to extend or curtail, temporary premises approval.

### **Persons barred from taking part in decision making with regard to applications for outline consent or premises approval**

**62.—**(1) No person is to take part in determining any application for outline consent (including determining when it is to come into effect), premises approval or temporary premises approval, or in taking decisions under regulation 50, 53 or 57, who—

- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
- (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
- (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
- (d) is a provider of primary medical services;
- (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- (f) is employed or engaged by a primary medical services provider or a PCTMS practice; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

whether or not their involvement would give rise to a reasonable suspicion of bias.

(2) No other person is to take part in determining any application, or taking any decision, referred to in paragraph (1) if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

## Appeals against decisions under Part 8

63.—(1) A person with appeal rights (as provided for in this regulation) may appeal to the Secretary of State against the following decisions by a Primary Care Trust (PCT1)—

- (a) a decision under regulation 48(5)(b) to require a dispensing doctor to undertake to provide pharmaceutical services, in respect of which the only person with appeal rights is the dispensing doctor;
- (b) a decision under regulation 50, requiring the termination of arrangements to provide pharmaceutical services, subject to any postponement of the discontinuation, in respect of which the only people with appeal rights are—
  - (i) the dispensing doctor who is being required to terminate arrangements, subject to any postponement of the discontinuation, and
  - (ii) if there is any postponement of the discontinuation, the NHS pharmacist listed in relation to any pharmacy premises, the presence of which, or the choice of a patient to obtain services from which, led to the determination of PCT1;
- (c) a decision to refuse an application for—
  - (i) outline consent under regulation 51,
  - (ii) premises approval under regulation 51, 54 or 55, or
  - (iii) temporary premises approval under regulation 58,in respect of which the only person with appeal rights is the applicant;
- (d) a decision to grant an application for—
  - (i) outline consent under regulation 51, or
  - (ii) premises approval under regulation 51, 54 or 55,in respect of which the only person with appeal rights is a person who has third party appeal rights;
- (e) a determination of—
  - (i) a change to a provisional date under regulation 53(11), or
  - (ii) whether outline consent is to come into effect under regulation 53(14),in respect of which the only person with appeal rights is the person to whom the relevant outline consent was granted; and
- (f) a decision to impose, or a failure to impose, conditions under regulation 57, in respect of which the only people with appeal rights are—
  - (i) the dispensing doctor, and
  - (ii) an NHS pharmacist or LPS chemist who has third party appeal rights in relation to the related application for premises approval,

provided they notify the Secretary of State with a valid notice of appeal within 30 days of the date on which the person bringing the appeal was notified of the decision that is being appealed.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

(3) For the purposes of paragraph (1)(d) or (f), a person (P1) has third party appeal rights if—

- (a) P1 was a person whom PCT1 was required to notify about the relevant application for outline consent or premises approval by virtue of P1 being—
  - (i) included in its pharmaceutical list,
  - (ii) entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but not (yet) included,
  - (iii) an LPS chemist with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, or

(iv) (except in relation to paragraph (1)(f)), a provider of primary medical services, or any other person on PCT1's dispensing doctors list if it has one (being a performer but not a provider of primary medical services),

and a person whose interests might, in the opinion of PCT1, be significantly affected by the decision;

(b) P1 made representations in writing about the application under regulation 52(4); and

(c) subject to sub-paragraph (5), PCT1 is satisfied, having regard to those representations in writing and any oral representations made at any oral hearing, that P1—

(i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and

(ii) has grounds for opposing the application, which—

(aa) do not amount to a challenge to the legality or reasonableness of PCT1's pharmaceutical needs assessment, or to the fairness of the process by which PCT1 undertook that assessment, and

(bb) are not vexatious or frivolous.

(4) If PCT1 considers that a person notified under regulation 52(1) to (3)(a) is a person with third party appeal rights, it must notify that person of that fact when it notifies that person of a decision (D1) in respect of which that person may be able to exercise those rights.

(5) A person to whom paragraph (3)(a) and (b) applies (P2) who is not notified by the Primary Care Trust that they are person with third party appeal rights may appeal to the Secretary of State against the determination (D2) by the Primary Care Trust that it is not satisfied as mentioned in sub-paragraph (3)(c), provided that P2—

(a) notifies the Secretary of State within 30 days of the date on which that person was notified of PCT1's decision that P2 wishes to appeal against both D1 and D2; and

(b) includes within that notification concise and reasoned statements of P2's grounds of appeal against both D1 and D2,

and if the appeal against D2 is successful, P2 is a person with third party appeal rights in relation to D1 for the purposes of this regulation.

(6) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under this Part (as it does in relation to appeals against decisions under Parts 2 to 5, 7, 10 and 12 and Schedule 2).

## PART 9

Conditional inclusion in pharmaceutical lists: certain specific conditions that do not relate to fitness or performance

### Distance selling premises: specific conditions

64.—(1) If an application in respect of distance selling premises—

(a) to which regulation 25(1) applies is granted; or

(b) to which regulation 13(1)(d) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted,

paragraph (2) applies.

(2) The inclusion in the pharmaceutical list of the person (X) listed in relation to—

(a) those distance selling premises; or

(b) if there has been a relocation of the retail pharmacy business or appliance contractor business at those distance selling premises to other premises, those other premises,

is subject to the conditions set out in paragraph (3).

- (3) Those conditions are—
- (a) X must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises;
  - (b) the means by which X provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises;
  - (c) the listed chemist premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
  - (d) in the case of pharmacy premises, the pharmacy procedures for the premises must be such as to secure—
    - (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
    - (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and X or X's staff; and
  - (e) nothing in X's practice leaflet, in X's publicity material in respect of the listed chemist premises, in material published on behalf of X publicising services provided at or from the listed chemist premises or in any communication (written or oral) from X or X's staff to any person seeking the provision of essential services from X must represent, either expressly or impliedly, that—
    - (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
    - (ii) X is likely to refuse, for reasons other than those provided for in X's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from X is limited to other categories of patients).
- (4) A Primary Care Trust may not vary or remove the conditions set out in paragraph (3).

### **Core opening hours conditions**

**65.**—(1) If an application to which regulation 13(1)(b) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted, the inclusion in the pharmaceutical list of the person listed in relation to—

- (a) the premises that were listed as a consequence of that application; or
- (b) if there has been a relocation of the retail pharmacy business or appliance contractor business at those premises to other premises, those other premises,

is subject to the condition set out in paragraph (2) (“the 100 hours condition”).

(2) The condition is that the premises must be kept open for at least 100 hours per week for the provision of pharmaceutical services.

(3) A Primary Care Trust may not vary or remove the 100 hours condition.

(4) Where, in the course of making a routine application or an excepted application to which regulation 24 or 26(2) applies—

- (a) for inclusion in a pharmaceutical list as mentioned in regulation 10(2)(a), or from a person already included in such a list to relocate to different pharmacy premises or to open, within the area of the Primary Care Trust, additional pharmacy premises—
  - (i) an NHS pharmacist undertook to provide pharmaceutical services at the proposed pharmacy premises for a specified number of core opening hours each week which is more than 40 (other than as a consequence of a 100 hours condition originally imposed by virtue of the 2005 Regulations),

- (ii) the NHS pharmacist and the Primary Care Trust agreed that pharmaceutical services are to be provided at the proposed pharmacy premises during the additional opening hours specified (that is, the hours which are the difference between the total number of hours specified and 40) at set times and on set days, and
  - (iii) the application was granted having regard to that undertaking and that agreement, when it includes the premises in its pharmaceutical list, the Primary Care Trust must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during the additional opening hours at the set times and on the set days so agreed;
- (b) for inclusion in a pharmaceutical list as mentioned in regulation 10(2)(b), or from a person already included in such a list to relocate to different appliance contractor premises or to open, within the area of the Primary Care Trust, additional appliance contractor premises—
- (i) an NHS appliance contractor undertook to provide pharmaceutical services at proposed appliance contractor premises for a specified number of core opening hours each week which is more than 30 (other than as a consequence of a 100 hours condition originally imposed by virtue of the 2005 Regulations),
  - (ii) the NHS appliance contractor and the Primary Care Trust agreed that pharmaceutical services are to be provided at the appliance contractor premises during the additional opening hours specified (that is, the hours which are the difference between the total number of hours specified and 30) at set times and on set days, and
  - (iii) the application was granted having regard to that undertaking and that agreement, when it includes the premises in its pharmaceutical list, the Primary Care Trust must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during the additional opening hours at the set times and on the set days so agreed.
- (5) Where a Primary Care Trust has—
- (a) invited an NHS chemist to increase the total number of core opening hours during which the NHS chemist is to provide pharmaceutical services at listed chemist premises; and
  - (b) thereafter agreed with the NHS chemist—
    - (i) an increased number of core opening hours, and
    - (ii) if the NHS chemist—
      - (aa) is an NHS pharmacist, that pharmaceutical services are to be provided at the pharmacy premises during any additional opening hours (that is, the hours which are the difference between the total number of hours specified and 40) at set times and on set days, and
      - (bb) is an NHS appliance contractor, that pharmaceutical services are to be provided at the appliance contractor premises during any additional opening hours (that is, the hours which are the difference between the total number of hours specified and 30) at set times and on set days,

the Primary Care Trust must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during any additional opening hours at the set times and on the set days so agreed.

(6) Except as provided for under paragraph (5) and subject to paragraph (7), a Primary Care Trust may only vary a direction given under paragraph (4) or (5) in accordance with paragraph 25 or 26 of Schedule 4 or paragraph 15 or 16 of Schedule 5.

(7) A direction given under paragraph (4) or (5) must not be varied within 3 years of the direction being given.



## Conditions relating to providing directed services

66.—(1) Where, immediately before these Regulations came into force, the inclusion in the pharmaceutical list of an NHS chemist (C1) was subject to a condition imposed in relation to listed chemist premises by virtue of regulation 13(3)(b) of the 2005 Regulations (exemption from the necessary or expedient test), including such a condition as varied in accordance with regulation 14 of the 2005 Regulations<sup>(a)</sup> (variation of directed services in respect of exempted premises), it is a condition of the inclusion in the pharmaceutical list of the person listed in relation to those premises—

- (a) if, before these Regulations came into force, C1 had not been requested by the Primary Care Trust to provide the directed services specified as regards C1 for the purposes of that condition, that they must provide those directed services at those premises, where requested to do so by the Primary Care Trust;
- (b) if, before these Regulations came into force, C1 was providing, or had been requested by the Primary Care Trust to provide, the directed services specified as regards C1 for purposes of that condition, that they must provide those directed services at those premises.

(2) The person listed in relation to the premises may apply to a Primary Care Trust to vary the directed services specified for the purposes of the condition imposed by virtue of paragraph (1), or to remove the condition, but only if at least 3 years have elapsed—

- (a) since the condition was imposed by virtue of the 2005 Regulations; and
- (b) during that period the Primary Care Trust has not requested that the services be provided at the premises in respect of which the condition was imposed,

but otherwise the Primary Care Trust may not vary or remove the condition imposed by virtue of paragraph (1).

(3) If, pursuant to an application under paragraph (2), the Primary Care Trust does vary the directed services specified for the purposes of the condition imposed by virtue of paragraph (1) in respect of any premises, it is a condition of the inclusion in the pharmaceutical list of the person listed in relation to those premises that they must—

- (a) provide the directed services specified as regards C1 as a consequence of the application, if the Primary Care Trust commissions the services within 3 years of the date on which the condition is imposed by virtue of these Regulations;
- (b) not withhold agreement to a service specification for those services unreasonably.

(4) Where, in the course of making a routine or excepted application, an NHS chemist undertook—

- (a) to provide the directed services mentioned in the application, if the Primary Care Trust commissioned the services within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates; and
- (b) if the directed services were commissioned, to provide the services in accordance with an agreed service specification; and
- (c) not to withhold agreement to a service specification unreasonably,

the inclusion in the pharmaceutical list of the person (C2) listed in relation to the premises that were listed as a consequence of that application is subject to the condition set out in paragraph (5).

(5) The condition is that, at those premises, C2 must—

- (a) provide the directed services mentioned in the application (whether or not C2 was the applicant); and
- (b) not to withhold agreement to a service specification for those services unreasonably,

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<sup>(a)</sup> Prior to its repeal, regulation 14 was amended by S.I. 2006/3373.



if the Primary Care Trust commissions the services from C2 within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates.

(6) Where a Primary Care Trust specifies that a requirement to provide directed services arising out of a condition imposed by virtue of this regulation is to take effect by a specified date, the requirement takes effect—

- (a) on that date; or
- (b) on the date on which provision of the directed service is commenced,

whichever is the sooner.

(7) A Primary Care Trust may not vary or remove the condition imposed by virtue of paragraphs (3) to (5).

### **Conditions relating to voluntary closure of premises**

**67.**—(1) Except in the circumstances described in paragraph (3), where an NHS chemist (C) wishes, other than as a consequence of a change of ownership application—

- (a) to withdraw from a pharmaceutical list, or
- (b) for particular listed chemist premises no longer to be listed in relation to C,

C must comply with paragraph (2).

(2) C must notify the Primary Care Trust of C's wish—

- (a) unless sub-paragraph (b) applies, at least 3 months in advance of the date on which pharmaceutical services are no longer to be provided;
- (b) at least—
  - (i) 6 months in advance of that date, if in respect of C the 100 hours condition is imposed as regards those premises, or
  - (ii) 30 days in advance of that date, if—
    - (aa) a condition is imposed under regulation 35,
    - (bb) C appeals that condition to the First-tier Tribunal,
    - (cc) on appeal, the First-tier Tribunal confirms the imposition of that condition or imposes another condition, and
    - (dd) within 30 days of being informed of the decision of the First-tier Tribunal, C notifies the Primary Care Trust that C wishes to withdraw from its pharmaceutical list within a shorter period of not less than 30 days,

unless it is impracticable for C to do so in which case C must notify the Primary Care Trust as soon as it is practicable for C to do so.

(3) If C has consented to—

- (a) particular listed chemist premises no longer being listed in relation to C by a Primary Care Trust (PCT1); or
- (b) being removed from the pharmaceutical list of PCT1,

in the context of a relocation application, paragraph (4) applies.

(4) In the circumstances described in paragraph (3), C must, where the relocation application is granted—

- (a) if C is relocating to the area of a different Primary Care Trust (PCT2)—
  - (i) notify PCT1 of the grant as soon as is practicable after C is notified of the grant by PCT2, and
  - (ii) when C gives notice to PCT2 of C's intention to commence the provision of pharmaceutical services at the new premises (in accordance with paragraph 34 of Schedule 2), give notice to PCT1 of when, before C commences the provision of

pharmaceutical services at the new premises, C is to cease to provide pharmaceutical services at the existing premises; and

- (b) if C is relocating within the area of PCT1, when C gives notice to PCT1 of C's intention to commence the provision of pharmaceutical services at the new premises (in accordance with paragraph 34 of Schedule 2), also give notice to PCT1 of when, before C commences the provision of pharmaceutical services at the new premises, C is to cease to provide pharmaceutical services at the existing premises.

#### **Conditions relating to local resolution of disputes over terms of service**

**68.**—(1) It is a condition of the inclusion of each NHS chemist (C) in a pharmaceutical list by a Primary Care Trust (PCT1) that C makes every reasonable effort to communicate and co-operate with PCT1 with a view to resolving any dispute between C and PCT1 relating to C's compliance with the terms of service under which C provides pharmaceutical services for PCT1.

- (2) A Primary Care Trust may not vary or remove the condition imposed by virtue of paragraph (1).

## **PART 10**

### **Performance related sanctions and market exit**

#### **Local dispute resolution before serving remedial notices or breach notices**

**69.**—(1) Subject to paragraph (3), before issuing a notice under regulation 70 or 71, a Primary Care Trust (PCT1) must make every reasonable effort to communicate and co-operate with an NHS chemist on its pharmaceutical list (C) with a view to resolving any dispute between C and PCT1 relating to C's compliance with C's terms of service.

(2) Where an NHS pharmacist invites the Local Pharmaceutical Committee for its area to participate in the attempts to resolve the dispute, PCT1 must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the dispute.

(3) Paragraphs (1) and (2) do not apply where PCT1 is satisfied—

- (a) the dispute relates to a matter that has already been the subject of dispute resolution between PCT1 and C and there are no new issues of substance that justify delay in issuing a notice under regulation 70 or 71; or
- (b) that it is appropriate to proceed immediately to issuing a notice under regulation 70 or 71—
  - (i) because listed chemist premises are not, or have not been, open during core opening hours or supplementary opening hours without good cause,
  - (ii) to protect the safety of any persons to whom C may provide pharmaceutical services, or
  - (iii) to protect PCT1 from material financial loss.

#### **Breaches of terms of service: remedial notices**

**70.**—(1) Where an NHS chemist (C) breaches a term of service and the breach is capable of remedy, the Primary Care Trust (PCT1) with which C has the arrangements to provide the pharmaceutical services to which the breach relates may by a notice ("a remedial notice") require C to remedy the breach.

(2) To be valid, the remedial notice must include—

- (a) the nature of the breach;
- (b) the steps C must take, to the satisfaction of PCT1, in order to remedy the breach;
- (c) the period ("the notice period") during which the steps must be taken; and

- (d) an explanation of how C's rights of appeal under regulation 77(1)(a) may be exercised.
- (3) The notice period must be not less than 30 days, unless PCT1 is satisfied that a shorter period is appropriate—
  - (a) to protect the safety of any persons to whom C may provide pharmaceutical services; or
  - (b) to protect PCT1 from material financial loss.
- (4) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that C is required to provide, the remedial notice may provide that—
  - (a) as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, PCT1 is to withhold all or part of the remuneration due to C in respect of that period under the Drug Tariff or a determination as mentioned in regulation 91(2);
  - (b) pending C taking the steps that C must take, to the satisfaction of PCT1, in order to remedy the breach, PCT1 is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(2), and in these circumstances—
    - (i) as regards any period for which C remains in breach, any withholding that is attributable to that period is to be permanent, and
    - (ii) once C has taken the steps that C must take, to the satisfaction of PCT1, any withholding that has taken place which is attributable to a period when C is no longer in breach is to be restored to C, provided that C submits a claim, in accordance with the Drug Tariff or a determination as mentioned in regulation 91(2), for restoration of the withheld remuneration attributable to that period.
- (5) The remedial notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 91(2) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.
- (6) The period referred to in paragraph (4)(b)(i) may be a longer period than the notice period.
- (7) If PCT1 refuses to restore all or part of any withheld remuneration which is claimed under paragraph (4)(b)(ii), it must notify C of that decision as soon as is practicable, and that notification must include—
  - (a) a statement of the reasons for the decision; and
  - (b) an explanation of how C's rights of appeal under regulation 77(1)(b) may be exercised.

**Breaches of terms of service: breach notices**

**71.—**(1) Where an NHS chemist (C) breaches a term of service and the breach is not capable of remedy, the Primary Care Trust (PCT1) with which C has the arrangements to provide the pharmaceutical services to which the breach relates may by a notice (“a breach notice”) require C not to repeat the breach.

- (2) To be valid, the breach notice must include—
  - (a) the nature of the breach; and
  - (b) an explanation of how C's rights of appeal under regulation 77(1)(c) may be exercised.
- (3) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that C is required to provide, the breach notice may provide that, as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, PCT1 is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(2) in respect of that period.
- (4) The breach notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 91(2) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.

### **Payment withholdings: supplementary matters**

72.—(1) A remedial notice or breach notice may only provide for the withholding of all or any part of the remuneration of an NHS chemist (C) if—

- (a) the Primary Care Trust is satisfied that the breach to which the withholding relates is, or was, without good cause;
- (b) the amount withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it;
- (c) the Primary Care Trust includes in the notice its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and (where applicable) are to be, withheld.

(2) The Primary Care Trust need not take into account the reasons for the breach, pursuant to paragraph (1)(b), if it has made every reasonable effort to communicate with C to discover the reasons but it has been unable to discover them.

(3) Withholdings of payments provided for in remedial notices and breach notices are without prejudice to the arrangements in place for recovering overpayments under regulation 94 and the Drug Tariff.

### **Removal of listings: cases relating to remedial notices and breach notices**

73.—(1) A Primary Care Trust (PCT1) may remove an NHS chemist (C) from its pharmaceutical list, or remove the listing of particular listed chemist premises in relation to C, if C—

- (a) fails to take the steps set out in a remedial notice that C must take, to the satisfaction of the PCT1, in order to remedy the breach, and PCT1 is satisfied that it is necessary to remove C from its pharmaceutical list, or remove the listing of particular listed chemist premises in relation to C—
  - (i) to protect the safety of any persons to whom C may provide pharmaceutical services, or
  - (ii) to protect PCT1 from material financial loss; or
- (b) has breached C's terms of service, and—
  - (i) C has repeatedly been issued with remedial notices or breach notices (or both) in relation to the relevant term of service,
  - (ii) previously been issued with a remedial notice or breach notice in relation to the relevant term of service, and PCT1 is satisfied that C is likely to persist in breaching the term of service without good cause, or
  - (iii) C has repeatedly been issued with remedial notices or breach notices (or both) in relation to different terms of service, and PCT1 is satisfied that C is likely to persist in breaching C's terms of service without good cause.

(2) For the purpose of paragraph (1), PCT1 may only remove—

- (a) particular chemist premises from C's listing if the relevant breaches all relate to those particular chemist premises; or
- (b) C from its pharmaceutical list if the relevant breaches all relate to listed chemist premises which are the only chemist premises listed in its pharmaceutical list in relation to C.

(3) PCT1 may only remove C, or chemist premises listed in relation to C, from its pharmaceutical list under paragraph (1) if—

- (a) the removal is justifiable and proportionate, having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them; and
- (b) PCT1, when it notifies C of the decision, includes in the notice its duly justified reasons for the decision.

(4) PCT1 need not take into account the reasons for the breaches (or likely breaches), pursuant to paragraph (3)(a), if it has made every reasonable effort to communicate with C to discover the reasons but has been unable to discover them.

(5) PCT1 must not remove C, or chemist premises listed in relation to C, from its pharmaceutical list under paragraph (1) because—

- (a) C has simply ceased to provide pharmaceutical services at particular listed chemist premises (regulation 74 applies in those circumstances); or
- (b) of failure to provide, or to provide to a reasonable standard, a directed service, unless C is required to provide that service pursuant to a condition imposed by virtue of regulation 66(1) or (3) to (5) (and the removal is justifiable and proportionate etc.).

(6) Where PCT1 is considering removing C, or remove the listing of particular listed chemist premises in relation to C, from its pharmaceutical list under paragraph (1), it must—

- (a) give notice to C, at least 30 days in advance of taking the decision, that PCT1 is minded to remove C or the premises from its pharmaceutical list;
- (b) as part of that notification, advise C that C may make—
  - (i) written representations to PCT1 with regard to that action, provided C notifies PCT1 with those representations within 30 days beginning with the date of the notification by PCT1, and
  - (ii) oral representations to PCT1 with regard to that action, provided—
    - (aa) C notifies PCT1 of C's wish to do so within 30 days beginning with the date of the notification by PCT1, and
    - (bb) C (or a representative of C) attends the hearing that PCT1 arranges for the purpose of hearing those representations, which PCT1 must give C reasonable notice of; and
- (c) consult any Local Pharmaceutical Committee for its area.

(7) If PCT1 does decide to remove C, or remove the listing of particular listed chemist premises in relation to C, from its pharmaceutical list under paragraph (1), it must, when it notifies C of that decision, include in that notification—

- (a) a statement of the reasons for the decision; and
- (b) an explanation of how C's rights of appeal under regulation 77(1)(d) may be exercised.

#### **Removal of listings: cases relating to death, incapacity or cessation of service**

**74.—**(1) Subject to paragraphs (2) and (4), if an NHS chemist (C)—

- (a) dies;
- (b) in the case of an NHS pharmacist, ceases to carry on a retail pharmacy business; or
- (c) in the case of an NHS appliance contractor, ceases to carry on a business in the course of which C supplies appliances either by retail sale or in circumstances corresponding to retail sale,

the Primary Care Trust (PCT1) in whose pharmaceutical list C is included must remove C from that list.

(2) Paragraph (1)(a) or (b) shall not apply in the case of an NHS pharmacist, if—

- (a) a representative of C (as defined in section 72 of the 1968 Act<sup>(a)</sup> (representative of pharmacist in case of death or disability)) is carrying on the retail pharmacy business of C that is included in PCT1's pharmaceutical list ("the business");

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(a) Section 72 has been amended by: the Insolvency Act 1985 (c. 65), Schedule 8, paragraph 15; the Insolvency Act 1986 (c. 45), Schedule 14; the Adults with Incapacity (Scotland) Act 2000 (asp 4), Schedule 5, paragraph 12, and Schedule 6; the Mental Incapacity Act 2005 (c. 9), Schedule 6, paragraph 14; the Health Act 2006 (c. 28), section 29; and S.I. 1989/2405, 2007/289 and 2010/231

- (b) the conditions specified in section 72(2) of the 1968 Act are fulfilled in relation to the representative and the business;
- (c) the period applicable in accordance with section 72(3) of the 1968 Act has not expired; and
- (d) the representative has agreed to be bound by, and continues to agree to be bound by, C's terms of service.

(3) If PCT1 determines that C has not, during the preceding 6 months, provided pharmaceutical services at particular listed chemist premises ("the particular premises")—

- (a) if there are other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove the listing of the particular premises in relation to C; or
- (b) if there are no other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove C from its pharmaceutical list.

(4) When determining, for the purposes of paragraph (1) or (3), whether C has ceased to carry on a business or ceased to provide pharmaceutical services, no account is to be taken of any time spent by C—

- (a) suspended from PCT1's pharmaceutical list;
- (b) in whole-time service in the armed forces of the Crown in a national emergency;
- (c) in compulsory whole-time service in the armed forces of the Crown (including service resulting from reserve liability); or
- (d) where C is liable for compulsory whole-time service in the armed forces of the Crown, in any equivalent service,

and in a case of C ceasing to carry on a business, no account is to be taken of the first 6 months after C completes that whole-time service in the armed forces of the Crown or equivalent service.

