STATUTORY INSTRUMENTS

2013 No. 349

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

PART 1

Introductory

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and come into force on 1st April 2013.

Interpretation

2.—(1) Subject to paragraph (7), in these Regulations—

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

"the 1968 Act" means the Medicines Act 1968 [M1];

"the 1992 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992 [M2], as in force on 31st March 2005;

"the 2005 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005 [M3], as in force on 31st August 2012;

"the 2006 Act" means the National Health Service Act 2006;

"the 2006 Regulations" means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 [M4], as in force immediately before the appointed day;

"the 2007 Act" means the Local Government and Public Involvement in Health Act 2007 [M5];

"the 2012 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2012 [M6], as in force immediately before the appointed day;

"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 which the NHSCB is required (as opposed to authorised) to arrange by virtue of directions under section 127 of the 2006 Act [M7] (arrangements for additional pharmaceutical services);

"APMS contractor" means a person or partnership that provides primary medical services under contractual arrangements with the NHSCB 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 [M8] (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 for a pharmacist or a specialist nurse to review a person's use of a specified appliance;

"appointed day" means 1st April 2013;

"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 [M9] (definitions applying for the purposes of whole Act).

"arrangements for recharging" means arrangements under paragraph 3 of Schedule 12A to the 2006 Act [M10] (pharmaceutical remuneration – other pharmaceutical remuneration) under which the NHSCB requires a person to reimburse it for any pharmaceutical remuneration to which that paragraph applies;

"bank holiday" means any day that is by virtue of section 1 of or Schedule 1 to the Banking and Financial Dealings Act 1971 [M11] (which relate to bank holidays) a bank holiday in England;

"batch issue" means a form, in the format required by the NHSCB (or a person exercising its functions) and approved by the Secretary of State, which—

(a) is issued by a prescriber at the same time as a non-electronic repeatable prescription to enable an NHS chemist, an LPS chemist or a 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 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);

"CCG" means a clinical commissioning group;

"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 [M12];

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

"chiropodist or podiatrist independent prescriber" means a chiropodist or podiatrist who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001 [M13] (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiropodist or podiatrist is qualified to order drugs and appliances as a chiropodist or podiatrist independent prescriber;

"continuity principles" is to be construed in accordance with paragraph 1(8) of Schedule 9;

"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) or paragraph 7(4) of Schedule 9;

"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;

"director" includes a member of a limited liability partnership;

"dispensing contractor" means an NHS chemist, an LPS 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 [M14] (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 compatible with the systems used by the NHSCB (or a person exercising its functions) for—

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

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

unless the NHS chemist, dispensing doctor or LPS chemist dispensing the prescription is to receive no pharmaceutical remuneration of any kind in respect of any drug or appliance ordered on the form;

(b) is signed with a prescriber's advanced electronic signature;

(c) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and

(d) 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 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;

"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 which the NHSCB is authorised (as opposed to required) to arrange by virtue of directions under section 127 of the 2006 Act;

"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 managed by the Information Centre;

"excepted application" means an application to which section 129(2A) of the 2006 Act [M15] (regulations as to pharmaceutical services) does 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 the NHSCB;

"GMS Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2004 [M16];

"GPhC register" means the register maintained under article 19 of the Pharmacy Order 2010 [M17] (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 [M18] (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 [M19] (the Professional Standards Authority for Health and Social Care);

"Health Education England" means Health Education England established by the Health Education England (Establishment and Constitution) Order 2012 [M20];

"home Primary Care Trust" has the same meaning as in the 2012 Regulations;

"HWB" means a Health and Wellbeing Board [M21];

"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;

"Information Centre" means the Health and Social Care Information Centre established under section 252 of the Health and Social Care Act 2012 (the Health and Social Care Information Centre);

"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 Healthwatch organisation" is to be construed in accordance with section 222(2A) of the 2007 Act [M22] (arrangements under section 221(1));

"LPS chemist" means a party, other than the commissioning body, to—

(a) an LPS pilot scheme; or

(b) an LPS scheme for the provision of LP services;

"LPS contractor" means a person who is an LPS chemist by virtue of being a party to an LPS scheme which is not an LPS pilot scheme;

"LPS pilot scheme" means a pilot scheme within the meaning given in section 134(2) of the 2006 Act [M23] (pilot schemes);

"LPS scheme", except in the context of Part 13 or Schedule 7, includes an LPS pilot scheme;

"medical performers list" means a list of medical practitioners prepared, maintained and published under regulations under section 91 of the 2006 Act [M24] (persons performing primary medical services);

"medical practice premises" means—

(a) in relation to a provider of primary medical services, premises which are identified in the provider's arrangements with the NHSCB 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 general practitioner on a dispensing doctor list who is not a provider of primary medical services but 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;

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

(a) a member of or 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 [M25] (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 2012 Regulations;

"neighbouring HWB", in relation to a HWB (HWB1), means the HWB of an area that borders any part of the area of HWB1;

"NHSCB" means the National Health Service Commissioning Board;

"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 [M26];

"NHS chemist" means an NHS appliance contractor or an NHS pharmacist;

"NHS dispute resolution procedure", in relation to an LPS scheme which is not an LPS pilot scheme, means the dispute resolution procedure set out in paragraphs 22 and 23 of Schedule 7;

