STATUTORY INSTRUMENTS

2012 No. 1909

The National Health Service (Pharmaceutical Services) Regulations 2012

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(**1**);

"the 1992 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992(**2**), as in force on 31st March 2005;

"the 2005 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005(**3**), 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(**4**) (remuneration for persons providing pharmaceutical services);

(**1**) 1968 c. 67.
(**2**) 1992/662; revoked by S.I. 2005/641.
(**3**) 2005/641; revoked by Schedule 7 to these Regulations.
(**4**) 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.

"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;

"appliance" means an appliance included in a list approved by the Secretary of State for the purposes of section 126 of the 2006 Act(**5**) (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(**6**) (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(**7**) (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 sub-paragraph (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(**8**);

"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);

(**5**) *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.
(**6**) 2006 c. 52.
(**7**) 1971 c.80.
(**8**) S.I. 2000/620.

"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);

"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(**9**) (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;

(**9**) 2000 c.7. The definition of "electronic communication" has been amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

"excepted application" means an application to which section 129(2A) and (2B) of the 2006 Act(**10**) (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(**11**), but in the context of Schedule 7 means those Regulations as in force immediately before the appointed day;

"GPhC register" means the register maintained under article 19 of the Pharmacy Order 2010(**12**) (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(**13**) (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(**14**) (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(**15**) (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(**16**) (pilot schemes);

(**10**) Inserted by the Health Act 2009 (c. 21), section 26(3).
(**11**) S.I. 2004/291.
(**12**) S.I. 2010/231.
(**13**) 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).
(**14**) 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.
(**15**) 2006 c. 42.
(**16**) Section 134(2) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraph 8.

"LPS Regulations" means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(**17**);

"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(**18**) (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—

(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(**19**) (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(**20**);

"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(**21**);

"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;

(**17**) S.I. 2006/552.
(**18**) S.I. 2004/585; regulation 3 has been amended by S.I. 2008/1187.
(**19**) Section 159 has been amended by S.I. 2010/22.
(**20**) S.I. 2011/2237.
(**21**) S.I. 2005/2414.

"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 (INNM);

(c) a British Approved Name (BAN);

(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(**22**) 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(**23**) (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(**24**) (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

(**22**) The British Pharmacopoeia Commission was originally established by S.I. 1970/1256 and is at 151 Buckingham Palace Road, London SW1 9SZ.
(**23**) S.I. 2002/253; amended by S.I. 2009/1182.
(**24**) 1989 c.44; amended by S.I. 2005/848.

(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(**25**) (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(**26**);

"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);

"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(**27**) (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(**28**) (the responsible pharmacist);

"PMS contractor" means—

(**25**) 2007 c.28.
(**26**) S.I. 2004/906. *See* regulation 2(2) of those Regulations.
(**27**) S.I. 1976/1213 (N.I. 22).
(**28**) Section 72A was inserted by the Health Act 2006 (c. 28), section 30, and has been amended by S.I. 2006/2407.

(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(**29**), 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;

"prescription form", except in the context of the expression "electronic prescription form" or "non-electronic prescription from", 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(**30**);

"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(**31**) (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations(**32**) (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(**33**) (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;

(**29**) S.I. 2004/627.
(**30**) S.I. 2004/629.
(**31**) Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.
(**32**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
(**33**) 2010 c. 15.

"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(**34**) (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(**35**);

"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—

(**34**) 2009 c. 1 (N.I.).
(**35**) S.I. 2003/2382.

(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(**36**) (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(**37**), 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(**38**) (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;

(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(**39**) (bodies corporate);

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

(**36**) Prior to its repeal, regulation 35 was amended by S.I. 2005/1501.
(**37**) S.I. 1992/664. These Regulations, together with the amendments to them, are revoked by paragraph 1 of Schedule 8.
(**38**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
(**39**) 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.

"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(**40**) (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,

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.

(**40**) 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).

(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(**41**) (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

(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).

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

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(**42**) (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)).

(**42**) 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(**43**) (health and social care: joint strategic needs assessments)—

(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(**44**) (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 sub-paragraph (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.