(5) Before taking a decision to remove C, or chemist premises listed in relation to C, from its pharmaceutical list under paragraph (1) or (3), PCT1 must—

- (a) give notice to C (or, in appropriate circumstances, a person whom PCT1 reasonably believes is representing C or is an executor of C) of the decision that PCT1 is minded to take;
- (b) as part of that notification, advise C (or the representative or executor) that they may make—
  - (i) written representations to PCT1 with regard to that action, provided they notify PCT1 with those representations within 30 days beginning with the date of the notification by PCT1, and
  - (ii) oral representations to PCT1 with regard to that action, provided—
    - (aa) they notify PCT1 of their wish to do so within 30 days beginning with the date of the notification by PCT1, and
    - (bb) C (or the representative or executor, or someone representing the representative or executor) attends the hearing that PCT1 arranges for the purpose of hearing those representations, which PCT1 must give C reasonable notice of; and
- (c) consult any Local Pharmaceutical Committee for its area.

(6) If PCT1 does decide to remove C from its pharmaceutical list under paragraph (1) or (3), it must, when it notifies C of that decision, include in that notification—

- (a) a statement of the reasons for the decision; and
- (b) an explanation of how C's rights of appeal under regulation 77(1)(d) may be exercised.



### **Voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure**

**75.**—(1) If, as a consequence of a change of ownership application, an NHS chemist (C) is no longer to be the person listed in the pharmaceutical list of a Primary Care Trust (PCT1), in relation to particular pharmacy premises—

- (a) if there are other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove the listing of the particular premises in relation to C; or
- (b) if there are no other chemist premises listed in its pharmaceutical list in relation to C, subject to regulation 76, PCT1 must remove C from its pharmaceutical list.

(2) If C is relocating from existing chemist premises to new chemist premises—

- (a) if—
  - (i) there are other chemist premises listed by PCT1 in its pharmaceutical list in relation to C, or
  - (ii) the new chemist premises are in the area of PCT1,

PCT1 must remove the listing of the existing premises in relation to C with effect from the date that C is required to notify to PCT1 under regulation 67(4)(b); or

- (b) if—
  - (i) there are no other premises listed by PCT1 in its pharmaceutical list in relation to C, and
  - (ii) the new chemist premises are in the area of another Primary Care Trust, subject to regulation 76, PCT1 must remove C from its pharmaceutical list with effect from the date that C is required to notify to PCT1 under regulation 67(4)(a)(ii).

(3) If C has been providing pharmaceutical services on behalf of a suspended NHS chemist at listed chemist premises (“the temporary provision premises”), once the fixed period referred to in regulation 27(3) expires, if—

- (a) other chemist premises are listed by PCT1 in its pharmaceutical list in relation to C, PCT1 must remove the listing of the temporary provision premises in relation to C; or
- (b) apart from the temporary provision premises, there are no other chemist premises listed by PCT1 in its pharmaceutical list in relation to C, PCT1 must remove C from its pharmaceutical list.

(4) Paragraph (5) applies if C—

- (a) wishes, other than as provided for in paragraphs (1) to (3), to close particular listed chemist premises and so—
  - (i) to withdraw from a pharmaceutical list, or
  - (ii) for particular listed chemist premises no longer to be listed in relation to C; and
- (b) has complied with regulation 67(2).

(5) In the circumstances described in paragraph (4)—

- (a) if there are other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove the listing of the particular premises in relation to C; or
- (b) if there are no other chemist premises listed in its pharmaceutical list in relation to C, subject to regulation 76, PCT1 must remove C from its pharmaceutical list.

(6) If PCT1 decides not to remove C from its pharmaceutical list under paragraph (5), it must, when it notifies C of that decision, include in that notification—

- (a) a statement of the reasons for the decision; and
- (b) where appropriate, an explanation of how any rights of appeal that C has under regulation 77(1)(e) may be exercised.

### **Limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing**

**76.**—(1) If a Primary Care Trust (PCT1) would otherwise remove an NHS chemist (C) from its pharmaceutical list under regulation 75, but—

- (a) is investigating an NHS chemist (C) in order to see whether there are grounds for exercising its powers in relation to C under section 151, 152 or 154 of the 2006 Act (a)(which relate to disqualification of practitioners, contingent removal and suspension), or regulation 80;
- (b) has decided to—
  - (i) remove C from its pharmaceutical list under section 151 or 152 of the 2006 Act or regulation 80, or
  - (ii) contingently remove C under section 152 of the 2006 Act, but C has not yet been removed or contingently removed; or
- (c) has suspended C under section 154 of the 2006 Act,

it must not, without the consent of the Secretary of State, remove C from its pharmaceutical list under regulation 75 until the relevant investigation or proceedings have been concluded.

(2) If C's name is kept on PCT1's pharmaceutical list pursuant to paragraph (1)—

- (a) as regards C, PCT1 may exercise its functions under—
  - (i) Part 11 of these Regulations, and
  - (ii) Chapter 6 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – disqualification); but
- (b) for all other purposes, C is to be treated as having been removed from its pharmaceutical list under regulation 75.

### **Appeals against decisions under Part 10**

**77.**—(1) An NHS chemist (C) may appeal against the following decisions by a Primary Care Trust—

- (a) the issuing of a remedial notice under regulation 70, including—
  - (i) the specified steps that C must take that are in the notice,
  - (ii) the duration of the notice period in the notice,
  - (iii) any decision to provide for a withholding of remuneration that is included in the notice, and
  - (iv) the amount of any withholding;
- (b) a decision not to restore remuneration to C, as provided for in a remedial notice in accordance with regulation 70(4)(b)(ii), or to restore a smaller amount than the amount that C considers should be restored;
- (c) the issuing of a breach notice under regulation 71, including—
  - (i) any decision to provide for a withholding of remuneration that is included in the notice, and
  - (ii) the amount of any withholding;
- (d) a decision to remove C from its pharmaceutical list, or remove the listing of particular listed chemist premises in relation to C, under regulation 73(1) or 74(1) or (3);
- (e) a refusal to remove C from its pharmaceutical list under regulation 75(5), other than a decision to keep C on the pharmaceutical list for limited purposes pursuant to regulation 76,

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(a) Section 154 has been amended by S.I. 2010/22.

provided that C notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which C was notified of the decision that is being appealed.

(2) A notice under paragraph (1) is valid only if it includes a concise and reasoned statement of the grounds of appeal.

(3) The Primary Care Trust must not remove C or the listing of particular listed chemist premises in relation to C (as the case may be) from its pharmaceutical list under regulation 73(1) or 74(1) or (3)—

- (a) if no appeal is brought against the decision to remove, until the period for bringing the appeal has elapsed; or
- (b) if an appeal is brought against the decision to remove but it is unsuccessful, before the appeal is determined by the Secretary of State.

(4) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under this Part (as it does in relation to appeals against decisions under Parts 2 to 5, 7, 8 and 12 and Schedule 2).

## PART 11

### Enforcement, reviews and appeals relating to fitness matters

#### **Extended meaning of “health scheme” in fraud cases**

**78.** The schemes prescribed under section 151(7)(b) of the 2006 Act (disqualification of practitioners) are schemes in the course of which health or medical services are paid for out of public funds and provided—

- (a) other than as part of the health services referred to in section 151(7)(a)—
  - (i) by port health authorities,
  - (ii) by the armed forces of the Crown, or
  - (iii) to persons in accommodation in which they are required in accordance with law to be detained (but not naval, military and air force prisons, which are covered by subparagraph (ii)); or
- (b) by or on behalf of the government of a country or territory outside the United Kingdom.

#### **Review of decisions to impose fitness conditions originally imposed on grants of applications**

**79.—(1)** Where a Primary Care Trust (PCT1) has imposed a condition on an NHS chemist (C) under regulation 35 (or thereafter under this regulation), it may review the decision to impose the condition—

- (a) at its own volition; or
- (b) where requested to do so by C, but C may not make such a request—
  - (i) in the case of the first such request, until at least 3 months have elapsed since C was included in the Primary Care Trust’s pharmaceutical list, or
  - (ii) thereafter, until at least 6 months have elapsed since the Primary Care Trust determined the outcome of the previous review.

(2) If PCT1 is undertaking the review of its own volition, it must inform C that it is doing so.

(3) As part of any review under paragraph (1), PCT1 must afford C an opportunity to make representations to it in writing.

(4) As a result of the review, PCT1 may remove the condition, leave the condition unchanged, vary the condition or impose a different condition, but any varied or different condition must be a condition with a view to—

- (a) preventing any prejudice to the efficiency of the services, or any of the services, which C has undertaken to provide; or
  - (b) preventing any act or omission within section 151(3)(a) of the 2006 Act (disqualification of practitioners).
- (5) PCT1 must notify C of a decision under paragraph (4), and it must include with the notification an explanation of—
- (a) the reasons for the decision;
  - (b) C’s right of appeal against its decision on the review to the First-tier Tribunal (which C has by virtue of this sub-paragraph);
  - (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008(a), the application notice must be sent to the Tribunal if an appeal is to be brought; and
  - (d) the continuing application of the condition that applied prior to the review, if there is an appeal, pending the outcome of the appeal.
- (6) If the outcome of the review is that the condition is to be varied or a different decision is to be imposed, that decision is to take effect—
- (a) if no appeal is brought against the decision, once the period for bringing an appeal has elapsed; or
  - (b) if an appeal is brought against the decision, and the decision of PCT1 is not changed by the First-tier Tribunal, once the First-tier Tribunal has determined the appeal (if the First-tier Tribunal takes a different decision to the decision taken by PCT1, that decision takes effect upon the taking of that decision, unless the First-tier Tribunal directs otherwise).

**Removal for breach of fitness conditions imposed under regulation 35 or 79**

**80.** If, in the course of a review under regulation 79 or otherwise, a Primary Care Trust determines that an NHS chemist has failed to comply with a condition imposed under regulation 35 or 79, or as varied under regulation 79, it may remove that NHS chemist from its pharmaceutical list.

**Mandatory removal in suitability cases**

**81.** In unsuitability cases, a Primary Care Trust must remove an NHS chemist (C) from its pharmaceutical list if—

- (a) C (or where C is a body corporate, any director or superintendent of C) has been convicted in the United Kingdom of murder;
- (b) C (or where C is a body corporate, any director or superintendent of C) has been convicted in the United Kingdom of a criminal offence, other than murder—
  - (i) which was committed after 1st April 2005, and
  - (ii) has been sentenced to a term of imprisonment of over 6 months; or
- (c) C is the subject of a national disqualification.

**Fitness cases: procedures for removal or contingent removal from pharmaceutical lists**

**82.—**(1) This paragraph applies where a Primary Care Trust (PCT1) is considering—

- (a) removing an NHS chemist (C) from its pharmaceutical list under section 151 or 152(3)(b) of the 2006 Act (which relate to disqualification of practitioners and contingent removal);
- (b) removing C from its pharmaceutical list under regulation 80; or

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(a) S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.

- (c) contingently removing C from its pharmaceutical list under section 152(1) of the 2006 Act.
- (2) Where paragraph (1) applies, before reaching its decision, PCT1 must—
- (a) notify C of the action PCT1 is considering taking and its grounds for considering taking that action; and
  - (b) as part of that notification—
    - (i) inform C of any allegation against C, and
    - (ii) advise C that C may make—
      - (aa) written representations to PCT1 with regard to that action, provided C notifies PCT1 with those representations within 30 days beginning with the date of the notification by PCT1, and
      - (bb) oral representations to PCT1 with regard to that action, provided C notifies PCT1 of C's wish to do so within 30 days beginning with the date of the notification by PCT1 and C (or a representative of C) attends the hearing that PCT1 arranges for the purpose of hearing those representations, which PCT1 must give C reasonable notice of; and
  - (c) in an unsuitability case to which regulation 81(a) or (b) applies, if C is a body corporate, advise C that PCT1 will not remove C from its pharmaceutical list as a consequence of that regulation (without prejudice to any other action it may take), provided that—
    - (i) the director or superintendent ceases to be a director or superintendent of C within the period of 30 days that begins on the date of the notification by PCT1, and
    - (ii) within that period, C notifies PCT1 of the date on which the director or superintendent has ceased or is to cease to be a director or superintendent of C.
- (3) Once PCT1 has taken its decision, it must notify C of its decision, and it must include with the notification (which may be combined, in appropriate cases, with a notification under regulation 79(5)) an explanation of—
- (a) the reasons for the decision;
  - (b) if PCT1 has decided to remove or contingently remove C from its pharmaceutical list—
    - (i) C's rights of appeal in relation to that decision under section 158 of the 2006 Act(a) (appeals), and
    - (ii) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008(b), the application notice must be sent to the Tribunal if an appeal is to be brought; and
  - (c) if PCT1 has decided to contingently remove C, the arrangements for review of the conditions under section 157(1) of the 2006 Act(c) (review of decisions).
- (4) If PCT1 has decided to remove or contingently remove C from its pharmaceutical list in accordance with this regulation, that decision is not to take effect—
- (a) if C does not appeal against the decision, until the period for bringing an appeal against the decision has elapsed; or
  - (b) if C does appeal against the decision, unless the First-tier Tribunal has determined the appeal and confirmed the decision of PCT1 (if the First-tier Tribunal takes a different decision to the decision taken by PCT1, that decision takes effect upon the taking of that decision, unless the First-tier Tribunal directs otherwise).

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(a) Section 158 has been amended by S.I. 2010/22.  
 (b) S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.  
 (c) Section 157 has been amended by S.I. 2010/22.

### **Procedure for suspensions in fitness cases**

**83.**—(1) Where a Primary Care Trust (PCT1) is considering suspending an NHS chemist (C) from its pharmaceutical list under section 154(1) or section 155(2) of the 2006 Act<sup>(a)</sup> (which relate to suspension and suspension pending appeal), before reaching its decision, it must—

- (a) notify C of the action PCT1 is considering taking and its grounds for considering taking that action; and
- (b) as part of that notification—
  - (i) where PCT1 is considering taking action under section 154(1), inform C of any allegation against C, and
  - (ii) advise C that C may make oral representations to PCT1 with regard to the possible suspension on a specified day, provided C notifies PCT1 of C's wish to do so within a specified period (of not less than 24 hours).

(2) If, within the specified period—

- (a) C does not advise PCT1 that C wishes to make oral representations to PCT1 on the specified day, thereafter PCT1 may suspend C with immediate effect; or
- (b) C does advise PCT1 that C wishes to make oral representations to PCT1 on the specified day, PCT1 must not suspend C until after the oral hearing, but may then do so with immediate effect.

(3) Once PCT1 has taken its decision, it must notify C of its decision as soon as is practicable, and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision;
- (b) if PCT1 has decided to suspend C under section 154(1), the arrangements for review of the suspension under section 157(1) of the 2006 Act (review of decisions).

### **Procedure for reviewing some suspensions and contingent removal conditions**

**84.**—(1) This paragraph applies where a Primary Care Trust (PCT1)—

- (a) is required to review a contingent removal or a suspension under section 157(1) of the 2006 Act<sup>(b)</sup> (review of decisions); or
- (b) decides to review a contingent removal or a suspension that it could be required to review under that section (if section 157(2) were satisfied).

(2) Where paragraph (1) applies, as part of the review, PCT1 must afford the NHS chemist who has been contingently removed or is suspended (C) the opportunity to make—

- (a) written representations to PCT1, provided C notifies PCT1 with those representations within 30 days beginning with the date of the notification by PCT1; and
- (b) oral representations to PCT1 with regard to that action, provided—
  - (i) C notifies PCT1 of C's wish to do so within 30 days beginning with the date of the notification by PCT1, and
  - (ii) C (or a representative of C) attends the hearing that PCT1 arranges for the purpose of hearing those representations, which PCT1 must give C reasonable notice of.

(3) Once PCT1 has taken its decision under section 157(3), it must notify C of its decision, and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision;
- (b) if C has a right of appeal in relation to the decision—

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<sup>(a)</sup> Sections 154 and 155 have been amended by S.I. 2010/22.

<sup>(b)</sup> Section 157 has been amended by S.I. 2010/22.



- (i) the right of appeal that C has in relation to that decision under section 158 of the 2006 Act<sup>(a)</sup> (appeals), and
- (ii) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008<sup>(b)</sup>, the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (c) if C has been or remains suspended or contingently removed, the arrangements for review of the suspension or the conditions under section 157(1) of the 2006 Act.

### **General power to revoke suspensions in appropriate circumstances**

**85.**—(1) If an NHS chemist is suspended from the pharmaceutical list of a Primary Care Trust (PCT1), in addition to PCT1’s powers to terminate suspensions under section 157(3)(b) of the 2006 Act (review of decisions) on a review, PCT1 may terminate a suspension at any time, in appropriate circumstances.

(2) If PCT1 terminates a suspension under paragraph (1), it must notify the NHS chemist that it has done so.

### **Evidence of unsuitability, fraud or inefficiency in service provision: specific matters**

**86.**—(1) When considering whether or not—

- (a) to vary or impose a condition on an NHS chemist (C) under regulation 79 or section 152(2) or (3)(a) of the 2006 Act (contingent removal);
- (b) to remove C from its pharmaceutical list under section 151 (disqualification of practitioners) or 152 of the 2006 Act or regulation 80, or to contingently remove C from its pharmaceutical list under section 152 of the 2006 Act;
- (c) to suspend C from its pharmaceutical list under section 154 or 155 of the 2006 Act<sup>(c)</sup> (which relate to suspension and suspension pending appeal),

a Primary Care Trust (PCT1) is to have regard, as appropriate, to the matters set out in paragraph (2) (in addition to other relevant matters).

(2) Those matters are—

- (a) in a case that is or may be a fraud case or an efficiency case, relevant breaches of any condition imposed by virtue of regulation 35 or 79 or section 152(2) or (3)(a) of the 2006 Act, or as varied by virtue of regulation 79 or section 152(3)(a) of the 2006 Act;
- (b) any evidence received from C, or which C is required to provide, under paragraph 31 of Schedule 4 or paragraph 21 of Schedule 5;
- (c) any evidence received by PCT1 from the Secretary of State, the NHS BSA, the police or any regulatory or licensing body relating to past or current investigations or proceedings involving or relating to C (and where C is a body corporate, any director or superintendent of C), and where PCT1 does receive such evidence, it must take into account in particular—
  - (i) the nature of any offence, investigation or incident;
  - (ii) the length of time since any offence, incident, conviction or investigation;
  - (iii) whether there are other offences, incidents or investigations to be considered;
  - (iv) any action taken or penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation;
  - (v) the relevance of any offence, investigation or incident to the provision by C of pharmaceutical services and any likely risk to users of pharmaceutical services or to public finances;

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<sup>(a)</sup> Section 158 has been amended by S.I. 2010/22.

<sup>(b)</sup> See rule 19 of those Rules.

<sup>(c)</sup> Sections 154 and 155 have been amended by S.I. 2010/22.

- (vi) in a case that is or may be an unsuitability case, whether any offence was a sexual offence to which Part 1 of the Sexual Offences Act 2003<sup>(a)</sup> (sexual offences) applies, or if it had been committed in England and Wales, would have applied;
- (vii) where C (and where C is a body corporate, any director or superintendent of C) has been refused inclusion in, conditionally included in, removed, contingently removed or is currently suspended from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, the facts which led to such action and the reasons given by the Primary Care Trust or other primary care organisation for such action; or
- (viii) where C (and where C is a body corporate, any director or superintendent of C) is—
  - (aa) a director or superintendent of a body corporate which has been refused inclusion in, conditionally included in, removed or contingently removed from a relevant list, or
  - (bb) suspended from a relevant list,
 for a reason relating to unsuitability, fraud or efficiency of service provision, the facts which led to such action and the reasons given by the Primary Care Trust or other primary care organisation in each case.

(3) When PCT1 has regard to matters set out in paragraph (2), it must consider the overall effect of all the matters being considered.

### **Review periods for national disqualifications**

**87.**—(1) Section 159(8)(a) of the 2006 Act<sup>(b)</sup> (national disqualification) is to have effect as if the reference to “two years” were a reference to “five years”, if the First-tier Tribunal determines, when it imposes the national disqualification, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a review being successful if held within five years.

(2) Section 159(8)(b) of the 2006 Act is to have effect as if the reference to “one year” were a reference to “three years”, if the First-tier Tribunal determines, on a review, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a further review being successful if held within three years.

(3) Section 159(8) of the 2006 Act is to have effect as if the references to “two years” and “one year”—

- (a) in a case where—
  - (i) a national disqualification has been imposed as a consequence of a criminal conviction, and
  - (ii) on appeal, the conviction has been quashed or the penalty imposed by the court has been reduced; or
- (b) in a case where—
  - (i) a national disqualification has been imposed as a consequence of an adverse decision of a licensing body, and
  - (ii) on appeal, the decision of the licensing body has been quashed or the penalty imposed by it has been reduced,

were a reference to a period equal to the period between the date on which that appeal was determined and the date on which the national disqualification was imposed or last reviewed.

### **Wider notifications of fitness decisions**

**88.**—(1) Where a Primary Care Trust (PCT1)—

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(a) 2003 c. 42.  
 (b) Section 159 has been amended by S.I. 2010/22.

- (a) refuses an application from a person (P) by virtue of regulation 33;
- (b) grants an application subject to conditions imposed on P by virtue of regulation 35;
- (c) imposes or varies a condition imposed on P by virtue of regulation 79;
- (d) removes P from its pharmaceutical list by virtue of section 151 or 152(3)(b) of the 2006 Act (which relate to disqualification of practitioners and contingent removal);
- (e) contingently removes P from its pharmaceutical list by virtue of section 152 of the 2006 Act, or varies or imposes a different condition on P by virtue of that section; or
- (f) suspends P under section 154 or 155 of the 2006 Act<sup>(a)</sup> (which relate to suspension and suspension pending appeal),

PCT1 must notify the persons listed in paragraph (2) that it has done so.

(2) Those persons are—

- (a) the Secretary of State;
- (b) where known to PCT1, any other Primary Care Trust or other primary care organisation that—
  - (i) has included P, or a body corporate of which P is a director or superintendent, in a relevant list, or
  - (ii) is considering including P, or a body corporate of which P is a director or superintendent, in a relevant list;
- (c) the Scottish Ministers;
- (d) the Welsh Ministers;
- (e) the Northern Ireland Executive;
- (f) the General Pharmaceutical Council;
- (g) any Local Pharmaceutical Committee for PCT1's area (including a Local Pharmaceutical Committee for its area and that of one or more other Primary Care Trusts);
- (h) the National Health Service Commissioning Board;
- (i) in a case that is or may be a fraud case, the NHS BSA; and
- (j) any person who may and does request to be notified of an adverse fitness decision as regards P.

(3) A person (Q) comes within paragraph (2)(j) if Q establishes to the satisfaction of PCT1 that Q—

- (a) has employed or engaged, is employing or engaging or is considering employing or engaging P, or a director or superintendent of P, in a professional capacity; or
- (b) is a member of a partnership of which P has been or is a member, or which is considering inviting P to be a member.

(4) A notification under paragraph (1) must include—

- (a) where P is an individual or a partnership—
  - (i) P's, or each member of the partnership's, name, address and date of birth, and
  - (ii) P's, or each member of the partnership's, registration number in the Register of Pharmacists; and
- (b) where P is a body corporate—
  - (i) P's name, company registration number and the address of P's registered office, and
  - (ii) the registration number in the Register of Pharmacists of P's superintendent and of any director of P who is a registered pharmacist;
- (c) a copy of the notification of the decision that was sent to P; and

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<sup>(a)</sup> Sections 154 and 155 have been amended by S.I. 2010/22.

- (d) the name of and contact details for a person at PCT1 who is in a position to respond to further enquiries.
- (5) PCT1 must notify P of whom it has notified under paragraph (1) and include, when it does so, the content of that notification.
- (6) If, in response to an enquiry from a person notified under paragraph (1), PCT1 notifies that person with further documentation (including documentation in an electronic form) that relates to P, PCT1 must also notify P with—
  - (a) that documentation; and
  - (b) details of the person to whom it has been sent.
- (7) If PCT1 is notified by the First-tier Tribunal of a national disqualification, or the outcome of the review of a national disqualification, it must notify that information to the persons it notified about its own decision in relation to P under paragraph (2)(b) and (g) to (j).
- (8) If, having notified a person (Q) under paragraph (1) of a suspension or a condition (including a condition imposed on contingent removal), PCT1 terminates the suspension or removes the condition, PCT1 must notify Q with the notification given to P of the decision to terminate the suspension or remove the condition.

## PART 12

### Remuneration, charges and refunds

#### **The Drug Tariff and section 164: general provisions**

**89.**—(1) The Drug Tariff referred to in section 127(4) of the 2006 Act (arrangements for additional pharmaceutical services) is the aggregate of—

- (a) the determinations of remuneration made by the Secretary of State, acting as a determining authority, under section 164 of the 2006 Act<sup>(a)</sup> (remuneration for persons providing pharmaceutical services), but not the remuneration of dispensing doctors; and
- (b) any other instruments that the Secretary of State is required by virtue of these Regulations or the 2006 Act to publish, or does publish, together with those determinations,

in the publication known as the Drug Tariff, which the Secretary of State shall publish in such format as the Secretary of State thinks fit.

(2) Determinations under section 164 of the 2006 Act by the Secretary of State may be made by reference to—

- (a) the drugs and appliances dispensed or expected to be dispensed in accordance with NHS prescriptions during a reference period determined by the Secretary of State;
- (b) lists of published prices produced by suppliers of the drugs or appliances that are available from them on NHS prescription;
- (c) scales, indices or other data that relate to volume and price that are produced by suppliers of the drugs or appliances that are available from them on NHS prescription; and
- (d) any other scales, indices or other data (including formulae) by reference to which the Secretary of State considers it appropriate to make such a determination, and in these circumstances, the Secretary of State may provide that remuneration is to be determined by reference to data which is—
  - (i) in the form current at the time of the determination; and
  - (ii) in any subsequent form taking effect after that time.

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<sup>(a)</sup> Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4.

(3) Amendments may be made to the Drug Tariff at such intervals as the Secretary of State thinks fit, but must be published in a consolidated version of the Drug Tariff that has the amendments included in it.

(4) The consultation that the Secretary of State must undertake under section 165(1) of the 2006 Act (section 164: supplementary) prior to the inclusion of, or change to, a price of a drug or appliance which is to form part of a calculation of remuneration shall be by way of consultation on the process for determining the price to be included or changed, not on the proposed price itself (unless it is impossible to carry out an effective consultation in any other way).

(5) The Drug Tariff is to include the arrangements for the claiming of payments by NHS chemists and the making of payments to NHS chemists under it, and—

- (a) claims by NHS chemists for payments under the Drug Tariff must be made in accordance with those arrangements; and
- (b) payments under the Drug Tariff must be made—
  - (i) by the Primary Care Trust responsible for making the payment, and
  - (ii) in accordance with those arrangements, subject as appropriate to any deduction that may or must be made in accordance either with those arrangements or with any provision of, or made under, the 2006 Act (including the Drug Tariff).

### **Data to be provided to assist Drug Tariff determinations**

**90.**—(1) For the purposes of regulation 89(2)(d), the data to which reference may be made may include information obtained pursuant to paragraph (3) by the Secretary of State or a person appointed by the Secretary of State under this paragraph (“a nominee”).

(2) Before appointing a person to be a nominee, the Secretary of State must consult, as the Secretary of State considers appropriate, organisations representative of the NHS chemists to whose remuneration the possible determination arising out of the data would relate.

(3) An NHS chemist must, within 30 days of a request to do so, provide the Secretary of State or a nominee with information (for example invoices) which the Secretary of State considers to be relevant to the matters the Secretary of State may take into account prior to making a determination under section 164 of the 2006 Act<sup>(a)</sup> (remuneration for persons providing pharmaceutical services).

(4) A nominee may handle and process information obtained under paragraph (3).

(5) The Secretary of State may require—

- (a) information obtained by a nominee under paragraph (3) to be obtained; and
- (b) information processed or handled by a nominee under paragraph (4) to be processed or handled,

in such manner as the Secretary of State may reasonably specify.

### **Remuneration in respect of enhanced services**

**91.**—(1) Before determining the remuneration payable by it in respect of an enhanced service, a Primary Care Trust must consult any Local Pharmaceutical Committee for its area (including a Local Pharmaceutical Committee for its area and that of one or more other Primary Care Trusts).

(2) Where a Primary Care Trust makes a determination of the remuneration payable in respect of an enhanced service, it must—

- (a) publish the determination in such manner as it thinks appropriate for bringing it to the attention of persons included in its pharmaceutical lists; and
- (b) make the determination available for inspection.

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<sup>(a)</sup> Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4.

(3) The arrangements for claiming and paying any remuneration thus determined must allow for the making for any deduction that may or must be made from that remuneration by virtue of any provision of, or made under, the 2006 Act (for example, a deduction that may or must be made by virtue of regulations 70 to 72).

### **Dispensing doctor remuneration**

**92.**—(1) As regards the pharmaceutical services provided by dispensing doctors—

- (a) if a drug, appliance or related additional service is provided by a dispensing doctor in circumstances where the dispensing doctor could provide it under pharmaceutical services or related arrangements for the provision of primary medical services, the remuneration in respect of providing that drug, appliance or service is to be the remuneration payable in respect of that drug, appliance or service under the related arrangements; and
- (b) in all other cases, the remuneration payable to a dispensing doctor in respect of those services is to be the remuneration payable under a GMS contract to a GMS practice in respect of those services by virtue of directions under section 87 of the 2006 Act (GMS contracts: payments), whether or not the dispensing doctor is a GMS practice.

(2) Claims for remuneration in respect of pharmaceutical services by or on behalf of a dispensing doctor are to be made to the NHS BSA (which calculates the amount of the payment on behalf of the Primary Care Trust with whom the dispensing doctor has made arrangements for the provision of pharmaceutical services) in such manner as the NHS BSA determines.

(3) The making of payments by a Primary Care Trust pursuant to a claim made in accordance with paragraph (2) is to be in accordance with the arrangements—

- (a) that the dispensing doctor has with the Primary Care Trust for the provision of primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services; or
- (b) if the dispensing doctor has no such arrangements—
  - (i) that the Primary Care Trust has with a provider of primary medical services for the provision of primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services, or
  - (ii) under which a PCTMS practice provides primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services,

subject as appropriate to any deduction that may or must be made in accordance either with those arrangements or with any provision of, or made under, the 2006 Act (including the determinations mentioned in paragraph (1)).

### **The taking effect of determinations**

**93.**—(1) A determination of remuneration under section 164 of the Act<sup>(a)</sup> (remuneration for persons providing pharmaceutical services) is to have effect—

- (a) in relation to remuneration in respect of a period beginning on or as from a date specified in the determination, on or as from that date; or
- (b) if no such date is specified, in relation to remuneration in respect of the period beginning on the date that the determination is published.

(2) A date before the date a determination is published may only be specified under paragraph (1)(a) if, taking the determination as a whole, it is not detrimental to the persons to whose remuneration it relates.

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(a) Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4.



## Overpayments

**94.**—(1) Where a Primary Care Trust considers that a payment has been made to an NHS chemist pursuant to the arrangements mentioned in regulation 89(5) or 91(3) in circumstances where it was not due, it must (except to the extent that the Secretary of State, on the application of the Primary Care Trust, directs otherwise) draw the overpayment to the attention of the NHS chemist, and—

- (a) where the NHS chemist admits the overpayment; or
- (b) if the NHS chemist does not admit there has been an overpayment, where the final outcome of an investigation or appeal is that there has been an overpayment,

the amount overpaid shall be recoverable by deduction from other remuneration payable to the NHS chemist in respect of pharmaceutical services or as a civil debt.

(2) Where a Primary Care Trust considers that a payment has been made to a dispensing doctor or provider of primary medical services pursuant to the arrangements mentioned in regulation 92(2) in circumstances where it was not due, it must (except to the extent that the Secretary of State, on the application of the Primary Care Trust, directs otherwise) seek to recover that overpayment under those arrangements.

(3) Recovery under this regulation of an overpayment is to be without prejudice to the investigation of any related breach of the relevant NHS chemist's or dispensing doctor's terms of service.

## Free supply of drugs, appliances and containers where the drug or appliance is supplied under pharmaceutical services

**95.** Subject to any provision of regulations made under Part 9 of the 2006 Act (charging) to the contrary and without prejudice to regulation 92(1)(a), any drug, appliance or container supplied under arrangements made by a Primary Care Trust for the provision of pharmaceutical services must be supplied free of charge (although a prescription charge may be payable).

## Refunds of prescription charges

**96.**—(1) Where any person is entitled to repayment of a charge paid under the Charges Regulations presents an NHS pharmacist with a valid claim for the repayment within 3 months of the date on which the charge was paid, the NHS pharmacist must make the repayment.

(2) For the purposes of paragraph (1), a claim for repayment is only valid if duly made—

- (a) in such form and manner as the Secretary of State has determined for an application for such a repayment under regulation 10(2)(b) of the Charges Regulations<sup>(a)</sup> (repayment of charges); or
- (b) on the equivalent form issued in Scotland, Wales or Northern Ireland.

## Reward scheme

**97.**—(1) An NHS chemist who is presented with or receives an order under paragraph 5(2) or (3) of Schedule 4, or paragraph 4(2) or (3) of Schedule 5, is eligible to claim a payment from the Primary Care Trust, in accordance with the Drug Tariff, if—

- (a) the NHS chemist has refused, in accordance with paragraph 9 of Schedule 4 or paragraph 8 of Schedule 5, to provide a drug or appliance and has informed the Primary Care Trust of this action as soon as practicable; or
- (b) has provided a drug or appliance pursuant to paragraph 5(2) or (3) of Schedule 4, or paragraph 4(2) or (3) of Schedule 5 but has reason to believe (whether or not this was the case at the time that the drug or appliance was dispensed) that the order was not a genuine

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(a) Regulation 10 has been amended by S.I. 2000/3189, 2002/2352 and 2004/696.

order on NHS prescription and has informed the Primary Care Trust of this belief as soon as is practicable,

and in either case has sent the order (or, in the case of an electronic prescription, details of it) to the Primary Care Trust.

(2) Where a Primary Care Trust establishes that an order about which it has been notified in accordance with paragraph (1) was not a genuine order, the Primary Care Trust must make such payment as is due to the NHS chemist under the Drug Tariff.

(3) In this regulation, “order” includes a purported order.

### **Payments to suspended chemists**

**98.**—(1) If an NHS chemist (C) is suspended from a pharmaceutical list of a Primary Care Trust, the Primary Care must make payments to C, in accordance with the determination that is to be made by the Secretary of State under this paragraph in relation to such payments.

(2) A determination under paragraph (1) may be amended from time to time by a further determination under that paragraph.

(3) Before making a determination under paragraph (1), the Secretary of State must consult such organisations as appear to the Secretary of State to be representative of NHS chemists.

(4) A determination under paragraph (1) must be published in the Drug Tariff.

(5) A determination under paragraph (1) may include provision that payments in accordance with the determination are not to exceed a specified amount in a specified period.

(6) If a payment has been made pursuant to a determination under paragraph (1) to C when it was not due, it must (except to the extent that the Secretary of State, on the application of the Primary Care Trust, directs otherwise) draw the overpayment to the attention of C, and—

(a) where C admits the overpayment; or

(b) if C does not admit there has been an overpayment, where the final outcome of an investigation or appeal is that there has been an overpayment,

the amount overpaid shall be recoverable by deduction from other remuneration payable to C in respect of pharmaceutical services (for example, from subsequent payments under the determination or from payments for pharmaceutical services where C resumes the provision of pharmaceutical services) or as a civil debt.

(7) C may appeal to the Secretary of State against the following decisions by a Primary Care Trust—

(a) a refusal to make payments to C under the determination under paragraph (1);

(b) the level of any payments made to C under the determination under paragraph (1); or

(c) a deduction from remuneration under paragraph (6),

provided that C notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which C was notified of the decision that is being appealed.

(8) A notice under paragraph (7) is valid only if it includes a concise and reasoned statement of the grounds of appeal.

(9) Schedule 3 has effect in relation to appeals to the Secretary of State under paragraph (7) (as it does in relation to appeals against decisions under Parts 2 to 5, 7, 8 to 10 and Schedule 2).

## PART 13

### Miscellaneous

#### **Sharing of information by home Primary Care Trusts**

**99.**—(1) The home Primary Care Trust of a body corporate that is an NHS chemist (C), or that is applying to be an NHS chemist, may share information that it holds about that body corporate with any other Primary Care Trust, where doing so is for the purpose of assisting that Primary Care Trust in the performance of its functions—

- (a) under these Regulations; or
- (b) in respect of arrangements for the provision of local pharmaceutical services.

(2) Where a home Primary Care Trust receives information by virtue of paragraph 31 of Schedule 4 or paragraph 21 of Schedule 5, or under arrangements for the provision of local pharmaceutical services, it must consider the information and decide whether it raises any questions about the continued listing of C in a relevant list.

(3) If the home Primary Care Trust is of the opinion that the information does raise a question about C's continued listing, it must make a recommendation about the appropriate action to be taken (if any) in relation to C.

(4) The recommendation must set out all the relevant facts and shall be fully reasoned.

(5) The home Primary Care Trust must pass any of the information provided by C and any recommendation it has made under paragraph (3) to any other Primary Care Trust—

- (a) in whose pharmaceutical list C is included; or
- (b) with which C has made arrangements for the provision of local pharmaceutical services, where requested to do so by the Primary Care Trust, within 30 days of receiving such a request.

#### **Notification by a Primary Care Trust of changes to its pharmaceutical lists**

**100.** Where, in accordance with the provisions of these Regulations, the 2005 Regulations (as they continue to have effect by virtue of Schedule 7) or the 2006 Act, a Primary Care Trust—

- (a) removes a person from its pharmaceutical list or dispensing doctor list; or
- (b) removes the listing of premises in relation to a person on its pharmaceutical list or dispensing doctor list,

it must notify the person of the change to its list that has taken place.

#### **Proceedings with regard to overridden arrangements during an emergency requiring the flexible provision of pharmaceutical services**

**101.** Where, during an emergency requiring the flexible provision of pharmaceutical services, arrangements for the provision of pharmaceutical services are overridden by temporary arrangements—

- (a) any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed during the emergency for other reasons); and
- (b) if as a result of those proceedings the overridden arrangements require amendment before the end of the temporary arrangements, when the emergency ends, the reversion to overridden arrangements is to be to the original overridden arrangements as amended as a result of those proceedings.

#### **Authorised persons to apply for services**

**102.** An application to an NHS chemist for pharmaceutical services may be made (other than by the NHS chemist concerned)—

- (a) on behalf of a child by either parent, or in the absence of both parents, the guardian or other person who has care of the child;
- (b) on behalf of any person, other than a child under the age of 18 years of age who is—
  - (i) in the care of an authority to whose care that person has been committed under the Children Act 1989(a), by a person duly authorised by that authority, or
  - (ii) in the care of a voluntary organisation, by that organisation or a person duly authorised by them;
- (c) on behalf of any adult who is incapable of making such an application or authorising such an application to be made on their behalf, by a relative or the primary carer (who may be an adult or an organisation) of that person; or
- (d) on behalf of any other person by a duly authorised person.

**Transitional provisions**

103. The transitional provisions set out in Schedule 7 have effect.

**Amendments and revocations**

104. The amendments to and revocations of enactments set out in Schedule 8 have effect.

**Review of these Regulations**

105. Before the end of the period of five years beginning with the appointed day, the Secretary of State must—

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

Signed by authority of the Secretary of State for Health.

*Earl Howe*  
Parliamentary Under-Secretary of State  
Department of Health

18th July 2012

**SCHEDULE 1**

Regulation 4(1)

**Information to be contained in pharmaceutical needs assessments**

**Necessary services: current provision**

1. A statement of the pharmaceutical services that the Primary Care Trust has identified as services that are provided—

- (a) in the area of the Primary Care Trust and which are necessary to meet the need for pharmaceutical services in its area; and
- (b) outside the area of the Primary Care Trust but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the Primary Care Trust has identified such services).

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(a) 1989 c. 41.

### **Necessary services: gaps in provision**

2. A statement of the pharmaceutical services that the Primary Care Trust has identified (if it has) as services that are not provided in the area of the Primary Care Trust but which the Primary Care Trust is satisfied—

- (a) need to be provided (whether or not they are located in the area of the Primary Care Trust) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;
- (b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the Primary Care Trust) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

### **Other relevant services: current provision**

3. A statement of the pharmaceutical services that the Primary Care Trust has identified (if it has) as services that are provided—

- (a) in the area of the Primary Care Trust and which, although they are not necessary to meet the need for pharmaceutical services in its area, nevertheless have secured improvements to, or better access to, pharmaceutical services in its area;
- (b) outside the area of the Primary Care Trust and which, although they do not contribute towards meeting the need for pharmaceutical services in its area, nevertheless have secured improvements to, or better access to, pharmaceutical services in its area;
- (c) in or outside the area of the Primary Care Trust and, whilst not being services of the types described in sub-paragraph (a) or (b), or paragraph 1, they nevertheless affect the assessment by the Primary Care Trust of the need for pharmaceutical services in its area.

### **Improvements and better access: gaps in provision**

4. A statement of the pharmaceutical services that the Primary Care Trust has identified (if it has) as services that are not provided in the area of the Primary Care Trust but which the Primary Care Trust is satisfied—

- (a) would, if they were provided (whether or not they were located in the area of the Primary Care Trust), secure improvements to, or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area,
- (b) would, if in specified future circumstances they were provided (whether or not they were located in the area of the Primary Care Trust), secure future improvements to, or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.

### **Other NHS services**

5. A statement of any NHS services provided by the Primary Care Trust, another Primary Care Trust, an NHS trust or an NHS foundation trust to which the Primary Care Trust has had regard in its assessment, which affect—

- (a) the need for pharmaceutical services, or pharmaceutical services of a specified type, in its area; or
- (b) whether further provision of pharmaceutical services in its area would secure improvements to or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.

### **How the assessment was carried out**

6. An explanation of how the assessment has been carried out, and in particular—

- (a) how it has determined what are the localities in its area;

- (b) how it has taken into account (where applicable)—
  - (i) the different needs of different localities in its area, and
  - (ii) the different needs of people in its area who share a protected characteristic; and
- (c) a report on the consultation that it has undertaken.

**Map of provision**

7. A map that identifies the premises at which pharmaceutical services are provided in the area of the Primary Care Trust.

**SCHEDULE 2**

Regulation 10(6)

**Applications in respect of pharmaceutical lists and the procedures to be followed**

**PART 1**

**Information to be included in routine and excepted applications**

**Information to be included in all routine and excepted applications**

1.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications.

(2) The name of the Primary Care Trust to which the application is made.

(3) The type of application being made (for example, the application is for inclusion in a pharmaceutical list and a change of ownership application), including a statement of whether the application is a routine or an excepted application.

(4) The name and address of the applicant (A).

(5) If A is an individual or a partnership carrying on a retail pharmacy business, A or each partner's registration number in the GPhC register.

(6) If A is a body corporate carrying on a retail pharmacy business, the name and registration number in the GPhC register of A's superintendent.

(7) If A is seeking the listing of premises not already listed in relation to A (whether or not A is already listed)—

(a) either—

(i) the address of the premises, or

(ii) if the address is not known and it is a routine application, A's best estimate of where the proposed premises will be;

(b) whether the applicant is currently in possession of the premises;

(c) the proposed core opening hours in respect of the premises; and

(d) the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).

(8) If A is seeking to provide directed services—

(a) details of the directed services to be provided;

(b) confirmation that A is accredited to provide the services, where that accreditation is a prerequisite for the provision of those services;

(c) confirmation that the premises are accredited in respect of the provision of the services, where that accreditation is a prerequisite for the provision of those services; and



(d) a floor plan showing the consultation area where A proposes to offer directed services (where relevant, unless one cannot be provided for reasons that are good cause).

(9) A is not entitled to ask for a routine application to be considered, in the alternative, as an excepted application, or for an excepted application to be considered, in the alternative, as a routine application.

(10) An estimate of the location of premises is only a “best estimate” for the purposes of subparagraph (7)(a)(ii) if the Primary Care Trust to whom the application is made is satisfied that—

- (a) it is the best estimate that A can reasonably make at the time of the application of the location of the premises; and
- (b) its reasons for granting or refusing the application would be essentially the same if the applicant located, if the application was granted, at any location within the range of possible locations covered by the estimate.

### **Information to be included in all routine and excepted applications for inclusion in a pharmaceutical list**

2.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

(2) If the applicant (A) is an individual or a partnership—

- (a) A’s or each partner’s full name;
- (b) A’s or each partner’s sex;
- (c) A’s or each partner’s date of birth;
- (d) A’s or each partner’s private address and telephone number;
- (e) a declaration that A or each partner is a registered pharmacist, if A is seeking entry in the list mentioned in regulation 10(2)(a);
- (f) if A is a partnership, a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act<sup>(a)</sup> (general provisions), if A is seeking entry in the list mentioned in regulation 10(2)(a); and
- (g) if A is already included in Part 3 of the GPhC register in respect of any premises, A’s registration number in that Part of the GPhC register.

(3) If A is a body corporate—

- (a) A’s registered name and any other name under which A trades;
- (b) A’s company registration number;
- (c) A’s registered office and any fixed line telephone number relating to that office;
- (d) the private address and date of birth of A’s superintendent (if A is seeking entry in the list mentioned in regulation 10(2)(a));
- (e) the name, private address and date of birth of each director of A (who is not A’s superintendent), and if any director of A (who is not A’s superintendent) is a registered pharmacist, that director’s registration number in the GPhC register;
- (f) a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act, if A is seeking entry in the list mentioned in regulation 10(2)(a); and
- (g) if A is already included in Part 3 of the GPhC register in respect of any premises, A’s registration number in that Part of the GPhC register.

(4) If the services that A undertakes to provide consists of or includes the supply of appliances, the appliances A undertakes to supply.

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(a) Section 69 has been amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1, Part 12, and by S.I. 1976/1213, 2007/289 and 3101 and 2010/231.

### **Fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list**

3.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list, as regards any person (P) who is—

- (a) the individual who is making the application;
- (b) a partner in the partnership that is making the application; or
- (c) a director or (if A is seeking entry in the list mentioned in regulation 10(2)(a)) superintendent of the body corporate that is making the application.

(2) Details of whether P—

- (a) has been convicted of any criminal offence in the United Kingdom;
- (b) has been bound over following a criminal conviction in the United Kingdom;
- (c) has accepted 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 P absolutely (without proceeding to conviction); or
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(a) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(b) (penalty as alternative to prosecution).

(3) Details of whether P has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which P is currently subject—

- (a) in the United Kingdom; or
- (b) elsewhere than the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's fitness to practise by a licensing body—

- (a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or
- (b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(6) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's professional conduct by an employer—

- (a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or
- (b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(7) If P is a pharmacist, details of P's—

- (a) pharmaceutical qualifications (including where obtained); and
- (b) professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why P was dismissed from any post (if not already covered by the details provided pursuant to sub-paragraph (6)(b)).

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(a) 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; and the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1).

(b) 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and has been amended by the Social Security Fraud Act 2001 (c. 11), section 14.

(8) If P is a pharmacist, names and addresses of 2 referees who are willing to provide references in respect of 2 recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, details of why and the names and addresses of alternative referees who are acceptable to the Primary Care Trust.

(9) If P is, to P's knowledge, or has been subject to any investigation or proceedings that could lead or could have led to P's removal from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(10) If P is, to P's knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(11) If P has been refused inclusion in, or conditionally included in, or contingently removed or suspended from, any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of same.

(12) If P is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

- (a) any deferment of that application; or
- (b) refusal or conditional inclusion where the refusal or conditional inclusion has not yet reached its final outcome.

(13) If P—

- (a) is the person making the application; and
- (b) qualified as a pharmacist in Switzerland or an EEA State other than the United Kingdom, details that demonstrate that P has the level of knowledge of English which, in the interests of P and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the Primary Care Trust.

#### **Fitness information about corporate bodies: routine and excepted applications for inclusion in a pharmaceutical list**

4.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list by a body corporate (C1)—

- (a) as regards C1; or
- (b) as regards any other body corporate (C2) of which a director or superintendent of C1—
  - (i) is a director or superintendent or has been a director or superintendent in the 6 months prior to the date of the application, or
  - (ii) has been a director or superintendent for more than 6 months prior to the date of the application, where they were a director or superintendent of C2 at the time of the originating events to which the information relates.

(2) Details of any convictions that C1 or C2 has for offences committed in the United Kingdom that are not spent convictions.

(3) Details of whether C1 or C2 (being corporate bodies registered within the United Kingdom) has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which C1 or C2 is currently subject—

- (a) in the United Kingdom; or
- (b) elsewhere than in the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) Details of any investigation to which C1 or C2—

- (a) is, to its knowledge, subject by the General Pharmaceutical Council in relation to an entry in Part 3 of the GPhC register; or
- (b) has been subject by the General Pharmaceutical Council, the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland in relation to an entry in the register required to be kept under section 75 of the 1968 Act<sup>(a)</sup> (registration of premises), the outcome of which was adverse.

(6) If C1 or C2, to its knowledge, is or has been subject to any investigation or proceedings that could lead or could have led to its removal from a relevant list, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(7) If C1 or C2 is, to its knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(8) If C1 or C2 has been refused inclusion in, or conditionally included in (other than by reason of a condition imposed under Part 9), a relevant list, details of that refusal or conditional inclusion.

(9) If C1 or C2 is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

- (a) any deferment of that application; or
- (b) any refusal or conditional inclusion, where the refusal or conditional inclusion has not yet reached its final outcome.

#### **Providing fitness information instead to a home Primary Care Trust**

5.—(1) Where an applicant is a body corporate with a registered office in England—

- (a) it may provide any information that it is required to include in a routine or excepted application (“the current application”) pursuant to paragraph 3 or 4 to its home Primary Care Trust instead of to the Primary Care Trust to which it is making the current application (PCT1), if different; and
- (b) if it has already provided information to its home Primary Care Trust on a previous occasion, it need not provide that information again to its home Primary Care Trust in relation to the current application.

(2) An applicant relying on paragraph (1) must, when making its application—

- (a) confirm to PCT1 that A’s home Primary Care Trust already has all the information required under paragraphs 3 and 4; or
- (b) undertake to provide any missing information required under those paragraphs to its home Primary Care Trust and confirm to PCT1 when that has taken place.

#### **Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises**

6. If, as regards a routine or excepted application—

- (a) for inclusion in a pharmaceutical list by a person not already included; or
- (b) by a person already included in a pharmaceutical list for inclusion also in respect of premises other than those already listed in relation to that person,

the premises which the applicant (A) is seeking to be listed in relation to A are already listed chemist premises or are adjacent to or in close proximity to such premises, A must include with the application details that explain why A believes the application should not be refused pursuant to regulation 31.

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(a) Amended by S.I. 1968/1699 and 2010/231.

### **Additional information to be included with routine applications**

7.—(1) If an applicant (A) is making a routine application and is seeking to satisfy a Primary Care Trust that granting that application would meet a need for pharmaceutical services, or secure improvements to or better access to pharmaceutical services, in circumstances where—

- (a) that need, those improvements or that better access has or have been identified in the Primary Care Trust's pharmaceutical needs assessment, A must include in that application details that explain how A intends to meet that need, or secure those improvements or that better access (in whole or in part); or
- (b) that need, those improvements or that better access has or have not been identified in the Primary Care Trust's pharmaceutical needs assessment, A must include in that application, details that explain A's belief that regulation 18(1)(b) is satisfied in relation to that application.

(2) Where an applicant includes information in an application pursuant to paragraph (a) but not paragraph (b) of sub-paragraph (1), the Primary Care Trust must not consider whether regulation 18(1)(b) applies in relation to that application when it determines that application.

### **Additional information to be included with excepted applications**

8. If the applicant (A) is making an excepted application, A must include in that application details that explain—

- (a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act<sup>(a)</sup> (regulations as to pharmaceutical services) are not to apply in relation to that application; and
- (b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

### **Undertakings**

9. An applicant (A) must provide the following undertakings—

- (a) an undertaking to notify the Primary Care Trust within 7 days of any material changes to the information provided in the application that occur before—
  - (i) the application is withdrawn,
  - (ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
  - (iii) if the application is granted, A commences the provision of the services to which the application relates,whichever is the latest of these events to take place;
- (b) an undertaking to notify the Primary Care Trust if A is included, or applies to be included, in any other relevant list before—
  - (i) the application is withdrawn,
  - (ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
  - (iii) if the application is granted, A commences the provision of the services to which the application relates,whichever is the latest of these events to take place;

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<sup>(a)</sup> Section 129(2A) and (2B) were inserted by the Health Act 2006 (c. 21), section 26(3).