(**43**) 2007 c.28.
(**44**) 2010 c. 15.

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

(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(**45**) (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;

(**45**) S.I. 2008/915.

(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(**46**) (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 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

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

(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(**47**) (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;

(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;

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

(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(**48**) (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;

(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

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

(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 are 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(**49**) (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;

(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;

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

(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(**50**) (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—

(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

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

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 are 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(**51**) (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;

(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).

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

(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(**52**) (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—

(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

(**52**) Prior to its repeal, the heading of regulation 13 was amended by S.I. 2009/2205.

regulation 16 of the 2005 Regulations(**53**) (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(**54**) (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(**55**) (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

(**53**) Prior to its repeal, regulation 16 was amended by S.I. 2005/1501.
(**54**) Prior to their repeal, regulations 6 and 7 were both amended by S.I. 2005/1501 and 2006/3373.
(**55**) Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

Care Trust for inclusion in the 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 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(**56**) (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,

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

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—

(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(**57**) (regulations as to pharmaceutical services) do not apply to an application—

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

(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—

(i) regulation 4 of the National Health Service (Local Pharmaceutical Services) (No. 2) Regulations 2002(**58**) (right of return to pharmaceutical lists), or

(ii) regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(**59**) (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(**60**) (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)

(**58**) S.I. 2002/2016.
(**59**) S.I. 2006/552.
(**60**) Section 129(2A) and (2B) were inserted by the Health Act 2009 (c. 21), section 26(3).

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

(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(**61**) (designation of 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;

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

(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(**62**) (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,

(**62**) 2003 c. 42.

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

(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(**63**), 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.

(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.

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

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(**64**) (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

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

(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,

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(**65**) (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(**66**) (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.

(**65**) Prior to its repeal, regulation 20 was amended by S.I. 2006/552.
(**66**) S.I. 2008/915.

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 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(**67**) (refusal: outline consent and premises approval where patients are in a controlled locality),

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.

(**67**) Prior to its repeal, regulation 18(2) was amended by S.I. 2005/1501 and 2010/914.

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(**68**) (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—

(**68**) Prior to its repeal, regulation 65 was amended by S.I. 2006/3373.

(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.

(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(**69**) (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

(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.

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

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(**70**) (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—

(**70**) Prior to its repeal, regulation 14 was amended by S.I. 2006/3373.

(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,

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(**71**) (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");

(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

(**71**) 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

(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 (**72**)(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

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

(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,

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 sub-paragraph (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(**73**), 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.

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

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

(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(**74**) (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(**75**), 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(**76**) (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).

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(**77**) (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)—

(**74**) Section 158 has been amended by S.I. 2010/22.
(**75**) S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.
(**76**) Section 157 has been amended by S.I. 2010/22.
(**77**) Sections 154 and 155 have been amended by S.I. 2010/22.

(a) is required to review a contingent removal or a suspension under section 157(1) of the 2006 Act(**78**) (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—

(i) the right of appeal that C has in relation to that decision under section 158 of the 2006 Act(**79**) (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(**80**), 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(**81**) (which relate to suspension and suspension pending appeal),

(**78**) Section 157 has been amended by S.I. 2010/22.
(**79**) Section 158 has been amended by S.I. 2010/22.
(**80**) *See* rule 19 of those Rules.
(**81**) Sections 154 and 155 have been amended by S.I. 2010/22.

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;

(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(**82**) (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(**83**) (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,

(**82**) 2003 c. 42.
(**83**) Section 159 has been amended by S.I. 2010/22.

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)—

(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(**84**) (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;

(**84**) Sections 154 and 155 have been amended by S.I. 2010/22.

(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

(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(**85**) (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.

(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

(**85**) Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4.

(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(**86**) (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.

(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

(**86**) Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4.

(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(**87**) (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.

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.

(**87**) Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), section 141(1), and Schedule 15, Part 4.

(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(**88**) (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 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.

(**88**) Regulation 10 has been amended by S.I. 2000/3189, 2002/2352 and 2004/696.

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(**89**), by a person duly authorised by that authority, or

(**89**) 1989 c. 41.

(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