- (c) if A is seeking inclusion in a pharmaceutical list or (if A is already listed in that list) the listing of premises in relation to A that are not already listed in relation to A, an undertaking—
  - (i) to comply with all the obligations that are to be their terms of service under regulation 11 if the application is granted, and
  - (ii) in particular, in relation to any proposed pharmacy premises, to provide all the services and perform all the activities at those premises that are required under the terms of service to be provided or performed as or in connection with essential services; and
- (d) if A is seeking to provide directed services an undertaking—
  - (i) that A will provide the directed services mentioned in the application, if the Primary Care Trust does commission the services from A within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates,
  - (ii) if the services are commissioned by the Primary Care Trust, that A will provide the services in accordance with an agreed service specification, and
  - (iii) A's agreement to a service specification will not be unreasonably withheld.

**Nature of details to be supplied**

**10.** Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy the Primary Care Trust in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Primary Care Trust may need to make of the information or documentation when carrying out its functions.

## PART 2

### Preliminary matters

**Relevant information or documentation**

**11.—(1)** As regards any routine or excepted application, if the Primary Care Trust to which the application is made considers that relevant information or documentation is missing—

- (a) it may request the missing relevant information or documentation from the applicant; and
- (b) the applicant must, within the period reasonably specified by the Primary Care Trust in the request under paragraph (a)—
  - (i) provide any information or documentation reasonably requested,
  - (ii) notify the Primary Care Trust that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or
  - (iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the Primary Care Trust of that and seek a review by the Primary Care Trust of the reasonableness of the request.

(2) If an applicant refuses to comply with a request under sub-paragraph (1)(a)—

- (a) within the period—
  - (i) reasonably specified by the Primary Care Trust under paragraph (1)(b), or
  - (ii) ending on the date specified by the applicant in accordance with paragraph (1)(b)(ii), if the Primary Care Trust is satisfied that a delay beyond the period it specified, and the length of the delay, are for good cause,

unless paragraph (b) applies, the application is to be treated as withdrawn;



- (b) in circumstances where the applicant has, in accordance with sub-paragraph (1)(b)(iii), sought a review by the Primary Care Trust of the reasonableness of the request, if the review determines that any or all of the information or documentation requested—
  - (i) must after all, be provided, the application is to be treated as withdrawn unless the information or documentation that must still be provided is provided within a new period reasonably specified by the Primary Care Trust for the provision of that information or documentation,
  - (ii) need not be provided by the applicant, the request of the Primary Care Trust is to be treated as withdrawn to the extent that it relates to information or documentation that need not be provided.

(3) A Primary Care Trust may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application, but it must consider whether or not it needs to request information or documentation under this paragraph prior to notifying an application (where it is required to do so) under Part 3.

### **Failure to provide undertakings**

**12.—**(1) If, when an applicant (A) submits an application, A fails to provide with the application the undertakings referred to in paragraph 9 that are relevant to the application, the Primary Care Trust must, prior to notifying the application under Part 3, request that A provide the relevant undertakings within a specified period.

(2) If A fails to comply with a request under sub-paragraph (1) within a period reasonably specified by the Primary Care Trust under that sub-paragraph, the application is to be treated as withdrawn.

### **Functions of a home Primary Care Trust in relation to certain applications**

**13.—**(1) Where an applicant (A) is relying on paragraph 5(1), the Primary Care Trust to which A's application is made (PCT1) must notify A's home Primary Care Trust (PCT2) of the application and seek a recommendation from it as to whether the application should be refused or deferred under regulation 33 or 34.

(2) Where it receives a notification under sub-paragraph (1), PCT2 must consider whether the application should be refused or deferred under regulation 33 or 34, and having done so, it must make a recommendation to PCT1 within 30 days of having received the notification.

(3) The recommendation must—

- (a) set out all the relevant facts and be fully reasoned; and
- (b) if it is that the application be refused or deferred, be sent by PCT1 as soon as is practicable to A, and PCT1 must at the same time seek the views of A on the accuracy of the facts set out by PCT2.

### **Deferral of notifiable applications prior to notification**

**14.—**(1) A Primary Care Trust that receives—

- (a) a routine application, consideration of which may or must be deferred under regulation 14(1) to (3), 16(1) to (4), 19(1) to (4), 21(1) to (4) or 38(4); or
- (b) a notifiable application, consideration of which may be deferred under regulation 32 or 34,

must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not to defer consideration of that application under those provisions.

(2) If consideration of the application is deferred prior to notification, once the Primary Care Trust no longer has grounds for deferring the application, it must proceed as soon as is practicable with the notification of the application, unless the application has been withdrawn or the Primary Care Trust is required to treat it as withdrawn.

(3) Notification must not be delayed because of a deferral under regulation 34 in a case where the applicant is relying on paragraph 5(1), unless prior to the decision to defer the applicant's home Primary Care Trust has provided PCT1 with its recommendation under paragraph 13(2).

#### **Refusal of notifiable applications prior to notification because of the language requirement for some NHS pharmacists**

15. A Primary Care Trust that receives a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list may, without notifying that application under Part 3 (or if no notification is required, as soon as is practicable), decide to refuse that application under regulation 30.

#### **Refusal of notifiable applications on fitness grounds prior to notification**

16. A Primary Care Trust that receives a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list may, without notifying that application under Part 3, decide to refuse that application under regulation 33(1).

#### **Proposed new pharmacy premises in controlled localities: refusal of routine applications because of preliminary matters prior to notification**

17. A Primary Care Trust that receives a routine application where the applicant is seeking the listing of pharmacy premises must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not the application needs to be refused under regulation 40(2).

## **PART 3**

### **Notification of certain applications**

#### **Applications requiring notifications**

18. An application is a "notifiable application" for the purposes of this Schedule if—

- (a) it is a routine application; or
- (b) it is an excepted application pursuant to regulation 24, 25 or 26(2),

and the Primary Care Trust to whom the application was made has not decided to dispense with the notification pursuant to paragraphs 15 to 17.

#### **Notification procedure for notifiable applications**

19.—(1) As soon as is practicable (having regard to its functions under Part 2), the Primary Care Trust (PCT1) must give notice of a notifiable application to—

- (a) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (b) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (c) any person—
  - (i) included in its pharmaceutical list, or
  - (ii) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;

- (d) any LPS chemist—

- (i) with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, and
  - (ii) whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;
- (e) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT1, has a significant interest in the outcome of the application;
- (f) if the applicant is seeking to locate premises in, or within 1.6 kilometres of, a controlled locality in its area—
- (i) any provider of primary medical services, or
  - (ii) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services); and
- who, in the opinion of PCT1, has a significant interest in the outcome of the application;
- (g) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the proposed listed chemist premises to which the application relates.
- (2) PCT1 may also give notice of the notifiable application to any other person who, in the opinion of PCT1, has a significant interest in the outcome of the application.
- (3) A Primary Care Trust notified under sub-paragraph (1)(g) (PCT2) must, within 14 days of receiving the notification—
- (a) give notice of the application to—
    - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
    - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
    - (iii) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
    - (iv) any LPS chemist—
      - (aa) with whom PCT2 has made arrangements for the provision of any local pharmaceutical services, and
      - (bb) whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
    - (v) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT2, has a significant interest in the outcome of the application, and
    - (vi) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in its area—
      - (aa) any provider of primary medical services, or
      - (bb) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services),
 who, in the opinion of PCT2, has a significant interest in the outcome of the application; and
  - (b) notify PCT1 of the action that it has taken under sub-paragraph (a).
- (4) Those notified under sub-paragraphs (1) to (3)(a) may make representations in writing about the application that is the subject of the notification to PCT1, provided they do so—

- (a) within 45 days of the date on which notice of the application was given to them; or
- (b) in the case of notifications under sub-paragraph (2) or (3), within such longer period as PCT1 may specify.

### **Parallel notifications**

**20.**—(1) If the Primary Care Trust is considering, as a consequence of a notifiable application, making (including revising) a determination as to whether or not an area is or is not to be part of a controlled locality, it must give notice under this Part at the same time that it gives notice under regulation 38(1).

(2) If, as a consequence of a notifiable application, a Primary Care Trust is required, by virtue of regulation 41 to determine whether or not an area is a reserved location, the Primary Care Trust must consider giving notice under this Part at the same time that it gives notice under regulation 41(4).

### **Content of notifications**

**21.**—(1) A person notified under paragraph 19 (P)—

- (a) must be informed—
  - (i) of P’s right to make representations under paragraph 19(4);
  - (ii) of the circumstances in which notified persons would be permitted, pursuant to paragraph 25, to make oral representations at any oral hearing relating to the application, and
  - (iii) if the Primary Care Trust intends to consider the application together and in relation to any other application, of that intention;
- (b) need not be given the same information as other persons notified under paragraph 19 but, subject to sub-paragraphs (2) to (4), P must be provided with sufficient information, from the information supplied by the applicant, to enable P to make informed representations with regard to whether or not the application should be granted, having regard to P’s interest in the matter.

(2) P need not be provided with any information that is published as part of the Primary Care Trust’s pharmaceutical needs assessment.

(3) P must not be provided with—

- (a) information supplied by the applicant (A), or where applicable A’s home Primary Care Trust, under paragraphs 2 to 5 or 13; and
- (b) any private addresses, private telephone numbers or dates of birth supplied by A.

(4) If A advises the Primary Care Trust that—

- (a) information supplied by A is considered by A to be confidential to A; and
- (b) A does not consent to the information being disclosed as part of the notification,

the Primary Care Trust must withhold that information from P if it considers that the full disclosure principle does not require it to provide that information to P.

(5) The “full disclosure principle” is that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application, unless it is fair and proper for that information to be withheld from that individual.

(6) If information is being withheld from P under paragraph (4), P must be informed of the nature of the information that is being withheld from P.

## PART 4

### Determination and deferral of applications

#### **Flexibility with regard to determining or deferring applications**

**22.**—(1) Except in so far as these Regulations provide to the contrary, a Primary Care Trust is to determine or defer routine and excepted applications in such manner (including with regard to procedures) as it sees fit.

(2) A Primary Care Trust may determine a routine or excepted application without hearing any oral representations, if it considers that oral representations are unnecessary.

(3) Where appropriate, a Primary Care Trust may if it thinks fit consider 2 or more applications together and in relation to each other, but where it does so, it must give notice to the applicants of its intention to do so (if it has not already done so under Part 3).

#### **Additional matters for consideration in relation to applications for inclusion in a pharmaceutical list**

**23.**—(1) In the case of a routine or excepted application by a person (A) for inclusion in a pharmaceutical list who is not already included in it, a Primary Care Trust must, prior to determining the application—

- (a) check with the NHS BSA whether A, and if A is a body corporate whether any director or superintendent of A, has any record of, or is under investigation for, fraud;
- (b) check with the Secretary of State whether the Secretary of State holds any information about A, and if A is a body corporate about any director or superintendent of A, that is relevant to its consideration of whether—
  - (i) the application should be refused or deferred under regulations 33 or 34, or
  - (ii) conditions should be imposed under regulation 35;
- (c) take up references from, and check the references provided by, the referees whose details A is required to provide pursuant to paragraph 3(8).

(2) In such a case, having considered whether—

- (a) the application should be refused or deferred under regulations 33 or 34; or
- (b) conditions should be imposed under regulation 35,

if it is minded to impose conditions under regulation 35, it must notify A at least 7 days in advance of determining that it is to impose such conditions and consider any representations (which may be at an oral hearing) that A makes prior to the determination with regard to the notification.

#### **Action following deferrals**

**24.**—(1) Where a Primary Care Trust (PCT1) receives a routine or excepted application, consideration or determination of which may be deferred, if it does decide to defer consideration or determination of that application (whether before or after the application is notified, in the case of a notifiable application), it must—

- (a) notify the applicant (A) of its decision and the reasons for it; and
- (b) where possible, notify A of the period for which the application is being deferred (if necessary by reference to a future event rather than a period of time).

(2) If the application is—

- (a) a routine application, consideration of which may be deferred under regulation 14(1)(a), 16(1)(a), 19(2)(a) or 21(1)(a), it must proceed as soon as is practicable to invite other applications under regulation 14(1)(b), 16(1)(b), 19(2)(b) or 21(1)(b), in such manner as it sees fit;

- (b) a routine application, consideration of which may be deferred under regulation 14(2), 16(3), 19(3) or 21(3), it must make arrangements that enable it to consider the other applications at the same time as A’s application, as soon as is practicable;
- (c) a routine application, consideration of which may be deferred under regulation 14(3), 16(4), 19(4) or 21(4), it must, once the appeal relating to the other application has reached its final outcome, notify A of that outcome and that A must within a specified period (of not less than 30 days)—
  - (i) update A’s application, and
  - (ii) notify PCT1 as to whether or not A still wishes to proceed with the application;
- (d) a routine application, consideration of which may be deferred under regulation 16(2) or 21(2), it must keep under regular review the issue of whether the future circumstances that gave rise to the deferral have arisen;
- (e) a routine application, consideration of which may be deferred under regulation 32, it must—
  - (i) send A a copy of the designation that led to the decision,
  - (ii) review that decision once the designation that led to the decision has been cancelled or is varied in a manner which means the application may no longer be deferred under regulation 32,
  - (iii) notify A of the cancellation or variation, and
  - (iv) require A within a specified period (of not less than 30 days)—
    - (aa) to update A’s application, and
    - (bb) to notify PCT1 as to whether or not A still wishes to proceed with the application;
- (f) a routine or excepted application, consideration of which may be deferred under regulation 34, once the outcome of the cause for the deferral is known, PCT1 must notify A that A must within a specified period (of not less than 30 days)—
  - (i) update A’s application; and
  - (ii) notify PCT1 as to whether or not A still wishes to proceed with the application; and
- (g) a routine application, consideration of which must be deferred under regulation 38(4), it must proceed, as soon as is practicable, with the determination of whether the relevant area is or is not to be part of a controlled locality.

(3) If A informs the Primary Care Trust within the period specified under sub-paragraph (2)(c), (e)(iv) or (f) that A does not wish to proceed with the application, or fails to respond in the required manner to the notification within the specified period, the application is to be treated as withdrawn.

### Oral hearings

- 25.—**(1) If the Primary Care Trust does decide to hear oral representations, it must—
- (a) give the applicant and any additional presenters not less than 14 days notice of the time and place at which the oral representations are to be heard; and
  - (b) in the case of the applicant, advise the applicant of who apart from the applicant (including other applicants, where the hearing relates to more than one application), has been invited to make representations at the hearing.
- (2) For these purposes, a person (P) is an “additional presenter” if—
- (a) the application to which the oral hearing relates is a notifiable application;
  - (b) P was given notice of the application under Part 3 and made representations about the application in accordance with paragraph 19(4), which—
    - (i) indicated that, if there were to be an oral hearing in relation to the application, P would wish to make oral representations at that hearing, and



- (ii) identified a matter about which the Primary Care Trust considers it would be desirable to hear further evidence from P at the oral hearing; and
  - (c) the Primary Care Trust is satisfied that P made a reasonable attempt to express P's views on the application adequately in P's written representations.
- (3) If the Primary Care Trust decides at or after an oral hearing that an application is to be deferred, it may (but need not) hold a further oral hearing once the period for which the application is deferred expires.

**Persons barred from taking part in decision making on routine and excepted applications**

**26.**—(1) No person is to take part in determining or deferring any routine or excepted application who—

- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
- (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
- (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
- (d) is a provider of primary medical services;
- (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- (f) is employed or engaged by a primary medical services provider or a PCTMS practice; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

whether or not their involvement would give rise to a reasonable suspicion of bias.

(2) No other person is to take part in determining or deferring a particular routine or excepted application if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

**Timetable for determining applications**

**27.** As regards any routine or excepted application—

- (a) the Primary Care Trust must endeavour to determine it as soon as is practicable; and
- (b) unless consideration of it is deferred in accordance with these Regulations or there is other good cause for delay, in the case of—
  - (i) a notifiable application, the Primary Care Trust must determine it within 4 months of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it, or
  - (ii) an application which is not a notifiable application, the Primary Care Trust must determine it within 30 days of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it.

**PART 5**

Notification, taking effect of decisions and rights of appeal to the Secretary of State

**Notification of decisions on routine and excepted applications**

**28.**—(1) As regards any routine application, once it has determined the application, a Primary Care Trust (PCT1) must, as soon as is practicable, give notice of its decision to—

- (a) the applicant;

- (b) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
  - (c) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
  - (d) any person—
    - (i) included in its pharmaceutical list, or
    - (ii) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 whose interests might, in the opinion of PCT1, be significantly affected by the decision;
  - (e) any LPS chemist—
    - (i) with whom the Primary Care Trust has made arrangements for the provision of any local pharmaceutical services, and
    - (ii) whose interests might, in the opinion of PCT1, be significantly affected by the decision;
  - (f) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT1 has a significant interest in the decision;
  - (g) if the applicant is seeking to locate premises in or within 1.6 kilometres of a controlled locality in its area—
    - (i) any provider of primary medical services, or
    - (ii) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services),
 who, in the opinion of PCT1, has a significant interest in the decision;
  - (h) any person—
    - (i) whom PCT1 notified under paragraph 19(2), and
    - (ii) who made representations in writing about the application under paragraph 19(4); and
  - (i) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates.
- (2) A Primary Care Trust notified under paragraph (1)(i) (PCT2) must, as soon as is practicable—
- (a) give notice of the decision to—
    - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
    - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
    - (iii) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 whose interests might, in the opinion of PCT2, be significantly affected by the decision;
    - (iv) any LPS chemist—
      - (aa) with whom PCT2 has made arrangements for the provision of any local pharmaceutical services, and
      - (bb) whose interests might, in the opinion of PCT2, be significantly affected by the decision,

- (v) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT2 has a significant interest in the decision, and
  - (vi) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in its area—
    - (aa) any provider of primary medical services, or
    - (bb) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services),
 who, in the opinion of PCT2, has a significant interest in the decision, and
  - (b) notify the Primary Care Trust that gave it notice under sub-paragraph (1)(i) of the action that it has taken under paragraph (a).
- (3) As regards any excepted application, once it has determined the application, PCT1 must, as soon as is practicable, give notice of its decision to—
- (a) in the case of an application pursuant to regulation 23, the applicant;
  - (b) in the case of an application pursuant to regulation 24, 25 or 26(2)—
    - (i) the applicant,
    - (ii) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
    - (iii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts), and
    - (iv) any person whom a Primary Care Trust (not necessarily PCT1) notified under paragraph 19 and who made representations in writing about the application under paragraph 19(4);
  - (c) in the case of an application pursuant to regulation 26(1) or 27 to 29—
    - (i) the applicant,
    - (ii) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
    - (iii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
    - (iv) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 whose interests might, in the opinion of PCT1, be significantly affected by the decision;
    - (v) any LPS chemist—
      - (aa) with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, and
      - (bb) whose interests might, in the opinion of PCT1, be significantly affected by the decision,
    - (vi) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT1 has a significant interest in the decision, and
    - (vii) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates.
- (4) A Primary Care Trust notified under sub-paragraph (3)(c)(vii) (PCT3) must as soon as is practicable—
- (a) give notice of the decision to—

- (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
- (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
- (iii) any person—
  - (aa) included in its pharmaceutical list, or
  - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 

whose interests might, in the opinion of PCT3, be significantly affected by the decision;
- (iv) any LPS chemist—
  - (aa) with whom PCT3 has made arrangements for the provision of any local pharmaceutical services, and
  - (bb) whose interests might, in the opinion of PCT3, be significantly affected by the decision,
- (v) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT3 has a significant interest in the decision, and

(b) notify the Primary Care Trust that gave it notice under sub-paragraph (3)(c)(vii) of the action that it has taken under paragraph (a).

(5) Where a Primary Care Trust has decided to consider 2 or more applications together pursuant to paragraph 22(3), it must give notice to each applicant of the decision taken with regard to each other application considered together with their application.

(6) Each notification of a decision under this paragraph must include a statement by PCT1 of the reasons for the decision.

#### **Template notice of commencement to be included with a notice of decision**

29. A Primary Care Trust must send with a notice of decision under paragraph 28 in respect of the grant of an application a template of a notice of commencement, for the applicant to send to it under paragraph 34, in which the applicant is to provide the following information (some of which the Primary Care Trust may have included in the template that it sends)—

- (a) the address of the premises to which the application relates;
- (b) the services that are to be provided from those premises;
- (c) the date of the grant of the application;
- (d) a declaration with regard to when the applicant intends to commence the provision of those services at those premises;
- (e) in the case of pharmacy premises, the registration number for those premises with the General Pharmaceutical Council; and
- (f) a signature on behalf of the applicant and the date of the notice.

#### **Third party rights of appeal to the Secretary of State where an application is granted**

30.—(1) A person with third party rights (as provided for in this paragraph) may appeal to the Secretary of State against a decision of a Primary Care Trust (PCT1) to grant a notifiable application, or an application to which regulation 26(1), 27 or 28 applies, provided that the person notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which that person was notified of PCT1's decision under paragraph 28.

- (2) For the purposes of this Schedule, a person (P1) is a person with third party rights if—
  - (a) P1 is a person to whom sub-paragraph (3) applies; or

(b) P1 was entitled to receive notification of the decision to grant the application by virtue of paragraph 28(5).

(3) P1 is a person to whom this sub-paragraph applies if—

(a) P1 was a person whom a Primary Care Trust (not necessarily PCT1) was required to notify about the decision on the application by virtue of P1 being—

(i) included in its pharmaceutical list, or

(ii) entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

and a person whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision;

(b) in the case of a notifiable application, P1 made representations in writing about the application under paragraph 19(4); and

(c) in the case of a notifiable application but subject to sub-paragraph (6), PCT1 is satisfied, having regard to those representations in writing and any oral representations made in accordance with paragraph 25, that P1—

(i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and

(ii) has grounds for opposing the application, which—

(aa) do not amount to a challenge to the legality or reasonableness of PCT1's pharmaceutical needs assessment, or to the fairness of the process by which PCT1 undertook that assessment, and

(bb) are not vexatious or frivolous.

(4) If PCT1 considers that a person notified under paragraph 28 is a person with third party appeal rights, it must notify that person of that fact when it notifies that person of the determination.

(5) A notice of appeal under sub-paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

(6) A person to whom sub-paragraph (3)(a) and (b) applies (P2) who is not notified by the Primary Care Trust that they are person with third party appeal rights may appeal to the Secretary of State against the determination (D1) by the Primary Care Trust that it is not satisfied as mentioned in sub-paragraph (3)(c), provided that P2—

(a) notifies the Secretary of State within 30 days of the date on which that person was notified of PCT1's decision under paragraph 28 (D2) that P2 wishes to appeal against D1 and D2; and

(b) includes within that notification concise and reasoned statements of P2's grounds of appeal against both D1 and D2,

and if the appeal against D1 is successful, P2 is a person with third party appeal rights in relation to D2 for the purposes of this Schedule.

### **Conditional grant of applications where the address of the premises is unknown**

31.—(1) As regards any routine application, sub-paragraph (2) applies where—

(a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and

(b) prior to the determination of the application, A was only able to provide a best estimate of where the proposed listed chemist premises would be (not the address of those premises).

(2) Where this sub-paragraph applies, it is a condition of the grant of that application that A notifies to the Primary Care Trust that granted the application the address of the premises to be listed within 6 months of—

- (a) the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3);
- (b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, the date on which the appeal is determined by the Secretary of State; or
- (c) in a case of an application which is subject to a condition imposed by virtue of paragraph 33(2), the date on which that condition becomes spent,

whichever is the latest.

(3) A notification under sub-paragraph (2) is only valid if the Primary Care Trust is satisfied that the premises are at a location that is within the range of possible locations covered by the estimate referred to in sub-paragraph (1)(b).

(4) If a Primary Care Trust receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

- (a) notify A of whether or not it is satisfied that it is a valid notification;
- (b) if it is satisfied that it is a valid notification, notify the address to the persons notified of the decision to grant the application; and
- (c) if the Primary Care Trust is not satisfied that it is a valid notification, it must include with that notification—
  - (i) the reasons for its decision, and
  - (ii) an explanation of how A’s rights of appeal under paragraph 36(1)(b) may be exercised.

(5) A Primary Care Trust may not vary or remove a condition imposed by virtue of this paragraph.

(6) If A breaches a condition imposed by virtue of this paragraph, the grant of the application lapses.

**Changes to the premises specified in an application after its grant but before the listing of the premises**

32.—(1) As regards any routine application, sub-paragraph (2) applies where—

- (a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and
- (b) prior to the determination of the application, A provided the address of where the proposed listed chemist premises would be.

(2) Where this sub-paragraph applies, A may notify to the Primary Care Trust (PCT1) that granted the application a different address (“new address”) as the address to which the application relates within—

- (a) 4 months of the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3); or
- (b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, 4 months of the date on which the appeal is determined by the Secretary of State.

(3) A notification under sub-paragraph (2) is only valid if PCT1 is satisfied that accepting the notification as valid would neither—

- (a) result in a significant change to the arrangements that are in place (having regard to the grant of A’s application) for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
  - (i) in any part of its area, or



- (ii) in a controlled locality of a neighbouring Primary Care Trust, where that controlled locality is within 1.6 kilometres of the new address; nor
  - (b) cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area.
- (4) If PCT1 receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—
- (a) notify A of whether or not it is satisfied that it is a valid notification, together with the reasons for its decision;
  - (b) if PCT1 is not satisfied that it is a valid notification, it must include with that notification—
    - (i) the reasons for its decision, and
    - (ii) an explanation of how A’s rights of appeal under paragraph 36(1)(b) may be exercised.
  - (c) if it is satisfied that it is a valid notification, notify the new address to the persons notified of the decision to grant the application, and must include with that notification—
    - (i) the reasons for its decision, and
    - (ii) if the person has a right of appeal under sub-paragraph (5), an explanation of how that right of appeal may be exercised.
- (5) A person (X) who—
- (a) is notified under sub-paragraph (4)(c); and
  - (b) was entitled to be notified of the decision to grant the application—
    - (i) by virtue of paragraph 28(5), or
    - (ii) as a person whom a Primary Care Trust (not necessarily PCT1) was required to notify about the application by virtue of X being—
      - (aa) included in its pharmaceutical list, or
      - (bb) entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 and a person whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision;
- may appeal against a decision by PCT1 to accept the purported notification as a valid notification, provided X notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which X was notified under sub-paragraph (4)(c).
- (6) A notice of appeal under sub-paragraph (5) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

**Conditional grant in cases relating to future needs or future improvements or better access**

- 33.—**(1) Where a Primary Care Trust (PCT1) grants a routine application because doing so—
- (a) will meet a future need for pharmaceutical services, or pharmaceutical services of a specified type in its area; or
  - (b) will secure future improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type, in its area,
- sub-paragraph (2) applies.
- (2) Where this sub-paragraph applies, PCT1 may grant the application subject to a condition that pharmaceutical services are not provided at the listed chemist premises to which the application relates (or at any premises to which the business relocates) until—
- (a) some or all of the future circumstances, as a consequence of which the application was granted, have arisen; or

- (b) a specified date (having regard to when some or all of the future circumstances, as a consequence of which the application was granted, are likely to arise).
- (3) PCT1 may vary or remove a condition imposed by virtue of sub-paragraph (2), but if it varies the condition, the revised condition (which becomes a condition imposed by virtue of sub-paragraph (2)) must be a condition that it also meets the requirements of that paragraph.
- (4) The condition imposed by virtue of sub-paragraph (2) becomes spent once—
  - (a) where a date has been specified, that date passes; or
  - (b) where the condition relates to future circumstances arising, PCT1 notifies the successful applicant (P) that the future circumstances have arisen.
- (5) P may by a notice request a determination from PCT1 as to whether the future circumstances have arisen at any time (but only once in any 60 days), and PCT1 must give notice of that determination within 30 days of that request.

**Taking effect of listing decisions: general**

- 34.—(1) As regards any application—
- (a) for inclusion in a pharmaceutical list of a Primary Care Trust (PCT1) by a person who is not already included in it; or
  - (b) by a person who is included in a PCT1’s pharmaceutical list and who is seeking—
    - (i) to open, within the area of PCT1, additional premises from which to provide the same or different pharmaceutical services;
    - (ii) to relocate to different premises in the area of PCT1, and at those premises to provide the same or different pharmaceutical services;
    - (iii) to provide, from the person’s listed chemist premises within the area of PCT1, services that are in addition to those already listed in relation to that person,
- if the application is granted, paragraph (2) applies.
- (2) Subject to paragraph 35, PCT1 may only change its pharmaceutical list to give effect to that decision if the successful applicant (P) gives PCT1 a valid notice of commencement, in the correct form, informing PCT1 that P is to commence the provision of the services in respect of which the application was made and at the premises to which the application related in the next 14 days.
- (3) A notice of commencement is in the correct form if it—
    - (a) includes the information required under paragraph 29; and
    - (b) is in the same format as the version of the notice sent by the Primary Care Trust with the notice of decision under paragraph 28.
  - (4) A notice of commencement is invalid unless it is sent to PCT1 within—
    - (a) if, prior to PCT1 determining the application—
      - (i) P undertook to commence the provision of the services in respect of which the application was made within a period of less than 6 months, and
      - (ii) that undertaking was not withdrawn, that period;
    - (b) 6 months of—
      - (i) unless paragraph (a) applies, the date on which P was sent the notice of PCT1’s decision under paragraph 28 granting the application,
      - (ii) if the grant was appealed by a person with third party appeal rights, the date on which that appeal is determined by the Secretary of State,
      - (iii) if, in the course of granting the application, a decision is taken to impose a condition in accordance with regulation 35 and that condition is appealed by P, the date on which that appeal is determined by the First-tier Tribunal (unless regulation 35(8) applies),

- (iv) if the grant of the application was subject to a condition imposed by virtue of paragraph 31, the date on which—
  - (aa) P validly notifies to PCT1 under a condition imposed by virtue of paragraph 31 of the address of the premises, or
  - (bb) if P appeals successfully against a decision of PCT1 that a notification under a condition imposed by virtue of paragraph 31 is invalid, that appeal is determined by the Secretary of State,
- (v) if P, pursuant to paragraph 32—
  - (aa) notifies PCT1 of a new address,
  - (bb) PCT1 does not accept the validity of the notification, and
  - (cc) P appeals successfully against that decision,
 the date on which that appeal is determined by the Secretary of State, or
- (vi) if the grant of the application was subject to a condition imposed by virtue of paragraph 33, the date on which the condition imposed by virtue of that paragraph becomes spent or is removed on appeal, or  
whichever is the latest; or
- (c) such longer period—
  - (i) not exceeding a further 3 months as PCT1 may allow, or
  - (ii) if—
    - (aa) the grant is appealed by a person with third party appeal rights,
    - (bb) a decision to accept a notification pursuant to paragraph 32 is appealed by a third party,
    - (cc) P appeals successfully against a notice under paragraph 35, or
    - (dd) if P appeals successfully against a decision not to allow a longer period under sub-paragraph (i),
 as the Secretary of State may allow when the appeal is determined,

and so once a valid notice of commencement can no longer be sent in relation to an application (having regard also to paragraph 10(2) of Schedule 3), the grant of that application lapses.

(5) A notice of commencement ceases to have effect if the Secretary of State receives a valid notice of appeal—

- (a) from a person with third party appeal rights relating to the grant to which the notice of commencement relates; or
- (b) from a third party, in a case to which sub-paragraph (4)(c)(ii)(bb) applies.

**Notice requiring the commencement of pharmaceutical services**

**35.—**(1) A Primary Care Trust that has granted a routine application—

- (a) for inclusion in a pharmaceutical list by a person (P) not already included; or
- (b) if P is already included in that list, for inclusion also in relation to premises not already listed in relation to P,

may, if the grant has not lapsed and is not under appeal to the Secretary of State, give notice to P requiring P to commence the provision of pharmaceutical services by a date specified in the notice.

(2) If a Primary Care Trust gives notice under sub-paragraph (1) but afterwards a valid notice of appeal is given against the grant, the notice under sub-paragraph (1) lapses.

(3) A notice under sub-paragraph (1) may not specify a date that is—

- (a) earlier than 30 days from the date of the notice under that paragraph; or
- (b) later than 9 months after the date on which the grant of the application was notified to P.

- (4) The Primary Care Trust may change its pharmaceutical list to give effect to that notice—
- (a) on the specified date, unless the decision to give notice under sub-paragraph (1) is appealed; or
  - (b) if the notice under paragraph (1) is appealed and the appeal is unsuccessful or discontinued—
    - (i) if the appeal is discontinued, 30 days after P discontinues the appeal,
    - (ii) if the appeal is unsuccessful, 30 days after the appeal is determined, or
    - (iii) on the specified date,whichever is the latest.

### **Appeals to the Secretary of State by the applicant**

**36.**—(1) As regards any routine or excepted application, other than an application pursuant to regulation 29, the applicant (A) may appeal to the Secretary of State against a decision by a Primary Care Trust—

- (a) to refuse the application on grounds set out in Parts 3 to 5 or 7 of these Regulations;
- (b) that a notification pursuant to a condition imposed by virtue of paragraph 31 is invalid;
- (c) to refuse to accept that a notification under paragraph 32(2) is a valid notification;
- (d) to impose or vary a condition imposed pursuant to paragraph 33;
- (e) to refuse to allow A an extension period under paragraph 34(4)(c)(i); or
- (f) to give notice under paragraph 35,

provided A notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which A was notified of the decision that is being appealed.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

## **SCHEDULE 3** Regs 10(7), 45(3), 63(6), 77(4), 98(9)

### **Appeals to the Secretary of State**

#### **PART 1**

##### **Preliminary matters**

#### **Determination of third party appeal rights in certain cases**

**1.**—(1) If the Secretary of State has received a notification under paragraph 30(6) of Schedule 2 from a person (P1), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P1 is to have third party appeal rights on the basis that—

- (a) P1 is a person to whom paragraph 30(3)(a) and (b) of Schedule 2 applies; and
- (b) in relation to P1, the Primary Care Trust (PCT1) should have been satisfied as mentioned in paragraph 30(3)(c) of Schedule 2.

(2) If the Secretary of State has received a notification under regulation 63(5) from a person (P2), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P2 is to have third party appeal rights on the basis that—

- (a) P2 is a person to whom regulation 63(3)(a) and (b) applies; and
- (b) in relation to P2, the Primary Care Trust (PCT2) should have been satisfied as mentioned in regulation 63(3)(c).

(3) Once the Secretary of State has made a determination under paragraph (1) or (2), the Secretary of State must notify P1 and PCT1, or P2 and PCT2, of that determination and the reasons for it.

### **Misconceived appeals**

2. If the Secretary of State, after considering a valid notice of appeal under regulation 45, 63 or 77, or paragraph 30, 32(5) or 36 of Schedule 2, against a decision, is of the opinion that the notice—

- (a) contains no valid grounds of appeal (for example, because it amounts to a challenge to the legality or reasonableness of the Primary Care Trust's pharmaceutical needs assessment, or to the fairness of the process by which the Primary Care Trust undertook that assessment); or
- (b) contains no reasonable grounds for appeal (for example, where it is vexatious or frivolous),

the Secretary of State may determine the appeal by dismissing it (without proceeding to notify the appeal under Part 2).

## **PART 2**

### **Notification of appeals**

#### **Notification of appeals notices under paragraph 30, 32(5) or 36 of Schedule 2**

3.—(1) Unless the Secretary of State determines the appeal under paragraph 2, or the appeal relates to an application pursuant to regulation 23, the Secretary of State must send a copy of a valid notice of appeal sent under paragraph 30, 32(5) or 36 of Schedule 2 to—

- (a) the Primary Care Trust that took the decision that is being appealed;
- (b) in the case of an appeal against the grant of an application, any person who was entitled to receive notification of the decision by virtue of paragraph 28(5) of Schedule 2;
- (c) in the case of an appeal in relation to a notifiable application, including against decisions as mentioned in paragraphs 32(4) and 36(1)(b) to (f) of Schedule 2—
  - (i) the applicant (unless they are the person bringing the appeal),
  - (ii) any person who was notified in relation to that application under paragraph 19 of Schedule 2 who made representations in writing about the application under paragraph 19(4) of that Schedule (unless they are also the person bringing the appeal), and
- (d) in the case of an appeal in relation to an application pursuant to regulation 26(1), 27 or 28 (including against decisions as mentioned in paragraph 36(1)(d) to (f) of Schedule 2), any person notified in relation to the decision on that application under paragraph 28(3)(c) or (4).

(2) Any person to whom a notice of appeal is sent under sub-paragraph (1) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they are sent the notice of appeal by the Secretary of State.

#### **Notification of appeals relating to notices under regulation 45**

- 4.—(1) A valid notice of appeal under regulation 45(1)(b) does not need to be notified to others.
- (2) The Secretary of State must send a valid notice of appeal—
- (a) against a determination under regulation 36(2) to the persons given notice of the proposed determination under regulation 38(1) or (2); or
  - (b) against a determination under regulation 41(2) or 42(1) to—

- (i) the person making the routine application to which the determination relates, and
- (ii) any person given notice of the determination who is mentioned in regulation 43(1)(b)(ii),

unless they are the person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

#### **Notification of appeals relating to decisions under Part 8 of these Regulations**

- 5.**—(1) A valid notice of appeal under regulation 63(1)(a) does not need to be notified to others.
- (2) The Secretary of State must send a valid notice of appeal against—
- (a) a decision mentioned in regulation 63(1)(b) to the persons, other than the appellant, given notice of the decision under regulation 50(6); or
  - (b) a decision or determination mentioned in regulation 63(1)(c) to (f) to—
    - (i) the person who made the original application for outline consent or premises approval,
    - (ii) any person who was notified in relation to that application under regulation 52(1) to (3) who made representations in writing about the application under regulation 52(4), and
    - (iii) if the appeal is against a refusal to grant temporary premises approval, the applicant who made the relevant outstanding pharmacy application,
- unless they are person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

#### **Non notification of appeals relating to notices under regulation 77 or 98**

- 6.** A valid notice of appeal under regulation 77 or 98 does not need to be notified to others.

## **PART 3**

### **Determination of appeals**

#### **Flexibility with regard to the manner of determining appeals**

**7.**—(1) Except in so far as these Regulations provide to the contrary, the Secretary of State is to determine the appeal to which a valid notice of appeal under regulation 45, 63 or 77, or under paragraph 30, 32(5) or 36 of Schedule 2, relates in such manner (including with regard to procedures) as the Secretary of State sees fit.

(2) The Secretary of State may determine the appeal without hearing any oral representations, if the Secretary of State considers that oral representations are unnecessary.

(3) Where appropriate, the Secretary of State may, if the Secretary of State thinks fit, consider 2 or more appeals together and in relation to each other, but where the Secretary of State does so, the Secretary of State must give notice of the Secretary of State's intention to do so to—

- (a) the Primary Care Trust that took the decisions that are being appealed;
- (b) the appellants; and
- (c) any other person notified in relation to the appeals under Part 2.



## Oral hearings

8.—(1) If the Secretary of State does decide to hear oral representations, the Secretary of State must give not less than 14 days notice of the time and place at which the oral representations are to be heard to—

- (a) the Primary Care Trust that took the decision that is being appealed;
- (b) the person who made the original application to which the appeal relates;
- (c) if a person other than that applicant is bringing the appeal, the person bringing the appeal;
- (d) any Local Pharmaceutical Committee for the area of the Primary Care Trust (including one for its area and that of one or more other Primary Care Trusts);
- (e) any Local Medical Committee for the area of the Primary Care Trust (including one for its area and that of one or more other Primary Care Trusts); and
- (f) any additional presenters,

and they (or their duly authorised representatives) are to be the only persons entitled to make oral representations at the hearing.

(2) For these purposes, a person (P) is an “additional presenter” if—

- (a) P was notified of the appeal under Part 2 and has made written representations in accordance with paragraph 3(2), 4(3) or 5(3), which—
  - (i) indicated that, if there were to be an oral hearing in relation to the appeal, P would wish to make oral representations at that hearing, and
  - (ii) identified a matter about which the Secretary of State considers it would be desirable to hear further evidence from P at the oral hearing; and
- (b) the Secretary of State is satisfied that P made a reasonable attempt to express P’s views on the appeal adequately in P’s written representations.

## Decisions of the Secretary of State

9.—(1) On determining an appeal relating to a valid notice under paragraph 30 or 36, the Secretary of State may—

- (a) if the appeal is an appeal to which paragraph 30 or 36(1)(a) of Schedule 2 applies (that is, against a decision to grant or refuse a routine or excepted application)—
  - (i) confirm the decision of the Primary Care Trust,
  - (ii) quash the decision and redetermine the application, or
  - (iii) quash the decision and remit the matter to the Primary Care Trust for it to redetermine the application, where the Secretary of State considers that there should be a (further) notification under paragraph 19 of Schedule 2, subject to such directions as the Secretary of State considers appropriate; or
- (b) if the appeal is an appeal to which paragraph 32(5) or 36(1)(b) to (f) applies—
  - (i) confirm the decision of the Primary Care Trust, or
  - (ii) substitute for that decision any decision that the Primary Care Trust could have taken when it took that decision.

(2) If the Secretary of State grants or confirms the grant of a routine application, the Secretary of State may direct the Primary Care Trust—

- (a) to impose a condition under paragraph 33, in circumstances where the Primary Care Trust could have imposed such a decision if it had granted the application; or
- (b) to take such action under regulation 50(4) or (5) as the Secretary of State thinks fit.

(3) On determining an appeal relating to a valid notice under regulation 45, the Secretary of State may—

- (a) confirm the decision or determination of the Primary Care Trust;

- (b) substitute for that decision or determination any decision or determination that the Primary Care Trust could have taken when it took that decision or made that determination; or
  - (c) quash the decision or determination of the Primary Care Trust and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate.
- (4) On determining an appeal relating to a valid notice under regulation 63, the Secretary of State may—
- (a) in the case of decision or determination mentioned in regulation 63(1)(a), (b), (e) or (f)—
    - (i) confirm the decision or determination of the Primary Care Trust,
    - (ii) substitute for that decision or determination any decision or determination that the Primary Care Trust could have taken when it took that decision or made that determination, or
    - (iii) quash the decision or determination of the Primary Care Trust and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate; or
  - (b) if the appeal is against a decision to grant or refuse an application for outline consent or premises approval—
    - (i) confirm the decision of the Primary Care Trust,
    - (ii) quash the decision of the Primary Care Trust and redetermine the application, or
    - (iii) quash the decision of the Primary Care Trust and remit the matter to it for it to redetermine the application, subject to such directions as the Secretary of State considers appropriate.
- (5) On determining an appeal relating to a valid notice under regulation 77, the Secretary of State may—
- (a) confirm the decision of the Primary Care Trust; or
  - (b) substitute for that decision any decision that the Primary Care Trust could have taken when it took that decision.
- (6) If the Secretary of State grants or confirms the grant of an application for—
- (a) outline consent, the Secretary of State may direct the Primary Care Trust to take such action under regulation 53(4) as the Secretary of State thinks fit; or
  - (b) premises approval, the Secretary of State may direct the Primary Care Trust to take such action under regulation 57 as the Secretary of State thinks fit.

**Notification of decisions and subsequent action by the Primary Care Trust**

**10.—**(1) Once the Secretary of State has determined the appeal, the Secretary of State must notify the following—

- (a) the Primary Care Trust that took the decision that was being appealed;
- (b) the person who made the original application to which the appeal relates;
- (c) if a person other than that person brought the appeal, the person who brought the appeal; and
- (d) any person who made written representations relating to the application pursuant to the notification under Part 2,

and must include with that notification a statement of the reasons for the Secretary of State's decision and the Secretary of State's findings of fact.

(2) If the Secretary of State has granted or confirmed the grant of a routine or excepted application—

- (a) the Primary Care Trust notified under sub-paragraph (3)(a) must send to the applicant a template of the notice of commencement referred to in paragraph 29; and

- (b) the time periods in paragraphs 31, 32 and 34 thereafter apply as if the references to the applicant being sent notices of the Primary Care Trust's decision were reference to the applicant being notified by the Secretary of State under paragraph (3).
- (3) If the Secretary of State has granted or confirmed the grant of—
  - (a) a routine application, the Primary Care Trust must proceed as soon as is practicable to take such action under regulation 50(4) or (5) as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(2)(b);
  - (b) an application for outline consent, the Primary Care Trust must proceed as soon as is practicable to make a determination under regulation 53(4), subject to any directions of the Secretary of State under paragraph 9(6)(a); or
  - (c) an application for premises approval, the Primary Care Trust must proceed as soon as is practicable take such action under regulation 57 as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(6)(b).

### **Effect of decisions by the Secretary of State**

**11.** For the purposes of these Regulations, the Secretary of State's decision becomes the Primary Care Trust's decision on the matter (but no further appeal to the Secretary of State on that decision is possible), unless the Secretary of State's decision is overruled by a court.

## 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; and
  - (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<sup>(a)</sup> (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—

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

- (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(a), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a repeatable prescriber,
  - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a repeatable prescriber and including the reference “SLS”,
  - (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
  - (iv) an order for a restricted availability appliance, signed by a repeatable 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—

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(a) 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.  
 (b) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154 and 2009/3136, and Schedule 5 has been amended by S.I. 2005/2864.

- (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<sup>(a)</sup> (supply of drugs and appliances by chemists) by virtue of either—
- (a) entitlement to exemption under regulation 7(1) of the Charges Regulations<sup>(b)</sup> (exemptions); or
  - (b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations<sup>(c)</sup> (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 him.

(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

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(a) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727 and 2011/518.

(b) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.

(c) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.



- (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.

### **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<sup>(a)</sup> 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 (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

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(a) 1985 c.72.

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

(12) 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;
- (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.

(13) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (12) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(14) 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; or
- (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.

(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 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 (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) where P has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that 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 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 entry in the NHS Care Record—

- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; and
- (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 102(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

### **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<sup>(a)</sup>, 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).

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(a) Established by S.I. 2007/478.



(2) P is not required to accept any drugs for disposal unless the Primary Care Trust in whose pharmaceutical list P is included 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 Primary Care Trust or by a waste disposal contractor retained by the Primary Care Trust, separate solid drugs or ampoules, liquids and aerosols from each other;
- (b) store the drugs in containers provided by the Primary Care Trust, or by a waste disposal contractor retained by the Primary Care Trust, 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 shall co-operate with any suitable arrangements that the Primary Care Trust has in place for regular collection of the drugs from P's pharmacy premises by or on behalf of the Primary Care Trust.

#### **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 its Primary Care Trust, ensure that—

- (a) P (including P's staff) participates, in the manner reasonably requested by the Primary Care Trust, 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 Primary Care Trust, 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 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 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 a Primary Care Trust 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 Primary Care Trust 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 Primary Care Trust, 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 Primary Care Trust 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 Primary Care Trust with a return informing it of the change.

(7) Where P has notified to 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 Primary Care Trust, unless the Primary Care Trust 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 Primary Care Trust 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 a Primary Care Trust 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 Primary Care Trust—

- (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) A Primary Care Trust 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, the Primary Care Trust 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(2) in respect of those hours is “reasonable remuneration” for these purposes).

### **Determination of pharmacy premises core opening hours instigated by the Primary Care Trust**

**25.**—(1) Where it appears to the Primary Care Trust, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, 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 Primary Care Trust 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 Primary Care Trust about the proposed changes.
- (3) When it determines the outcome of its assessment, the Primary Care Trust 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 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 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 a Primary Care Trust 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) A Primary Care Trust 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) A Primary Care Trust 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 Primary Care Trust or take any action that the Primary Care Trust 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 a Primary Care Trust 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 Primary Care Trust with such information as the Primary Care Trust 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 Primary Care Trust must determine the application within 60 days of receiving it (including any information required of P in accordance with paragraph (2)).

(4) When it determines the application, the Primary Care Trust 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 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 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 a Primary Care Trust 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) A Primary Care Trust 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 Primary Care Trust is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee before determining the application.

(8) A Primary Care Trust 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 Primary Care Trust or take any action that the Primary Care Trust 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, a Primary Care Trust 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 Primary Care Trust, adequate reasons.

(2) The Primary Care Trust need not approve the request in advance of the change or closure, and if it does not do so but 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 Primary Care Trust, 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 Secretary of State 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 Primary Care Trust 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(a);
- (b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one other audit agreed by P’s Primary Care Trust 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,
  - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State(b) and the National Health Service Commissioning Board,
  - (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 that 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 child protection procedures,

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(a) 2010 c. 15.

(b) 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.

- (ix) appropriate vulnerable adult (as construed in accordance with section 59 of the Safeguarding Vulnerable Groups Act 2006<sup>(a)</sup> (vulnerable adults)) protection procedures, and
- (x) P's monitoring arrangements in respect of P's compliance with the Health and Safety at Work etc. Act 1974<sup>(b)</sup>;
- (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 Primary Care Trust 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—
    - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996<sup>(c)</sup> (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 Primary Care Trust 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 Primary Care Trust to access that assessment; and

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(a) 2006 c. 47; section 59 has been amended by: the Education and Skills Act 2008 (c. 25), section 147(8); the Health Act 2009 (c. 21), Schedule 1, paragraphs 12 and 15, and Schedule 6; and S.I. 2008/912.

(b) 1974 c. 37.

(c) 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), 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 Primary Care Trust under section 126 of the National Health Service Act 2006.

- (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 Secretary of State.

### **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 (X) 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 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; or
- (b) nominating P as X’s dispensing contractor (or one of them) in X’s entry in the NHS Care Record.
- (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;
- (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 the NHS Care Record; 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) Subject to paragraph 33, 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 Primary Care Trust 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(a) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(b) (penalty as alternative to prosecution);

(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 Trust or other 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.

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(a) 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; and the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1).

(b) 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and has been amended by the Social Security Fraud Act 2001 (c. 11), section 14.



(2) Subject to paragraph 33, 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 Primary Care Trust 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 Trust or other 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 Primary Care Trust 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 Primary Care Trust 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 Primary Care Trust 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 Primary Care Trust, if it so requests, the name of any pharmacist employed or engaged by P who is responsible for dispensing a particular prescription.

(3) Subject to paragraph 33, if P is a body corporate, it must give notice to the Primary Care Trust within 30 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 paragraph 33, 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 Primary Care Trust the information mentioned in paragraph 3 and 4 of Schedule 2 about that person.

(5) Subject to paragraph 33, 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 the Primary Care Trust's pharmaceutical list, they must supply in writing to the Primary Care Trust—

- (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) Subject to paragraph 33, P or the director or superintendent of P (if P is a body corporate) must inform the Primary Care Trust—

- (a) if they, or a body corporate of which they are a director or superintendent, apply to be included in a relevant list other than the Primary Care Trust's pharmaceutical list, and of the outcome of any such application; and
- (b) if they become a director or superintendent of another body corporate which is on the relevant list of another Primary Care Trust, or which applies to be included in such a list, and of the outcome of any such application.

### **Home Primary Care Trust of bodies corporate**

33. Where an NHS pharmacist (P) is a body corporate with a registered office in England, the information to be provided under paragraphs 31 and 32(3) to (6) may be provided instead to P's home Primary Care Trust, if P, when it provides the information to the home Primary Care Trust, also provides the home Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists P is included or with which P has arrangements to provide local pharmaceutical services.

### **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(a), 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 Primary Care Trust 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

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

- (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 Primary Care Trust 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 Primary Care Trust, in connection with its functions that relate to pharmaceutical services.

## SCHEDULE 5

Regulation 11(2)(a)(i)

### Terms of service of NHS appliance contractors

#### **Division of responsibilities between individuals and corporate bodies**

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

- (a) if the NHS appliance contractor is a natural person—
  - (i) that person must comply with that requirement, or
  - (ii) if the NHS appliance contractor employs or engages other natural persons in connection with the provision of pharmaceutical services, the NHS appliance contractor must either comply with that requirement or secure compliance with that requirement by the other natural persons whom the NHS appliance contractor employs or engages; and
- (b) if the NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by the natural persons whom the NHS appliance contractor employs or engages in connection with the provision of pharmaceutical services.

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

- (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 referring, as appropriate to the NHS appliance contractor (if a natural person) or to the NHS appliance contractor's staff.

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

#### **Breaches by directors**

2. Where this Schedule imposes a requirement on the director of a body corporate that is included in 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.

#### **Dispensing services**

3. An NHS appliance contractor must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for 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 appliances**

4.—(1) In this Part, “signed” includes signature with a prescriber’s advanced electronic signature.

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

- (a) any person presents to an NHS appliance contractor (C) a non-electronic prescription form which contains—
  - (i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
  - (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”; or
- (b) C receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) and (ii) and—
  - (i) any person requests the provision of an appliance in accordance with that prescription, or
  - (ii) C has previously arranged with the patient that C will dispense that prescription on receipt,

C must, with reasonable promptness, provide the appliance so ordered if C supplies it in the normal course of business.

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

- (a) any person presents to C a non-electronic repeatable prescription which contains—
  - (i) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
  - (ii) an order for a restricted availability appliance, signed by a repeatable prescriber and including the reference “SLS”,and also presents an associated batch issue; or
- (b) C receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) or (ii) and—
  - (i) any person requests the provision of appliances in accordance with that prescription, or
  - (ii) C has previously arranged with the patient that the supplier will dispense that prescription on receipt,

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

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

- (a) C has that prescription in the supplier’s possession; and
- (b) that person presents, or C has in C’s possession, an associated batch issue.

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

5.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS appliance contractor (C) to provide an appliance.

(2) C may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to—

- (a) give C a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made; or
- (b) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

### **Preliminary matters before providing appliances**

6.—(1) If a person specified in sub-paragraph (2) asks an NHS appliance contractor (C) to do so—

- (a) C must give an estimate of the time when the appliance will be ready; and
- (b) if it is not ready by then, P must give a revised estimate of the time when it will be ready (until it is 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 appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

(3) Before providing an appliance in accordance with a prescription form or repeatable prescription—

- (a) C must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations<sup>(a)</sup> (supply of drugs and appliances by chemists) by virtue of either—

- (i) entitlement to exemption under regulation 7(1) of the Charges Regulations<sup>(b)</sup> (exemptions), or
- (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations<sup>(c)</sup> (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 C already has such evidence available to C;

- (b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by paragraph (a), is produced to C, C must endorse the form on which the declaration is made to that effect; and

- (c) in the case of an electronic prescription form or an electronic repeatable prescription, C must transmit to the Electronic Prescription Service—

- (i) in a case where exemption from or remission of charges is claimed, a record of—

- (aa) 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

- (bb) whether or not satisfactory evidence was produced to C as required by sub-paragraph (a), and

- (ii) in any case where a charge is due, confirmation that the relevant charge was paid.

### **Providing appliances**

7.—(1) Where an NHS appliance contractor (C) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, C must only provide the appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4; and

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(a) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727 and 2011/518.

(b) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.

(c) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

(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(a) and the following provisions of this Schedule.

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

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

(3) If the order is for an 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 appliance provided must comply with the standard or formula specified therein.

### **Refusal to provide appliances ordered**

**8.—**(1) An NHS appliance contractor (C) may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) C reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription (for example because C reasonably believes it has been stolen or forged);
- (b) it appears to C 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 appliance would be contrary to C's clinical judgement;
- (c) C 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 appliances in accordance with an electronic prescription form or repeatable prescription, or by any person accompanying that person; or
- (d) the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) C must refuse to provide appliances ordered on a repeatable prescription where—

- (a) C has no record of that prescription (other than on the first occasion on which the prescription is presented);
- (b) C does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to the supplier;
- (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 an 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) C has been informed by the repeatable prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), C must only provide the appliance ordered if C is satisfied that—

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(a) 1985 c. 72.



- (a) the patient to whom the prescription relates—
  - (i) is using and is likely to continue to use the appliance appropriately, and
  - (ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient's treatment;
- (b) the 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**

9.—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor (C) must—

- (a) ensure that appropriate advice is given to patients about any appliances provided to them—
  - (i) to enable them to utilise the appliances appropriately, and
  - (ii) to meet the patient's reasonable needs for general information about the appliances;
- (b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances;
- (c) 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;
- (d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available;
- (e) provide a patient with a written note of C's name, address and telephone number;
- (f) keep and maintain records—
  - (i) of 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 prescription), and
  - (iii) of notes provided under paragraph (d);
- (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 C takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (i) if C provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the 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 appliances—
  - (i) which are not required, or
  - (ii) where a patient is refused an appliance pursuant to paragraph 8;

- (l) ensure that where a person is refused appliances pursuant to paragraph 8(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;
- (m) where a patient is provided with 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 appliances pursuant to paragraph 8(3); and
- (o) when providing specified appliances, comply with the additional requirements set out in paragraph 11.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, C is unable to provide an appliance, or stoma appliance customisation is required and C is unable to provide that, C must—

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

#### **Additional requirements in relation to electronic prescribing**

**10.**—(1) An NHS appliance contractor (C) 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 C's appliance contractor premises; and
- (b) where the Electronic Prescription Service is not available through C's appliance contractor premises, provide that person with the names of at least 2 NHS appliance contractors through whom the Electronic Prescription Service is available, if these details are known to C.

(2) Where the Electronic Prescription Service is available through C's appliance contractor premises, C must, if requested to do so by any person, enter in that person's entry in the NHS Care Record—

- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; and
- (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 would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(4) Regulation 102(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

#### **Additional requirements in relation to specified appliances**

**11.**—(1) This paragraph sets out the additional requirements referred to in paragraph 9(1)(o) relating to the provision of specified appliances.

(2) An NHS appliance contractor (C) 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) C 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), C 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 C 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 C is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), C 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 C.

(5) Where C provides a telephone care line in respect of the dispensing of any specified appliance, C 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<sup>(a)</sup>, or website address of NHS Direct National Health Service Trust on line, are made available to patients through the 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 the appliance contractor premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

## Signposting

12.—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor (C) is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within C’s normal course of business, C must—

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

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

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

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(a) Established by S.I. 2007/478.

### **Opening hours: general**

13.—(1) An NHS appliance contractor (C) must ensure that pharmaceutical services are provided at C’s appliance contractor premises—

- (a) for not less than 30 hours each week;
- (b) for not less than 100 hours per week, in the case of which a 100 hours condition (originally imposed under the 2005 Regulations) applies;
- (c) if 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 30 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 30 hours per week, and at set times and on set days, at the times and on the days so set; or
- (e) if 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 30 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 a Primary Care Trust 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 appliance contractor premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as “core opening hours”.

(3) C must exhibit a notice specifying the days on which and times at which the appliance contractor premises are open for the provision of appliances.

(4) C must, on request, submit a return to the Primary Care Trust setting out—

- (a) the days on which and times at which pharmaceutical services are provided at C’s appliance contractor premises (including times at which C is providing pharmaceutical services when C is not obliged to do so by virtue of sub-paragraph (1), which are referred to in these Regulations as “supplementary opening hours”); and
- (b) the pharmaceutical services which C ordinarily provides at those premises.

(5) Where C changes—

- (a) the supplementary opening hours of C’s appliance contractor premises; or
- (b) the pharmaceutical services which C is ordinarily to provide at those premises,

C must supply the Primary Care Trust with a return informing it of the change.

(6) Where C has notified to a Primary Care Trust the days on which and the times at which pharmaceutical services are to be provided at C’s appliance contractor premises (for example, in a return under sub-paragraph (4) or (5) or in an application for inclusion in a pharmaceutical list)—

- (a) C must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the time set out in that notification (unless the notification has been superseded by a return, or further return, under sub-paragraph (5)); and
- (b) C 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 that are neither additional opening hours

nor in total less than 30 (but if those core opening hours are additional opening hours, or are in total less than 30, regulation 65(5) to (7) and paragraphs 15 and 16 apply,

- (ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 15 and 16 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 Primary Care Trust, unless the Primary Care Trust agrees otherwise.

(7) Subject to sub-paragraph (8), where C is prevented by illness or other reasonable cause from complying with C's obligations under sub-paragraph (1), C must, where practicable, make arrangements with one or more NHS appliance contractors, 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.

(8) C may only make an arrangement with an LPS chemist under sub-paragraph (7) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which C ordinarily provides.

(9) Where there is a temporary suspension in the provision of pharmaceutical services by C for a reason beyond the control of C, C is not in breach of sub-paragraphs (1) and (6), provided that—

- (a) C notifies the Primary Care Trust of that suspension as soon as practical; and
- (b) C uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(10) Planned refurbishment of appliance contractor premises is neither a "reasonable cause" for the purposes of sub-paragraph (7) nor a "reason beyond the control of C" for the purposes of sub-paragraph (9).

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

(12) In this Schedule, the "additional opening hours", when they are required, are those hours during which C would not be providing pharmaceutical services, were C subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(e).

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

14.—(1) Where a Primary Care Trust issues a direction setting any days or times under this Schedule, it shall in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that 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 premises, for pharmaceutical services.

- (2) In considering the matters mentioned in sub-paragraph (1), the Primary Care Trust—
  - (a) must treat any local pharmaceutical services being provided in its area at the days and times in question 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 in circumstances where the person providing the services is not obliged to provide those services.

(3) The Primary Care Trust may only direct that an NHS appliance contractor (C) may provide pharmaceutical services at appliance contractor premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in its area are likely to be adequate to meet the need for such services at times when C 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, the Primary Care Trust may only direct that C must provide pharmaceutical services at premises for more than 30 hours in any week if it is satisfied that C is to receive reasonable remuneration in respect of the additional opening hours for which C is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(2) in respect of those hours is “reasonable remuneration” for these purposes).

#### **Determination of core opening hours instigated by the Primary Care Trust**

**15.—**(1) Where it appears to the Primary Care Trust, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which appliance contractor 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 appliance contractor 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 appliance contractor (C) to provide pharmaceutical services at the 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 Primary Care Trust must—

- (a) give notice to C of any proposed changes to the days on which or times at which the appliance contractor premises are to be open; and
- (b) allow C 30 days within which to make written representations to the Primary Care Trust about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Primary Care Trust 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 C must provide pharmaceutical services at the appliance contractor premises, provided that the existing direction (whether issued under regulation 65, this Schedule, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5);
- (c) either—
  - (i) revoke (without replacing it) any existing direction in respect of the times at which C must provide pharmaceutical services at the premises, whether issued under regulation 65, this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, or
  - (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(4) Where a Primary Care Trust issues a direction under sub-paragraph (3) in respect of appliance contractor premises that are to be required to be open—

- (a) for more than 30 hours each week, it shall set out in that direction—
  - (i) the total number of hours each week for which C must provide pharmaceutical services at the premises, and
  - (ii) as regards the additional opening hours for which C is to provide pharmaceutical services, the days on which and the times at which C is required to provide those services during those additional opening hours,

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



(b) for less than 30 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 those premises.

(5) The Primary Care Trust shall not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The Primary Care Trust shall notify C 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 appliance contractor is to provide pharmaceutical services at the premises, it shall include with the notification a statement of—

- (a) the reasons for the change; and
- (b) C's right of appeal under paragraph (7).

(7) C 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 C is to provide pharmaceutical services.

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

(9) The Secretary of State must notify C 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 C is to provide pharmaceutical services at appliance contractor premises have been changed in accordance with this paragraph, C must introduce the changes—

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

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

#### **Determination of core opening hours instigated by the NHS appliance contractor**

**16.—**(1) An NHS appliance contractor (C) may apply to a Primary Care Trust for it to change the days on which or times at which C is obliged to provide pharmaceutical services at C's premises, in a way that—

- (a) reduces the total number of hours for which C is obliged to provide pharmaceutical services each week (but not any of those required under a 100 hours condition); or
- (b) keeps that total number of hours the same.

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

(3) The Primary Care Trust must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of C in accordance with sub-paragraph (2)).

(4) In determining the application, the Primary Care Trust 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 C must provide pharmaceutical services at the premises, provided that the existing direction (whether

issued under regulation 65, this Schedule, 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 C must provide pharmaceutical services at the premises (whether issued under regulation 65, this Schedule, 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 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(5) Where a Primary Care Trust issues a direction under sub-paragraph (4) in respect of appliance contractor premises that are to be required to be open—

(a) for more than 30 hours each week, it must set out in that direction—

(i) the total number of hours each week for which C must provide pharmaceutical services at the premises, and

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

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

(b) for less than 30 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 those premises.

(6) The Primary Care Trust must not issue a direction under sub-paragraph (4) that has the effect simply of requiring appliance contractor premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring appliance contractor premises to be open for either more or less than 30 hours each week).

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

(8) A Primary Care Trust must notify C 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 C 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) C's right of appeal under sub-paragraph (9).

(9) C 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 Primary Care Trust or take any action that the Primary Care Trust could have taken under sub-paragraph (4).

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

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

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

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

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

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

17.—(1) Notwithstanding the provisions of paragraphs 13 to 16, during an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may, on application from an NHS appliance contractor (C), permit C a temporary change to the days on which or times at which C is obliged to provide pharmaceutical services at appliance contractor premises, or permit temporary closure of those premises, if—

- (a) C gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by C for the request are, in the opinion of the Primary Care Trust, adequate reasons.

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

### **Clinical governance**

18.—(1) An NHS appliance contractor (C) must, in connection with the pharmaceutical services provided by C, participate, in the manner reasonably required by the Primary Care Trust, 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 Secretary of State and comprises the following components—

- (a) a patient and public involvement programme, which includes—
  - (i) a requirement that C produces in an approved manner a practice leaflet containing approved particulars in respect of each of the premises from which the supplier provides pharmaceutical services,
  - (ii) a requirement that C publicises the NHS services that are available at or from C's appliance contractor premises,
  - (iii) a requirement that C undertakes an approved patient satisfaction survey annually, in an approved manner,
  - (iv) C's monitoring arrangements in respect of appliances owed to patients but which are out of stock,
  - (v) an approved complaints system (which meets the requirements of this Schedule),
  - (vi) a requirement that C co-operates appropriately with visits by an authorised representative of any relevant local involvement network and takes appropriate action following the outcome of such visits,
  - (vii) a requirement that C co-operates appropriately with any reasonable inspection or review that the Primary Care Trust or any relevant statutory authority wishes to undertake, and
  - (viii) C's monitoring arrangements in respect of C's compliance with the Equality Act 2010(a);
- (b) a clinical audit programme (normally of 5 days) twice in each financial year;
- (c) a risk management programme, which includes—

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(a) 2010 c. 15.

- (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,
  - (iv) appropriate standard operating procedures, including standard operating procedures in respect of dispensing appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,
  - (v) appropriate waste disposal arrangements for clinical and confidential waste,
  - (vi) identifying a clinical governance lead person in respect of each of C's appliance contractor premises,
  - (vii) the monitoring arrangements of the NHS appliance contractor in respect of the supplier's compliance with the Health and Safety at Work etc. Act 1974<sup>(a)</sup>;
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by C—
- (i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
  - (ii) to people caring for themselves or their families,
- and arrangements for ensuring that C, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 9(1)(f) in respect of the provision of appliances and 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, registered nurses and registered pharmacy technicians and any necessary accreditation in respect of the provision of directed services, and
  - (v) arrangements for addressing poor performance (in conjunction with a Primary Care Trust as appropriate); and
- (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 Primary Care Trust to access that assessment.

(3) For the purposes of sub-paragraph (2), “approved” means approved by the Secretary of State.

### **Professional Standards**

19. An NHS appliance contractor must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

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(a) 1974 c. 37.

### **Inducements etc.**

**20.**—(1) An NHS appliance contractor (C) (including C's staff) must not give, promise or offer to any person (X) any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his—

- (a) presenting an order for appliances on a prescription form or repeatable prescription; or
- (b) nominating C as X's dispensing contractor (or one of them) in X's entry in the NHS Care Record.

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

(3) C (including C'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 9(2)(b), 11(4) or 12(1)(b); or
- (b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 9(2)(a) or 12(1)(a) and providing no additional service in connection with the item on that prescription.

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

**21.**—(1) Subject to paragraph 23, an NHS appliance contractor (C) and, where C is a body corporate every director of C must, within 7 days of its occurrence, inform the Primary Care Trust 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(a) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(b) (penalty as alternative to prosecution);
- (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 subject to an 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 NHS BSA in relation to fraud;

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(a) 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; and the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1).

(b) 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and has been amended by the Social Security Fraud Act 2001 (c. 11), section 14.

- (l) become the subject of any investigation by another Primary Care Trust or equivalent body, 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) Subject to paragraph 23, if a person to whom paragraph (1) applies (X) is, or was at the time of the originating events, a director of a body corporate, X must in addition inform the Primary Care Trust 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 Trust or other 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 X 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) C or X must consent to a request being made by the Primary Care Trust 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**

**22.—**(1) An NHS appliance contractor (C) must give notice to the Primary Care Trust 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 C in the pharmaceutical list which C has not otherwise notified to the Primary Care Trust in accordance with these Regulations;
- (b) if C is an individual, any change of C's private address;
- (c) if C is a body corporate, any change to the name, registered number, registered office, telephone number relating to that office of the body corporate or the name and address of any director of the body corporate; and
- (d) any occurrence requiring C's addition to or removal from the EPS list or a change in the information recorded about C in that list.



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

(3) Subject to paragraph 23, if C is a body corporate, it must give notice to the Primary Care Trust within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors.

(4) Subject to paragraph 23, if C is a body corporate and appoints a director who was not listed on C's application for inclusion on a pharmaceutical list, C must, within 30 days of the person's appointment, supply to the Primary Care Trust the information mentioned in paragraphs 3 and 4 of Schedule 2 about that person.

(5) Subject to paragraph 23, if C or a director of C (if C is a body corporate) is on, or is a director of a body corporate which is on, a relevant list other than the Primary Care Trust's pharmaceutical list, they must supply in writing to the Primary Care Trust—

- (a) in the case of a director 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) Subject to paragraph 23, C or a director C (if C is a body corporate) must inform the Primary Care Trust—

- (a) if they, or a body corporate of which they are a director, apply to be included in a relevant list other than the Primary Care Trust's pharmaceutical list, and of the outcome of any such application; and
- (b) if they become a director of another body corporate which is on the relevant list of another Primary Care Trust, or which applies to be included in such a list, and the outcome of any such application.

### **Home Primary Care Trust of bodies corporate**

**23.** Where an NHS appliance contractor (C) is a body corporate with a registered office in England, the information to be provided under paragraphs 21 and 22(3) to (6) may be provided instead to C's home Primary Care Trust, if C, when C provides the information to the home Primary Care Trust, also provides the home Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists C is included.

### **Complaints**

**24.—**(1) An NHS appliance contractor must have in place arrangements, which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(a), 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 appliance contractor.

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

**25.—**(1) An NHS appliance contractor (C) must allow persons authorised in writing by the Primary Care Trust to enter and inspect any premises C uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not C is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by C, 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

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

(ii) the management by C of the pharmaceutical services C 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 premises are situated have been invited to be present at the inspection, where this is requested by C;
- (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) C must, at the request of the Primary Care Trust 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 Primary Care Trust, in connection with its functions that relate to pharmaceutical services.

## SCHEDULE 6

Regulation 47(1)(a)(i)

### Terms of service of dispensing doctors

#### **Persons duly authorised to dispense on behalf of dispensing doctors**

1.—(1) Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which the dispensing doctor has duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement; and
- (b) the dispensing doctor must secure compliance with that requirement by that other person.

(2) Where reference is made in this Schedule to a dispensing doctor—

- (a) being the subject of an activity, and in fact a person duly authorised by the dispensing doctor is the subject of that activity; or
- (b) forming a view, and in fact a person duly authorised by the dispensing doctor is to form that view,

that reference is to be construed as referring, as appropriate, to that duly authorised person.

(3) References in this Schedule to a dispensing doctor are to be construed in accordance with sub-paragraphs (1) and (2).

#### **Dispensing of drugs and appliances ordered by another prescriber**

2.—(1) In this paragraph, “signed” includes signature with a prescriber's advanced electronic signature.

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

- (a) any person presents to a dispensing doctor (D) 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 other than D,

- (ii) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations<sup>(a)</sup> (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber other than D, and including the reference “SLS”, or
  - (iii) an order for restricted availability appliances, signed by a prescriber other than D and including the reference “SLS”; or
- (b) subject to sub-paragraph (4), D 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) D has previously arranged with the patient that D will dispense that prescription on receipt,

and D is authorised or required by virtue of Part 8 to provide the drugs or appliances so ordered, D must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as D supplies in the normal course of business.

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

- (a) any person presents to D 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>(b)</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>(c)</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber other than D,
  - (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 other than D and including the reference “SLS”,
  - (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than D, or
  - (iv) an order for a restricted availability appliance, signed by a prescriber other than D, and including the reference “SLS”,
- and also presents an associated batch issue; or
- (b) D receives an electronic repeatable prescription from the Electronic Prescription Service 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) D has previously arranged with the patient that D will dispense that repeatable prescription on receipt,

and D is authorised or required by virtue of Part 8 to provide the drugs or appliances so ordered, D must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as D supplies in the normal course of business.

(4) D 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.

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

(b) 1971 c.38; *see* section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

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

(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) D has that prescription in D's possession; and
- (b) that person presents, or D has in D's possession, an associated batch issue.

(6) Drugs and appliances provided under this paragraph must be provided in a suitable container.

### **Dispensing of drugs and appliances ordered by the dispensing doctor**

**3.** In circumstances where paragraph 2 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor (D) is authorised or required by virtue of Part 8 to provide a drug or appliance to a person—

- (a) D must record any order for the provision of any drugs or appliances which are needed for the treatment of the patient, before the drugs or appliances are dispensed (unless it is personally administered)—
  - (i) on a prescription form completed in accordance with the term of the contract under which primary medical services are provided to the patient which gives effect to paragraph 39 of Schedule 6 to the GMS Regulations<sup>(a)</sup> (other contractual terms – prescribing) or an equivalent provision applying in relation to that contract,
  - (ii) if paragraph 39A of Schedule 6 to the GMS Regulations<sup>(b)</sup> (other contractual terms – electronic prescriptions) or an equivalent provision applies in relation to the contract under which primary medical services are provided to the patient, on an electronic prescription form, or
  - (iii) in the case of a personally administered vaccine in respect of which the NHS BSA does not require an individual prescription form in order to process payment, on the form provided by the NHS BSA for the purposes of claiming payments for administering that vaccine (as well, potentially, as claiming other payments), and in the manner required by the NHS BSA (which may be as part of an aggregate total);
- (b) D must provide those drugs or appliances in a suitable container (unless it is personally administered);
- (c) D must provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs, medicines and other substances that may be ordered only in certain circumstances) only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations<sup>(c)</sup> (other contractual terms – a restrictions on prescribing by medical practitioners) are satisfied; and
- (d) D must provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

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

**4.** Before providing any drugs or appliances in accordance with paragraph 3, or in the circumstances set out in paragraph 5—

- (a) a dispensing doctor (D) must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations<sup>(d)</sup> (supply of drugs and appliances by doctors) by virtue of either—

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(a) Paragraph 39 has been amended by S.I. 2005/893, 2007/3491 and 2009/2230.

(b) Paragraph 39A was inserted by S.I. 2005/893 and has been amended by S.I. 2007/3491.

(c) Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.

(d) Regulation 4 has been amended by S.I. 2000/2393, 2001/2887, 2002/548 and 2352, 2005/578, 2008/571, 2009/411, 2010/1727 and 2011/518.

- (i) entitlement to exemption under regulation 7(1) of the Charges Regulations<sup>(a)</sup> (exemptions), or
  - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations<sup>(b)</sup> (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 regulation 7 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5 of the Remission of Charges Regulations, and at the time of the declaration D has such evidence available to D;
- (b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (a), is produced to D, D must endorse the form on which the declaration is made to that effect; and
  - (c) in the case of an electronic prescription, D must transmit to the Electronic Prescription Service—
    - (i) 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—
      - (aa) 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
      - (bb) whether or not satisfactory evidence was produced to D as required by sub-paragraph (a),
    - (ii) in any case where a charge is due, confirmation that the relevant charge was paid, and
    - (iii) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

### **Provision of Scheduled drugs**

- 5.—(1) A dispensing doctor (D) must only provide for a patient any Scheduled drug if—
- (a) it is ordered as specified in sub-paragraph (2) or (4); or
  - (b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.
- (2) 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; and
  - (b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically).
- (3) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (2) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.
- (4) Nothing in this Schedule prevents D providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

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(a) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.  
 (b) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

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

6.—(1) A dispensing doctor (D) may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) D reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because D reasonably believes it has been stolen or forged); or
- (b) it appears to D 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 D's clinical judgement.

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

- (a) D has no record of that prescription;
- (b) D does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to D;
- (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 (whether electronically or otherwise) more than 6 months previously;
- (f) if 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) where D has been informed by the repeatable prescriber that the prescription is no longer required.

(3) 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), D must only provide the drugs or appliances ordered if D 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 the patient to whom the prescription relates has altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

### **Dispensing doctors issuing prescription forms which may be presented to an NHS chemist**

7. Notwithstanding the existence of arrangements under which a dispensing doctor (D) is to provide pharmaceutical services to a patient (P), if D determines that P requires a drug or appliance that is available on prescription from an NHS chemist—

- (a) D may with the agreement of P issue; or
- (b) if P so requests, D must not unreasonably refrain from issuing,

a prescription form that P may present to any NHS chemist instead of D supplying that drug or appliance to P.



## Complaints procedures

8. Where a dispensing doctor is a provider of primary medical services or a PCTMS practice, or is employed or engaged by such a provider or practice, the complaints procedure established by—

- (a) the provider or practice; or
- (b) the provider or practice that employs or engages the dispensing doctor,

to deal with complaints in relation to the provision of primary medical services is also to apply in relation to a complaint about any matter reasonably connected with the provision of pharmaceutical services by that provider, practice or individual.

## Inspections and access to information

9.—(1) A dispensing doctor (D) must allow persons authorised in writing by the Primary Care Trust to enter and inspect any premises D uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not D is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by D, in the course of providing pharmaceutical services, for patient care and treatment, and
  - (ii) the management by D of the pharmaceutical services D 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 Medical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by D;
- (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) D must, at the request of the Primary Care Trust 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 Primary Care Trust, in connection with its functions that relate to pharmaceutical services.

## Voluntary closure of premises

10.—(1) Where a dispensing doctor (D) wishes—

- (a) to withdraw from a dispensing doctor list, or
- (b) except in the circumstances described in paragraph (2), for particular listed dispensing premises no longer to be listed in relation to D,

D must notify the Primary Care Trust of D's wish at least 3 months in advance of the date on which pharmaceutical services are no longer to be provided, unless it is impracticable for D to do so, in which case D must notify the Primary Care Trust as soon as it is practicable for D to do so.

(2) If particular listed dispensing premises no longer need to be listed in relation to D as a consequence of a relocation application under regulation 55, before the date on which D commences the provision of pharmaceutical services at the new premises, D must give notice to the Primary Care Trust of when, before that date, D is to cease to provide pharmaceutical services at the existing premises.

## Transitional provisions

**Pharmaceutical needs assessments**

1.—(1) The pharmaceutical needs assessment of a Primary Care Trust immediately before the appointed day (including any supplementary statements that are part of that assessment)—

- (a) is not to be treated as invalidly made, for the purposes of these Regulations, by virtue of any differences between these Regulations and the 2005 Regulations; and
- (b) accordingly, unless invalidly made for some other reason, it continues in effect as if validly made under these Regulations (until it is replaced on or after the appointed day by a revised assessment).

(2) If, on the appointed day, a Primary Care Trust is consulting on the contents of its assessment as required by regulation 3F of the 2005 Regulations(a) (consultation)—

- (a) that consultation is not to be treated as invalidly carried out, for the purposes of these Regulations, by virtue of any differences between these Regulations and the 2005 Regulations; and
- (b) accordingly, unless invalidly carried out for some other reason, it is to be treated on the appointed day (and as appropriate thereafter) as being validly carried out under regulation 8.

**Listing applications: NHS chemists**

2.—(1) An application made under regulation 5(1) or 40(1) of the 2005 Regulations(b) (which relate to applications for inclusion in a pharmaceutical list and preliminary consent applications)—

- (a) which has not been determined before the appointed day;
- (b) which, if it were determined under the 2005 Regulations, would be determined having regard to regulation 12(1) or 13(1)(a) to (c) of those Regulations(c) (which relate to the necessary or expedient test and exemptions from that test); and
- (c) which has been notified—
  - (i) under regulation 23(2) of the 2005 Regulations(d) (notification of applications) and the period for making representations set out in that regulation 23(2) has elapsed before the appointed day, or
  - (ii) under regulation 33(2) of the 2005 Regulations(e) (notification of applications in respect of premises in a controlled locality) and the period for making representations set out in regulation 33(4) of those Regulations(f), as it applies in relation to notifications under that regulation 33(2), has elapsed before the appointed day,

is to be determined in accordance with the provisions of the 2005 Regulations, until that application is finally determined.

(2) An application to which sub-paragraph (1)(a) and (b) applies is to be treated as meeting the requirements of sub-paragraph (1)(c) if—

- (a) consideration of it was deferred by the Primary Care Trust under the 2005 Regulations (but not because the application was incomplete) for a period of at least 14 days; and

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(a) Prior to its repeal, regulation 3F was inserted by S.I. 2010/914.  
 (b) Prior to its repeal, regulation 5(1) was amended by S.I. 2005/1501.  
 (c) Prior to their repeal, regulation 12(1) and the heading of regulation 13(1) were amended by S.I. 2009/2205.  
 (d) Prior to its repeal, regulation 23(2) was amended by S.I. 2006/3373 and 2008/528.  
 (e) Prior to its repeal, regulation 33(2) was amended by S.I. 2008/528.  
 (f) Prior to its repeal, regulation 33(4) was amended by S.I. 2005/1501.

- (b) had the application been notified on the date of the deferral instead of being deferred, the relevant period for making representations, as mentioned in sub-paragraph (1)(c)(i) or (ii), would have elapsed before the appointed day.

(3) An application made under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations (which relate to applications for inclusion in a pharmaceutical list, preliminary consent applications and temporary provision during a period of suspension)—

- (a) which has not been determined before the appointed day;
- (b) to which, if it were determined under the 2005 Regulations, would be determined having regard to regulation 6 to 10, 13(1)(d) or 54 of those Regulations<sup>(a)</sup> (which relate to different types of exempt application, exemption from the necessary or expedient test and temporary provision during a period of suspension),

is to be determined in accordance with the provisions of the 2005 Regulations, until that application is finally determined.

(4) Where an application made under the 2005 Regulations for preliminary consent has been finally granted before the appointed day—

- (a) an application under regulation 5(1) of the 2005 Regulations that is in accordance with regulation 41(1) of those Regulations (effect of preliminary consent) may be made in relation to that consent; and
- (b) any such application is to be determined in accordance with the provisions of the 2005 Regulations, until that application is finally determined.

(5) Where an application made under 2005 Regulations for preliminary consent is made before the appointed day and that application is to be determined in accordance with those Regulations by virtue of sub-paragraph (1) or (3), if the application is granted—

- (a) an application under regulation 5(1) of the 2005 Regulations that is in accordance with regulation 41(1) of those Regulations may be made in relation to that consent; and
- (b) any such application is to be determined in accordance with the provisions of the 2005 Regulations, until that application is finally determined.

(6) Where by virtue of this paragraph, an application is to be determined in accordance with regulation 10 of the 2005 Regulations, as relevant—

- (a) the LPS Regulations<sup>(b)</sup>; or
- (b) the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002<sup>(c)</sup>,

apply as regards the determination of that application as in force immediately before the appointed day.

(7) Where an application under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations has been determined in accordance with those Regulations, whether before the appointed day or by virtue of this paragraph—

- (a) the arrangements for bringing an appeal in relation to that application; and
- (b) the determination of any appeal validly brought,

are to be in accordance with the provisions of the 2005 Regulations.

(8) Where an application under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations has not been determined before the appointed day and is not to be determined in accordance with those Regulations by virtue of this paragraph—

- (a) that application is void; and

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(a) Prior to their repeal, amendments were made to these provisions by S.I. 2005/1501, 2006/552 and 3373, 2007/289, and 2009/2205.

(b) S.I. 2006/552.

(c) S.I. 2002/2016.

- (b) any fee charged by the Primary Care Trust in relation to that application in accordance with directions under section 131 of the 2006 Act (power to charge) is to be treated as invalidly charged.

### **Listing applications: dispensing doctors**

3.—(1) An application made under Part 5 of the 2005 Regulations (provision of pharmaceutical services by doctors) for outline consent or premises approval (including temporary premises approval) which has not been determined before the appointed day is to be determined in accordance with the provisions of those Regulations, until that application is finally determined.

(2) Where an application under that Part has been determined in accordance with the 2005 Regulations, whether before the appointed day or by virtue of sub-paragraph (1)—

- (a) the arrangements for bringing an appeal in relation to that application (and so appeals relating to any of the decisions referred to in regulation 38((2)(e) to (j) of the 2005 Regulations(a) (appeals in connection with determinations in respect of controlled localities etc.); and
- (b) the determination of any appeal validly brought,

are to be in accordance with the provisions of the 2005 Regulations.

(3) If, before the appointed day, a Primary Care Trust requires a doctor to provide pharmaceutical services under regulation 60(4)(a) of the 2005 Regulations(b) (arrangements for provision of pharmaceutical services by doctors), and—

- (a) the doctor has appealed against that decision before the appointed day; or
- (b) the time limit for bringing an appeal against the decision in regulation 60(12) of the 2005 Regulations has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

### **Approved retail areas**

4. Where after the appointed day, by virtue of paragraph 2(1), an application is to be determined having regard to regulation 13(1)(a) of the 2005 Regulations (exemptions from the necessary or expedient test), for the purposes of that application an area is an approved retail area if immediately before the appointed day it was a retail area that was for the time being approved by the Secretary of State under regulation 15 of those Regulations (approved retail areas).

### **Controlled localities**

5.—(1) Each Primary Care Trust must, in respect of an area which on the appointed day continues to be, or to be part of, a controlled locality by virtue of regulation 36(1), delineate precisely the boundary of the controlled locality which that area is, or of which that area is a part—

- (a) on the map that it publishes alongside its pharmaceutical needs assessment map in accordance with regulation 39(2)(a)(ii)(aa); or
- (b) if it publishes no such map, in its pharmaceutical needs assessment map.

(2) Where—

- (a) before the appointed day, a Primary Care Trust has given notice under regulation 31(5) of the 2005 Regulations (determination that an area is a controlled locality) that it proposes to determine whether or not an area is or is not a controlled locality or part of a controlled locality; or

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(a) Prior to its repeal, regulation 38(2) was amended by S.I. 2006/3373.

(b) Prior to its repeal, regulation 60(4) was amended by S.I. 2005/1015 and 2006/3373.

- (b) a Primary Care Trust is required by virtue of paragraph 2 or 3 to determine an application and in connection with determining that application it needs also to determine whether or not an area is or is not a controlled locality or part of a controlled locality,

the consideration of whether the area in question is or is not either a controlled locality or part of a controlled locality, and the arrangements for bringing an appeal in relation to a related determination that an area is or is not a controlled locality, or part of a controlled locality, are to be in accordance with the 2005 Regulations.

(3) Where, by virtue of sub-paragraph (2), it is determined (whether by a Primary Care Trust or on appeal by the Secretary of State) that an area is or is not, or is or is not part of, a controlled locality—

- (a) the Primary Care Trust for that area must amend—
  - (i) the map that it publishes alongside its pharmaceutical needs assessment map in accordance with regulation 39(2)(a)(ii)(aa), or
  - (ii) if it publishes no such map, in its pharmaceutical needs assessment map, to reflect that determination (unless that determination does not change the controlled locality boundaries already included in that map); and
- (b) any area that becomes, or becomes part of, a controlled locality as a consequence of that determination is then a controlled locality, or part of a controlled locality, for the purposes of these Regulations (unless or until it is determined under these Regulations that it is no longer, or no longer part of, a controlled locality).

### **Reserved locations**

6.—(1) Where—

- (a) an application is received by a Primary Care Trust which it is required to determine—
  - (i) in accordance with paragraph 2, and
  - (ii) having regard to regulation 12 or 13 of the 2005 Regulations (which relate to the necessary or expedient test and exemptions from it); and
- (b) the premises or relevant location from which the applicant wishes to provide pharmaceutical services is or may be a reserved location,

pending the final determination of that application, the classification of any area in relation to those premises or that relevant location as a reserved location is to be determined in accordance with the provisions of the 2005 Regulations (if a further reserved location determination is required after the application is finally determined, it is to be in accordance with the provisions of these Regulations).

(2) Where, under regulation 35 of the 2005 Regulations<sup>(a)</sup> (pharmaceutical services in reserved locations)—

- (a) a determination of whether or not an area is a reserved location is made by virtue of sub-paragraph (1); or
- (b) a determination of whether or not an area is a reserved location has been made before the appointed day, and—
  - (i) that determination has been appealed before the appointed day; or
  - (ii) the time limit for bringing an appeal against the determination has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that determination, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

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<sup>(a)</sup> Prior to its repeal, regulation 35 was amended by S.I. 2005/1501.

(3) Where, by virtue of this paragraph, it is determined (whether by a Primary Care Trust or on appeal by the Secretary of State) that an area is or is not a reserved location, if as a consequence a reserved location thereafter takes effect—

- (a) the Primary Care Trust for that area must delineate precisely the boundary of the reserved location on the map on which it delineates the boundary of the related controlled locality pursuant to regulation 39(2)(a)(i); and
- (b) the reserved location is then a reserved location for the purposes of these Regulations (unless or until it is determined under these Regulations that it is no longer a reserved location).

### **Gradual discontinuation of the provision of pharmaceutical services by doctors**

7.—(1) Where, when granting an application which by virtue of paragraph 2 is finally determined in accordance with the 2005 Regulations, a Primary Care Trust is required to consider under regulation 20(2) of the 2005 Regulations (imposition of conditions)—

- (a) any termination of arrangements with any person on its dispensing doctor list; and
- (b) any postponement of any such termination,

arising out of that grant (but not for a reason set out in regulation 50(1)(a) to (c), (e) or (f) of these Regulations), that consideration and its decision are to be in accordance with the provisions of the 2005 Regulations.

(2) Where, under the 2005 Regulations—

- (a) a decision relating to termination of arrangements, or the postponement of the termination of arrangements, is made by virtue of sub-paragraph (1); or
- (b) before the appointed day, a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor has been made by a Primary Care Trust in a case where the Primary Care Trust could have postponed the termination of the arrangements, and—
  - (i) that decision has been appealed before the appointed day; or
  - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(3) Where before the appointed day a Primary Care Trust is considering under the 2005 Regulations, in any case in which it could postpone the termination of arrangements with a dispensing doctor, either the termination of arrangements with a dispensing doctor or the postponement of the termination of arrangements with a dispensing doctor—

- (a) that consideration and its decision are to be in accordance with the provisions of the 2005 Regulations; and
- (b) the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(4) Conditions imposed by virtue of regulation 20(2) or 35(6)(b) (pharmaceutical services in reserved locations) of the 2005 Regulations relating to the postponement of termination of arrangements with a dispensing doctor, whether or not imposed by virtue of this paragraph, continue to have effect as if imposed under these Regulations.

### **Gradual introduction of the provision of pharmaceutical services by doctors**

8.—(1) Where, when granting an application which by virtue of paragraph 3 is finally determined in accordance with the 2005 Regulations, a Primary Care Trust is required to consider under regulation 20(2) of the 2005 Regulations (imposition of conditions) any postponement of the making of arrangements with a dispensing doctor, arising out of that grant, that consideration and its decision are to be in accordance with the provisions of the 2005 Regulations.



- (2) Where, under regulation 20(2) of the 2005 Regulations—
- (a) a decision relating to postponement of the making of arrangements is made by virtue of sub-paragraph (1); or
  - (b) a decision relating to postponement of the making of arrangements, has been made before the appointed day, and—
    - (i) that decision has been appealed before the appointed day; or
    - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(3) Where before the appointed day a Primary Care Trust is considering under regulation 20(2) of the 2005 Regulations the postponement of the making of arrangements with a dispensing doctor—

- (a) that consideration and its decision are to be in accordance with the provisions of the 2005 Regulations; and
- (b) the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(4) Conditions imposed by virtue of regulation 20(2) of the 2005 Regulations relating to postponement of the making of arrangements with a dispensing doctor, whether or not imposed by virtue of this paragraph, continue to have effect as if imposed under these Regulations.

#### **Giving effect to listing decisions taken under the 2005 Regulations**

9. Where, before the appointed day or as a consequence of paragraph 2 or 3, a person is entitled on the basis of a decision (whether by a Primary Care Trust or on appeal)—

- (a) to be included in pharmaceutical list or dispensing doctor list but has not been included in that list;
- (b) to have listed in relation to their entry in a pharmaceutical list or dispensing doctor list premises that have not been listed in relation to them,

the arrangements for the listing of that person or those premises, and the circumstances in which that decision lapses, are as set out in the 2005 Regulations.

#### **Dispensing contractor lists**

10.—(1) Subject to sub-paragraphs (3) to (5), any contractor included in a dispensing contractor list of a Primary Care Trust before the appointed day (whether by virtue of paragraph 51(1) of Schedule 6 to the GMS Regulations or paragraph 51(1) of Schedule 5 to the PMS Regulations<sup>(a)</sup> (which relate to dispensing contractor lists)) is to be included in the dispensing doctor list of that Primary Care Trust with effect from the appointed day.

(2) As regards that listing—

- (a) a contractor who is not an individual general practitioner is to be listed as a provider of primary medical services (in the case of members of a provider of primary medical services, all the members of the provider who are to be listed may elect for listing of the provider, in accordance with regulation 46(4));
- (b) the premises approval to be listed in relation to the person listed is the premises approval of the contractor under the GMS Regulations or the PMS Regulations (for these purposes, any residual premises approval for the purposes of the GMS Regulations or the PMS Regulations is to be a premises approval for the purposes of these Regulations); and

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(a) Prior to their repeal, these provisions were amended by S.I. 2005/3315.

- (c) the area of outline consent to be listed in relation to the person listed is the area of the consent to dispense of the contractor under the GMS Regulations or the PMS Regulations.

(3) If before the appointed day the Primary Care Trust began a process which could have led to the removal of a contractor or premises from its dispensing contractor list (whether by virtue of paragraph 48B or 51(2) of Schedule 6 to the GMS Regulations or paragraph 47B or 51(2) of Schedule 5 to the PMS Regulations<sup>(a)</sup> (which relate to lapse of consent to dispense and premises approval, and to dispensing contractor lists) the outcome of that process is to be determined in accordance with the GMS Regulations or, as the case may be, the PMS Regulations.

(4) Pending the outcome of that process—

- (a) Part 3 of Schedule 6 to the GMS Regulations (prescribing and dispensing) or, as the case may be Part 3 of Schedule 5 of the PMS Regulations (prescribing and dispensing), continues to apply as regards any dispensing by the contractor; and
- (b) accordingly, the Primary Care Trust must maintain a dispensing contractor list until the outcome of that process is determined.

(5) Once the outcome of that process is determined—

- (a) if the contractor is not to be removed from the dispensing contractor list (even if additional premises of the contractor are to be removed), that contractor is to be included in the Primary Care Trust's dispensing doctor list, and sub-paragraph (2) applies as regards that listing as it would have applied had the determination been made before the appointed day and the contractor had been included in the dispensing doctor list with effect from the appointed day; or
- (b) if the contractor is to be removed from the dispensing contractor list, the requirement to continue to maintain a dispensing contractor list that arises because of that dispensing contractor ceases.

(6) An application made under Part 3 Schedule 6 to the GMS Regulations, or Part 3 of Schedule 5 to the PMS Regulations, for consent to dispense or premises approval (including temporary premises approval) which has not been determined before the appointed day is to be determined in accordance with the provisions of the GMS Regulations, or as the case may be the PMS Regulations, until that application is finally determined.

(7) Where an application made under Part 3 Schedule 6 to the GMS Regulations, or Part 3 of Schedule 5 to the PMS Regulations, for consent to dispense or premises approval (including temporary premises approval) has been determined in accordance with the GMS Regulations, or as the case may be the PMS Regulations, whether before the appointed day or by virtue of sub-paragraph (6)—

- (a) the arrangements for bringing an appeal in relation to that application; and
- (b) the determination of any appeal validly brought,

are to be in accordance with the provisions of the Regulations under which the application was determined.

(8) Where—

- (a) a Primary Care Trust grants an application for premises approval which by virtue of this regulation is finally determined in accordance with the GMS Regulations or the PMS Regulations; and
- (b) that Primary Care Trust is required to consider under the GMS Regulations or, as the case may be, the PMS Regulations any postponement of the making of arrangements to provide dispensing services, arising out of that grant,

that consideration and its decision on any postponement are to be in accordance with the provisions of the GMS Regulations or, as the case may be, the PMS Regulations.

(9) Where, under the GMS Regulations or the PMS Regulations—

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<sup>(a)</sup> Prior to their repeal, the cited provisions were inserted by, or amended by, S.I. 2005/3315.

- (a) a decision relating to postponement of the making of arrangements is made by virtue of sub-paragraph (8); or
- (b) a decision relating to postponement of the making of arrangements to provide dispensing services has been made before the appointed day, and—
  - (i) that decision has been appealed before the appointed day; or
  - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the GMS Regulations or, as the case may be, the PMS Regulations.

(10) Conditions imposed by virtue of the GMS Regulations or the PMS Regulations relating to postponement of the making of arrangements to provide dispensing services, whether or not imposed by virtue of this regulation, continue to have effect as if imposed under these Regulations in relation to the provision of pharmaceutical services.

(11) Any entry that would, but for the repeal of paragraph 51 of Schedule 6 to the GMS Regulations or paragraph 51 of Schedule 5 to the PMS Regulations, have been made in a Primary Care Trust's dispensing contractor list following the grant of an application by virtue of this regulation is instead to be made to that Primary Care Trust's dispensing doctor list, and sub-paragraph (2) is to apply as regards that listing as if, instead of the entry being made in its dispensing doctor list, the entry had been made immediately before the appointed day in its dispensing contractor list.

#### **Continuing matters: periods of time**

**11.—**(1) Where a period of time specified in a provision of the 2005 Regulations is current on the appointed day, and a period of time is also specified in a corresponding provision of these Regulations, these Regulations have effect as if the corresponding provision of these Regulations had been in force when that period began to run.

(2) Where—

- (a) consideration of a matter under a provision of these Regulations in respect of a specified period of time requires consideration of a period of time before the appointed day; and
- (b) a corresponding provision of the 2005 Regulations also required consideration of that matter in respect of a specified period of time,

the provision of these Regulations has effect as if it had been in force when the period of time specified in it began to run.

#### **Other continuing matters: NHS chemists**

**12.—**(1) A pharmaceutical list or ETP list of a Primary Care Trust that is the current list immediately before the appointed day is also the current pharmaceutical or EPS list at the start of the appointed day, unless the Primary Care Trust is required or entitled to give effect to a decision reached before the appointed day to change, remove or include an entry the list from the start of the appointed day, in which case the current list at the start of the appointed day is the list as modified to give effect to that decision.

(2) Subject to sub-paragraph (3), as regards the resolution of any matter arising under the 2005 Regulations and relating to—

- (a) compliance with the terms of service of a chemist before the appointed day (whether compliance by the chemist or a Primary Care Trust); or
- (b) an ongoing matter that arose before the appointed day and relates to changing or removing any entry in a pharmaceutical list by virtue of a provision of the 2005 Regulations (other than pursuant to an application under regulation 5(1), 40(1) or 54(2) of those Regulations, as regulation 3 applies in those cases),

that matter is to be resolved in accordance with the relevant provisions of the 2005 Regulations, and where applicable the SCAT Regulations and the Drug Tariff.

(3) Sub-paragraph (2) is without prejudice to the ability of Primary Care Trust to commence proceedings under Chapter 6 of Part 7 of the 2006 Act on or after the appointed day that relate to matters arising before the appointed day (potentially together with matters arising on or after the appointed day), but any decisions in those proceedings are to be reached in accordance with the relevant provisions of these Regulations (and that Chapter 6).

(4) Decisions and reviews of decisions in any proceedings commenced under Chapter 6 of Part 7 of the 2006 Act before the appointed day are to continue to be reached in accordance with the relevant provisions of the 2005 Regulations (and that Chapter 6), except in the case of a review of a decision where the request by the practitioner for a review is made on or after the appointed day (such a review is to be in accordance with the relevant provisions of these Regulations and that Chapter 6).

(5) Where a person was suspended from a pharmaceutical list by virtue of Chapter 6 of Part 7 of the 2006 Act before the appointed day, decisions on payments in respect of the period of suspension that preceded the appointed day, and any appeals relating to those decisions, are to be in accordance with the 2005 Regulations and with the determinations under regulation 58 of the 2005 Regulations<sup>(a)</sup> (payments to suspended chemists) that were in force immediately before the appointed day.

(6) Any direction or approval under a provision of Schedule 1 or 3 to the 2005 Regulations is to continue in effect as a direction or approval under the corresponding provision of Schedule 4 or 5 to these Regulations, until amended or revoked by virtue of that corresponding provision or sub-paragraph (1).

#### **Other continuing matters: dispensing doctors**

**13.—**(1) A dispensing list of a Primary Care Trust that is the current list immediately before the appointed day is also the current list at the start of the appointed day, unless—

- (a) the Primary Care Trust is required or entitled to give effect to a decision reached before the appointed day to change, remove or include an entry in the list from the start of the appointed day, in which case the current list at the start of the appointed day is the list as modified to give effect to that decision; or
- (b) immediately before the appointed day the Primary Care Trust had a dispensing contractor list, in which case its dispensing doctor list at the start of the appointed day is the list as modified to give effect to paragraph (a) and regulation 10.

(2) As regards the resolution of any matter arising under the 2005 Regulations and relating to—

- (a) compliance with the terms of service of a dispensing doctor before the appointed day (whether compliance by the dispensing doctor or a Primary Care Trust); or
- (b) an ongoing matter that arose before the appointed day and relates to changing or removing any entry in a dispensing doctor list by virtue of a provision of the 2005 Regulations (other than pursuant to an application under Part 5 of those Regulations for outline consent or premises approval, as regulation 4 applies in those cases),

that matter is to be resolved in accordance with the relevant provisions of the 2005 Regulations, and where applicable the SCAT Regulations and the relevant directions under section 87 of the 2006 Act (GMS contracts: payments).

#### **Continuing operation of SCAT arrangements**

**14.—**(1) Where—

- (a) before the appointed day; or

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<sup>(a)</sup> Prior to its repeal, regulation 58 was amended by S.I. 2006/3373.

(b) by virtue of paragraph 12 or 13,

a matter is or becomes the subject of proceedings under the SCAT Regulations, those proceedings and the undertaking of any related matter provided for under the SCAT Regulations are to be in accordance with the SCAT Regulations.

(2) The enactments amended by paragraph 1(2) and (3) of Schedule 8 continue to have effect without those amendments to the extent necessary to allow for anything that could have happened in connection with proceedings under the SCAT Regulations, or with any related matter, before the appointed day to happen on or after the appointed day.

#### **The application of Group 12 of Schedule 8 to the Value Added Tax Act 1994**

**15.** Pending amendment of Group 12 of Schedule 8 to the Value Added Tax Act 1994(a) (zero rating: drugs, medicines, aids for the handicapped, etc.) to take account of the repeal of the 2005 Regulations, the definition of “relevant provision” in Note (2D) shall apply in relation to supplies on or after 1st October 2010 as if for paragraph (j) there were substituted—

“(j) Part 8 of the National Health Service (Pharmaceutical Services) Regulations 2012.”.

#### **Terms of service for distance selling premises**

**16.—**(1) Until the end of the transitional period, regulation 64(3)(d) and (e) do not apply as regards listed chemist premises in respect of which the person listed in relation to them is, immediately before the appointed day, subject to the condition imposed by regulation 13(4) of the 2005 Regulations (exemption from necessary or expedient test).

(2) For these purposes, the transitional period begins on the appointed day and ends at the beginning of the day which is 6 months after the appointed day.

## **SCHEDULE 8**

Regulation 104

### **Amendments and revocations**

#### **Revocation of the National Health Service (Service Committees and Tribunal) Regulations 1992, and of amendments to and measures relating to those Regulations**

**1.—**(1) The following Regulations are revoked, in so far as they apply in relation to England—

- (a) the National Health Service (Service Committees and Tribunal) Regulations 1992(b);
- (b) the National Health Service (Service Committees and Tribunal) Amendment Regulations 1995(c);
- (c) the National Health Service (Service Committees and Tribunal) Amendment Regulations 1996(d); and
- (d) the National Health Service (Service Committees and Tribunal) Amendment Regulations 1998(e).

(2) In the Health Authorities (Membership and Procedure Regulations) 1996(f), in so far as they apply in relation to England—

- (a) in regulation 1(2) (citation, commencement and interpretation), omit the definitions of “discipline committee” and “service committee”; and

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(a) 1994 c.23; relevant amendments have been made to Group 12 by S.I. 2009/2972.

(b) S.I. 1992/664.

(c) S.I. 1995/3091.

(d) S.I. 1996/703.

(e) S.I. 1998/674.

(f) S.I. 1996/707.

- (b) in regulation 14(3) (appointment of committees and sub-committees), omit “a discipline committee, a service committee,”.
- (3) The following provisions are revoked, in so far as they apply in relation to England—
- (a) paragraph 58 of Schedule 1 and Part 2 of Schedule 12 to the National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002(a);
  - (b) paragraphs 3 and 4 of the Schedule to the National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002(b);
  - (c) Part 7 of, and paragraph 10 of Schedule 1 to, the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004(c);
  - (d) paragraph 44 of the Schedule to the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery Order) 2004(d);
  - (e) paragraph 24 of Schedule 1 to the Opticians Act 1989 (Amendment) Order 2005(e);
  - (f) paragraph 3 of Schedule 1 to the General Dental Services, Personal Dental Services and Abolition of Dental Practice Board Transitional and Consequential Provisions Order 2006(f);
  - (g) in the table in regulation 2 of the Administrative Justice and Tribunals Council (Listed Tribunals) Order 2007(g)—
    - (i) in the column headed “Tribunal”, the entry for “Committees of Primary Care Trusts in England”, and
    - (ii) the corresponding entry in the column headed “Legislation”;
  - (h) regulation 195 of the European Qualifications (Health and Social Care Professions) Order 2007(h);
  - (i) regulation 3.A.14 of the National Health Service Pension Scheme Regulations 2008(i);
  - (j) Part 3 of, and paragraph 3 of Schedule 1 to, the Primary Ophthalmic Services Amendment, Transitional and Consequential Provisions Regulations 2008(j);
  - (k) paragraphs 51 to 55 of Schedule 1 to the Tribunals, Courts and Enforcement Act 2007 (Transitional and Consequential Provisions) Order 2008(k); and
  - (l) paragraph 25 of Schedule 4 to the Pharmacy Order 2010(l).

#### **Amendment to the National Health Service (Indicative Amounts) Regulations 1997**

2. In regulation 1(2) of the National Health Service (Indicative Amounts) Regulations 1997(m) (citation, commencement and interpretation), for the definition of “Drug Tariff” substitute the following definition—

““Drug Tariff” has the same meaning as in the National Health Service (Pharmaceutical Services) Regulations 2012;”.

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- (a) S.I. 2002/2469.
  - (b) S.I. 2003/1937.
  - (c) S.I. 2004/865.
  - (d) S.I. 2004/1771.
  - (e) S.I. 2005/848.
  - (f) S.I. 2006/562.
  - (g) S.I. 2007/2951.
  - (h) S.I. 2007/3101.
  - (i) S.I. 2008/653.
  - (j) S.I. 2008/1700.
  - (k) S.I. 2008/2683.
  - (l) S.I. 2010/231.
  - (m) S.I. 1997/980; relevant amendments were made by S.I. 2007/1112 and 674.



### **Amendment to the National Health Service (Payments by Local Authorities to NHS Bodies) (Prescribed Functions) Regulations 2000**

3. In regulation 2(2)(d) of the National Health Service (Payments by Local Authorities to NHS Bodies) (Prescribed Functions) Regulations 2000(a) (prescribed functions of relevant NHS bodies), for “regulation 56(f) (provisions relating to determinations) of the National Health Service (Pharmaceutical Services) Regulations 2005” substitute “regulation 89(1) (the Drug Tariff: general provisions) of the National Health Service (Pharmaceutical Services) Regulations 2012”.

### **Amendments to the National Health Service (Charges for Drugs and Appliances) Regulations 2000**

4. In the Charges Regulations(b)—

(a) in regulation 2(1)(c) (interpretation)—

(i) for the definition of “Drug Tariff” substitute the following definition—

““Drug Tariff” has the same meaning as in the National Health Service (Pharmaceutical Services) Regulations 2012;”, and

(ii) in the definition of “repeatable prescriber” for “2005” substitute “2012”; and

(b) in regulation 7C(1)(d) (exemption from charges in respect of listed medicines), after sub-paragraph (b) insert the following sub-paragraph—

“(c) medicines for the prevention or treatment of a condition arising from an emergency that threatens, is causing or has caused serious damage to public health in England or any part of England,”

and in the heading of that regulation after “listed” insert “or emergency”.

### **Amendments to the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002**

5. In the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(e)—

(a) in regulation 1(3)(f) (citation, commencement and interpretation), in the definition of “the principal Regulations”, for “2005” substitute “2012”; and

(b) in regulation 3(7)(g) (designation of priority neighbourhoods or premises)—

(i) in sub-paragraph (c), for “regulation 4” substitute “regulation 10”, and

(ii) in sub-paragraph (d), for “regulation 68” substitute “regulation 46”.

### **Amendments to the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002**

6. In the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(h)—

(a) in regulation 1(3)(i) (interpretation), in the definition of “the principal Regulations”, for “2005” substitute “2012”; and

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(a) S.I. 2000/618; regulation 2 has been amended by S.I. 2004/865, 2007/674 and 2008/2828.

(b) S.I. 2000/620.

(c) Relevant amendments were made to regulation 2 by S.I. 2003/699, 2004/865, 2006/913 and 2007/674.

(d) Regulations 7C was inserted by S.I. 2009/2230.

(e) S.I. 2002/888.

(f) Regulation 1(3) has been amended by S.I. 2002/2469 and 2005/641.

(g) Regulation 3 has been amended by S.I. 2002/2469, 2005/641 and 2006/552.

(h) S.I. 2002/2016.

(i) Regulation 1(3) has been amended by S.I. 2002/2469 and 2005/641.

- (b) in regulation 4(1)(a) (right of return to pharmaceutical lists), for “regulation 10(2)” substitute “regulation 28(3)”.

#### **Amendments to the National Health Service (General Medical Services Contracts) Regulations 2004**

- 7.—(1) The GMS Regulations(b) are amended as follows.
- (2) In regulation 2(1)(c) (interpretation)—
  - (a) in the definition of “dispensing services”, for “regulation 60” substitute “regulation 48”;
  - (b) in the definition of “Drug Tariff”, for “regulation 56” substitute “regulation 89(1)”; and
  - (c) in the definition of “Pharmaceutical Regulations” for “2005” substitute “2012”.
- (3) In paragraph 1(k) of Schedule 5(d) (fees and charges)—
  - (a) for “regulation 60” substitute “regulation 48”; and
  - (b) omit “or paragraphs 47 or 49 of Schedule 6”.
- (4) In Part 3 of Schedule 6(e) (other contractual terms – prescribing and dispensing)—
  - (a) in paragraph 40(7)—
    - (i) omit paragraph (a), and
    - (ii) in paragraph (b), for “regulation 60” substitute “regulation 48”; and
  - (b) omit paragraphs 47 to 51.

#### **Amendments to the National Health Service (Personal Medical Services Agreements) Regulations 2004**

- 8.—(1) The PMS Regulations(f) are amended as follows.
- (2) In regulation 2(g) (interpretation)—
  - (a) in the definition of “dispensing services”, for “regulation 60” substitute “regulation 48”,
  - (b) in the definition of “Drug Tariff”, for “regulation 56” substitute “regulation 89(1)”, and
  - (c) in the definition of “Pharmaceutical Regulations” for “2005” substitute “2012”; and
- (3) In paragraph (k) of Schedule 3(h) (fees and charges)—
  - (a) for “regulation 60” substitute “regulation 48”; and
  - (b) omit “or paragraph 46, 48 or 49 of Schedule 5”.
- (4) In Part 3 of Schedule 5(i) (other contractual terms – prescribing and dispensing)—
  - (a) in paragraph 39(7)—
    - (i) omit paragraph (a), and
    - (ii) in paragraph (b), for “regulation 60” substitute “regulation 48”; and
  - (b) omit paragraphs 45 to 51.

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(a) Regulation 4(1) was substituted by S.I. 2006/552.  
(b) S.I. 2004/291.  
(c) Relevant amendments were made to regulation 2 by S.I. 2005/893.  
(d) Amended by S.I. 2005/893.  
(e) Part 3 has been amended by S.I. 2005/893 and 3315, 2006/1501, 2007/3491, 2008/528 and 2009/2230.  
(f) S.I. 2004/627.  
(g) Relevant amendments were made to regulation 2 by S.I. 2005/893.  
(h) Amended by S.I. 2005/893.  
(i) Part 3 has been amended by S.I. 2004/2694, 2005/893 and 3315, 2006/1501, 2007/3491, 2008/528, 2009/2230 and 2010/578.

## Revocation of the National Health Service (Pharmaceutical Services) Regulations 2005 and of amendments to those Regulations

- 9.—(1) The following Regulations are revoked—
- (a) National Health Service (Pharmaceutical Services) Regulations 2005(a);
  - (b) the National Health Service (Pharmaceutical Services) (Amendment No. 2) Regulations 2005(b);
  - (c) the National Health Service (Pharmaceutical Services) (Amendment) Regulations 2008(c);
  - (d) the National Health Service (Pharmaceutical Services) (Appliances) (Amendment) Regulations 2009(d);
  - (e) the National Health Service (Pharmaceutical Services) Amendment Regulations 2011(e); and
  - (f) the National Health Service (Pharmaceutical Services) Amendment Regulations 2012(f).
- (2) The following provisions are revoked—
- (a) regulation 2 of the National Health Service (Pharmaceutical Services) Amendment Regulations 2005(g);
  - (b) Part 4 of the National Health Service (Primary Medical Services) (Miscellaneous Amendments) (No. 2) Regulations 2005(h);
  - (c) regulation 12(11) of the National Health Service (Performers Lists) Amendment Regulations 2005(i);
  - (d) Part 1 of Schedule 3 to the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(j);
  - (e) paragraph 23 of Schedule 1 to the General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006(k);
  - (f) regulation 3 of the National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations 2006(l);
  - (g) paragraph 12 of the Schedule to the Smoking, Health and Social Care (Scotland) Act 2005 (Consequential Modifications) (England, Wales and Northern Ireland) Order 2006(m);
  - (h) Part 4 of the National Health Service (Primary Medical Services and Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2006(n);
  - (i) Part 3 of the National Health Service (Pharmaceutical Services) (Amendment) Regulations 2006(o);
  - (j) regulations 3 to 7 of the National Health Service (Pharmaceutical Services) (Remuneration for Persons Providing Pharmaceutical Services) (Amendment) Regulations 2007(p);

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- (a) S.I. 2005/641.
  - (b) S.I. 2005/1501.
  - (c) S.I. 2008/683.
  - (d) S.I. 2009/3340.
  - (e) S.I. 2011/2136.
  - (f) S.I. 2012/1399.
  - (g) S.I. 2005/1015.
  - (h) S.I. 2005/3315.
  - (i) S.I. 2005/3491.
  - (j) S.I. 2006/552.
  - (k) S.I. 2006/562.
  - (l) S.I. 2006/913.
  - (m) S.I. 2006/1056.
  - (n) S.I. 2006/1501.
  - (o) S.I. 2006/3373.
  - (p) S.I. 2007/674.

- (k) regulation 5 of the Local Involvement Networks (Miscellaneous Amendments) Regulations 2008(a);
- (l) paragraph 1 of the Schedule to the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(b);
- (m) regulation 2 of the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Amendment Regulations 2009(c);
- (n) Part 1 of the National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009(d);
- (o) paragraphs 77 to 89 of Schedule 3 to the Transfer of Tribunal Functions Order 2010(e);
- (p) in the Pharmacy Order 2010(f)—
  - (i) paragraph 47 of Schedule 4, and
  - (ii) paragraph 6 of Schedule 6; and
- (q) regulations 2 to 10 of the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment) Regulations 2010(g).

(3) In regulation 2 of the National Health Service (Pharmaceutical Services) (Remuneration for Persons Providing Pharmaceutical Services) (Amendment) Regulations 2007 (interpretation), omit the definition of “the principal Regulations”.

#### **Amendments to the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006**

##### **10. In the LPS Regulations(h)—**

- (a) in regulation 2(1)(i) (interpretation)—
  - (i) in the definition of “Drug Tariff”, for “regulation 56(f)” substitute “regulation 89(1)”,
  - (ii) in the definition of “emergency requiring the flexible provision of pharmaceutical services”, for “regulation 2(5)” substitute “regulation 29(4)”,
  - (iii) in the definition of “non-electronic repeatable prescription” for “has the same meaning as in” substitute “means a repeatable prescription that is not an “electronic repeatable prescription” for the purposes of”,
  - (iv) in the definition of “Pharmaceutical Services Regulations” for “2005” substitute “2012”, and
  - (v) in the definition of “pharmaceutical list”, for “regulation 4” substitute “regulation 10”;
- (b) in regulation 15(1)(j) (right of return to pharmaceutical lists), for “regulation 10(2)” substitute “regulation 28(1)”;
- (c) regulation 17 (duty to provide information about suitability etc.) is revoked; and
- (d) Part 1 of Schedule 3 (amendments to secondary legislation – amendments to the Pharmaceutical Services Regulations) is revoked.

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(a) S.I. 2008/1514.

(b) S.I. 2009/309.

(c) S.I. 2009/599.

(d) S.I. 2009/2205.

(e) S.I. 2010/22.

(f) S.I. 2010/231.

(g) S.I. 2010/914.

(h) S.I. 2006/552.

(i) Relevant amendments were made to regulation 2 by S.I. 2007/674 and 2009/2205.

(j) Amended by S.I. 2006/3373, 2008/528 and 2009/599 and 2205.

## **Amendments to the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009**

11. In the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(a), in the definition of “relevant complaints procedure” in regulation 2 (interpretation), for paragraphs (i) and (ii) of sub-paragraph (a) substitute the following paragraphs—

- “(i) paragraph 34 of Schedule 4 to the National Health Service (Pharmaceutical Services) Regulations 2012;
- (ia) paragraph 24 of Schedule 5 to the National Health Service (Pharmaceutical Services) Regulations 2012;
- (ii) paragraph 8 of Schedule 6 to the National Health Service (Pharmaceutical Services) Regulations 2012; or”.

### **EXPLANATORY NOTE**

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

These Regulations replace the National Health Service (Pharmaceutical Services) Regulations 2005 (“the 2005 Regulations”) as the Regulations which govern the arrangements, in England, for the provision of pharmaceutical services under Chapter 1 of Part 7 of the National Health Service Act 2006 (“the 2006 Act”).

Part 1 contains introductory provisions. Part 2 sets out the requirements relating to the production of pharmaceutical needs assessments (“PNAs”) A PNA is a statement of the assessment that each Primary Care Trust (“PCT”) must make, at least every 3 years, of the needs in its area for pharmaceutical services provided as part of the National Health Service. This Part includes the consultation requirements that have to be fulfilled before a PNA is completed and published (regulation 8) and the matters to which a PCT must have regard when producing a PNA (regulation 9) – and Schedule 1 thereafter sets out the information that must be included in PNAs. Pending full revision of a PNA, a PCT may address in a supplementary statement changes to the availability of pharmaceutical services since the PNA was published (regulation 6).

In order to provide services under the arrangements set out in these Regulations, retail pharmacy businesses and appliance contractors (together referred to as “chemists”) must be included in one or other of the pharmaceutical lists that each PCT is required to maintain (regulation 10). Part 3 includes general matters relating to pharmaceutical lists and applications from chemists join them – and also relating to applications from chemists on the lists to relocate to different premises or open new premises. The presumption is that “routine” applications (defined in regulation 12) will be assessed against the PCT’s PNA under new arrangements for entry into pharmaceutical lists introduced into Chapter 1 of Part 7 of the 2006 Act by section 26 of the Health Act 2009 (c. 21). The detail of the new arrangements, including the matters to which, in addition to its PNA, a PCT must have regard when determining applications, is set out in this Part. There is also provision (regulation 18) for granting routine applications that offer improvements or better access to pharmaceutical services that were not foreseen when the PCT’s PNA was published, in certain circumstances. Subject to this exception, routine applications must be refused unless they offer to meet needs, or secure improvements or better access, that are mentioned in the PCT’s PNA (regulation 22).

Part 4 sets out a number of types of applications in respect of pharmaceutical lists, known as “excepted” applications, that do not have to be assessed as provided for in Part 3. These include, for example, relocation applications that do not result in significant change to pharmaceutical services provision (regulation 24) and change of ownership applications (regulation 26). Under Chapter 6 of Part 7 of the 2006 Act, there are powers to suspend chemists on pharmaceutical lists during fitness investigations or pending fitness appeals – and an exception is also made in respect

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(a) S.I. 2009/309.

of a temporary chemist joining a pharmaceutical list to provide services in place of a suspended chemist (regulation 27). A further exception is made (in regulation 28) to allow chemists who provide local pharmaceutical services (a set of contractual arrangements under which chemists provide pharmaceutical services whilst not on a pharmaceutical list) a right of return to a pharmaceutical list in appropriate circumstances.

Part 5 contains some grounds for refusing different types of applications in respect of pharmaceutical lists, for example because the premises to which the application relates are in an area that has been set aside for tendering arrangements for a contract to provide local pharmaceutical services (regulation 32).

Part 6 provides for refusal and deferral of applications, and for conditional inclusion in pharmaceutical lists, for fitness reasons. There are some mandatory grounds (for example, murder convictions) as a consequence of which a person, partnership or body corporate must be refused entry onto a pharmaceutical list, and some discretionary grounds (regulation 33). If, instead of refusing an application, a PCT decides to grant it subject to permissible fitness conditions, and these conditions are not appealed or are upheld on appeal, the applicant has to decide within a set timetable whether or not they wish to withdraw the granted application (regulation 35).

Part 7 covers determinations as to whether or not an area is a controlled locality or a reserved location. Controlled locations are areas that are rural in character where doctors may apply to provide dispensing services (a restricted range of pharmaceutical services), if certain conditions are met. Determinations that an area is a controlled locality may only take place once every 5 years unless there is a substantial change of circumstances in the intervening period (regulation 36). Routine applications from retail pharmacy businesses to locate pharmacy premises in a controlled locality face two additional hurdles to those already set out in Part 3: firstly, applications in defined parts of a controlled locality cannot be made within 5 years of either the refusal of a similar pharmacy application or the grant of a relevant permission to doctors to dispense, unless there is a substantial change of circumstances affecting the locality (regulation 40); and secondly, the applications are subject to the “prejudice test” (regulation 44), under which the PCT is required to refuse the application if it would prejudice the proper provision of NHS services in its area or the area of another PCT. Where an application for a new pharmacy in a controlled locality is granted, the PCT may determine that the pharmacy is at the centre of a reserved location – that is, essentially, an area of below a specified population threshold in which patients are to have the option of receiving dispensing services from either a dispensing doctor or a retail pharmacy business.

The procedures, generally, for dealing with pharmaceutical list applications and related appeals are dealt with in Schedules 2 and 3. These procedures provide for the content of applications (Part 1 of Schedule 2), the process for notifying most types of applications to interested parties that might want to make representations in relation to them (Part 3 of Schedule 2), and the decision making processes – including provision for oral hearings (Part 4 of Schedule 2). There is also provision for the notification of decisions – and arrangements for when, and subject to what notification requirements, chemists may open new premises that are the subject of successful applications (Part 5 of Schedule 2). The procedures with regard to appeals, either by applicants against refusals or by third parties with appeal rights, are for the most part covered in Schedule 3 – and again there is provision for notification of interested parties both of appeals (to allow for third party representations in most cases) and of decisions on appeals.

Part 8 sets out the arrangements under which an NHS general practitioner who has, or whose practice has, a registered patient list may provide dispensing services. Generally to do so, individual general practitioners or their medical practice face three hurdles: firstly, the patients to whom they could provide dispensing services must have applied to them for such services (regulation 48); secondly, they must have been granted premises approval for the medical practice premises from which they wish to dispense; and thirdly, they must have been granted outline consent in relation to the area to whose residents they wish to dispense (or have relevant historic rights to dispense). The taking effect of decisions to grant outline consent and premises approval may be delayed to allow for the processing of outstanding pharmacy applications (regulations 52



and 56) and to mitigate the effects on other providers of pharmaceutical services locally (regulation 57).

Once included on the dispensing doctor list of a PCT (maintained under regulation 46) and so permitted to provide dispensing services, dispensing doctors may be required to discontinue that provision if the conditions that led to the grant of their entitlement to dispense no longer apply (generally, unless the practice premises are in a reserved location, discontinuation will result from the opening of a pharmacy nearby) – subject to arrangements for possible postponement of the discontinuation (regulation 50). There are also circumstances in which outline consent and premises approval may lapse, for example where it has been more than 6 months since any drug or appliance was dispensed under the arrangements with the dispensing doctor (regulation 60) – and there are also procedures for dealing with medical practices either relocating or amalgamating (regulations 54, 55 and 59).

Part 9 sets out some conditions that are to be imposed on chemists as part of their terms of service with their PCT, which include requirements relating to co-operation with the PCT over local resolution of disputes (regulation 68). These Part 9 conditions are in addition to the principal terms of service for chemists, which are in Schedule 4 for retail pharmacy businesses and Schedule 5 for appliance contractors. The terms of service in Schedule 4 include obligations to provide what are described as the essential services that must be provided at each pharmacy. These essential services include not only dispensing services but other services, for example disposal services in respect of unwanted drugs and promotion of healthy lifestyles. As well as providing essential services, retail pharmacy businesses are subject to other compulsory requirements by virtue of Schedule 4, for example with regard to having acceptable systems of clinical governance and providing information about fitness matters. The range of necessary services required of appliance contractors in Schedule 5 is more limited, but also includes requirements with regard to dispensing and additional compulsory requirements with regard to clinical governance and providing information about fitness matters. Both of these types of provider of pharmaceutical services are also subject to detailed requirements with regard to their opening hours and changes to them (the principal terms of service for dispensing doctors are set out in Schedule 6 and for the most part deal with specific issues relating to dispensing).

Part 10 sets out the arrangements for dealing with breaches of terms of service by chemists (breaches by dispensing doctors are now to be dealt with under their parallel arrangements for providing primary medical services to registered patients, which they must have in order to be providers of pharmaceutical services). Where a dispute between a chemist and a PCT cannot be resolved under the local dispute resolution procedures (or where that procedure may be bypassed), the chemist faces the possibility of a breach or remedial notice, as a part of which there may be a payment withholding (regulations 70 to 72). In some cases, repeated failures to comply with terms of service, or failures with particularly serious consequences, may thereafter lead to the removal of a chemist's business premises from a PCT's pharmaceutical list. Removal of such premises is also a possibility in other cases, for example (subject to exceptions) where a chemist has not provided NHS pharmaceutical services for more than 6 months, and there are also arrangements for voluntary removal, which may be prevented if the contractor is subject to ongoing fitness proceedings (regulations 73 to 76).

The powers to issue breach and remedial notices are enacted under new powers introduced by section 28 of the Health Act 2009, and the enforcement scheme predicated upon these notices replaces the arrangements for disciplinary proceedings for breaches of terms of service under the 2005 Regulations, under which matters were referred to the appropriate discipline committee of a PCT. As a consequence of the new enforcement arrangements for breaches of terms of service, Schedule 8 revokes the National Health Service (Service Committees and Tribunal) Regulations 1992, which set out the previous enforcement arrangements.

Part 11 contains procedures for dealing with fitness issues with regard to chemists on pharmaceutical lists. These include procedures for reviewing fitness conditions imposed under regulation 35 on chemists as a condition of their inclusion in a pharmaceutical list – but for the most part, the procedures complement the arrangements for imposing fitness sanctions that are set out in Chapter 6 of Part 7 to the 2006 Act. There are also substantive requirements that

complement those Chapter 6 arrangements, for example a prescribed list of grounds for which a PCT must remove a chemist from its pharmaceutical list in an unsuitability case under section 151(4) of the 2006 Act, a list which includes murder convictions (regulation 81). Where fitness sanctions are imposed, there are notification requirements that provide for dissemination of relevant information to other bodies that may need to consider taking action, for example the devolved administrations and the General Pharmaceutical Council, and to other persons who are entitled to request the information (regulation 88).

Part 12 contains provisions relating to financial matters. Regulation 89 provides for the publication of the Drug Tariff, the main statement of the financial entitlements of chemists that provide pharmaceutical services – although PCTs act as the determining authorities for the remuneration of some additional services provided by chemists and some obligations are also specified in relation to those determinations (regulation 91). Dispensing doctor remuneration is linked to what their entitlement is or would be under a general medical services contract (regulation 92). There are also provisions for dealing with supplemental matters, for example overpayments and refunds of prescription charges. The Secretary of State is also given powers to make a separate determination of remuneration which will apply to chemists who are suspended from a pharmaceutical list, either during an investigation or pending an appeal, for fitness reasons (regulation 98).

Part 13 deals with some miscellaneous matters, for example the sharing of information about fitness issues by home PCTs, which are the PCTs in whose area the corporate head office of a retail pharmacy business or appliance contractor is situated and which may act as a conduit for fitness information about that body corporate (regulation 99). There is also a provision that allows for applications for services to be made on behalf of some patients by duly authorised persons (regulation 102).

Regulation 103 introduces Schedule 7, which sets out a number of transitional provisions. These include arrangements to deal with the abolition of Primary Care Trusts' dispensing contractor lists, which were the arrangements under which general medical services and personal medical services contractors were able to provide dispensing services under their medical services contract rather than as a consequence of being on a Primary Care Trust's dispensing doctor list. Any such contractors are moved onto the Primary Care Trust's dispensing doctor list, provided there are no outstanding proceedings relating to the removal of the contractor from the dispensing contractor list which do, in due course, lead to their removal. Outstanding listing applications under the 2005 Regulations relating to dispensing doctor lists are preserved, and outstanding listing applications relating to pharmaceutical lists are preserved provided that, in the case of notifiable applications for which there is no equivalent type of listing application under these Regulations, the notification period has or should have ended prior to the coming into force of these Regulations.

Regulation 104 introduces Schedule 8, which contains a number of consequential amendments and revocations, together with a change to the National Health Service (Charges for Drugs and Appliances) Regulations 2000 relating to making medicines freely available, in certain circumstances, in the case of an emergency that threatens, is causing or has caused serious damage to public health (regulation 104).

These Regulations will be the subject of a published review within five years of these Regulations coming into force (regulation 105).

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health, Skipton House, 80 London Road, London SE1 8LH. It is also available alongside this instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).



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