"NHS Litigation Authority" means the National Health Service Litigation Authority established by the National Health Service Litigation Authority (Establishment and Constitution) Order 1995 [M27];

"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 (so includes services provided as part of the health service in pursuance of the public health functions of the Secretary of State or local authorities);

"nominated dispensing contractor" means an NHS chemist, an LPS chemist or a dispensing doctor who has been nominated in a particular patient's PDS patient details to dispense the electronic prescriptions of that patient;

"non-electronic prescription form" means a form for ordering a drug or appliance which—

(a) is compatible with the systems used by the NHSCB (or a person exercising its functions) for—

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

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

unless the NHS chemist, dispensing doctor or LPS chemist dispensing the prescription is to receive no pharmaceutical remuneration of any kind in respect of any drug or appliance ordered on the form;

(b) has been provided for use by a prescriber by—

(i) the NHSCB,

(ii) another primary care organisation,

(iii) a local authority, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,

(iv) the Secretary of State,

(v) a CCG, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,

(vi) an NHS Trust, or

(vii) an NHS Foundation Trust;

(c) if—

(i) it has been so provided for use by a prescriber in England, and

(ii) a prescription charge may be payable in relation to the prescription or a prescription charge exemption in the Charges Regulations may apply to it,

is in a format that has been approved by the Secretary of State;

(d) has been issued by a prescriber; and

(e) does not indicate that the drug or appliance ordered may be provided more than once;

"non-electronic repeatable prescription" means a repeatable prescription which is not an electronic repeatable prescription;

"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 in accordance with regulation 318 of the Human Medicines Regulations 2012 [M28] (lists of names) and which is in force;

"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 [M29] (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 [M30] (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;

(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; and

(d) as regards England in relation to any time prior to 1st April 2013, a Primary Care Trust;

"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 2012 Regulations;

"outstanding pharmacy application" has the meaning given in regulation 53(7);

"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 [M31];

"PDS patient details" means the information held about a patient in the Patient Demographics Service managed by the Information Centre;

"pharmaceutical needs assessment" is to be construed in accordance with regulations 3(1) and 7;

"pharmaceutical needs assessment map" means the map which a HWB 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 [M32] (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 is prescribing under arrangements for the provision of NHS services which are neither—

(i) pharmaceutical services, unless they are arrangements for the provision of enhanced services, nor

(ii) local pharmaceutical services, unless they are arrangements for the provision of services that are of the same type as enhanced services;

"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 [M33] (the responsible pharmacist);

"physiotherapist independent prescriber" means a physiotherapist who is registered in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2001, and against whose name in that register is recorded an annotation signifying that the physiotherapist is qualified to order drugs and appliances as a physiotherapist independent prescriber;

"PMS contractor" means—

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

(b) a partnership, the members of which have made arrangements in parallel under section 92 of the 2006 Act;

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

"the PMS Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2004 [M34];

"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 2012 Regulations;

"prescriber", unless the context otherwise requires, means a medical practitioner, a dental practitioner, a pharmacist independent prescriber, a supplementary prescriber, a chiropodist or podiatrist independent prescriber, a physiotherapist independent 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 form", means an electronic prescription form or a non-electronic prescription form;

"Prescription of Drugs Regulations" means the National Health Service (General Medical Services) (Prescription of Drugs etc.) Regulations 2004 [M35];

"prescription only medicine" has the same meaning as in the Human Medicines Regulations 2012 [M36];

"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 [M37] (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations [M38] (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 [M39] (public sector equality duty), and references to people sharing a protected characteristic are to be understood by referral to the provisions of Chapter 1 of Part 2 of that Act (protected characteristics);

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

"provisional date" is to be construed in accordance with regulation 53(8)(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 [M40] (Regional Health and Social Care Board);

"registered pharmacist" means a person who is registered in Part 1 or 4 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

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

"relevant HWB" means—

(a) in the context of an application for any entry of any type in a pharmaceutical list or dispensing doctor list (including from a person already included in the list), the HWB for the area to which the list relates;

(b) as regards a person with an entry of any type in a pharmaceutical list or dispensing doctor list, the HWB for the area to which the list relates;

(c) in the context of an application by a person for dispensing services, the HWB which is, as regards the dispensing doctor from whom the applicant is seeking dispensing services, the relevant HWB (by virtue of sub-paragraph (b)); and

(d) in the context of a decision to suspend or remove any type of entry of a person in a pharmaceutical list or dispensing doctor list, the HWB for the area to which the list relates;

"relevant list" means—

(a) a pharmaceutical list or an equivalent list maintained by another primary care organisation; or

(b) a list maintained by the NHSCB or another primary care organisation of approved performers or providers of primary medical, dental or ophthalmic services;

"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 [M41];

"repeat dispensing services" means pharmaceutical or local pharmaceutical services which involve the provision of drugs or appliances in accordance with a repeatable prescription;

"repeatable prescription" means an electronic repeatable prescription or a form for ordering drugs or appliances which—

(a) is compatible with the systems used by the NHSCB (or a person exercising its functions) for—

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

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

unless the NHS chemist, dispensing doctor or LPS chemist dispensing the prescription is to receive no pharmaceutical remuneration of any kind in respect of any drug or appliance ordered on the form;

(b) has been provided for use by a prescriber by—

(i) the NHSCB,

(ii) another primary care organisation,

(iii) a local authority, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,

(iv) the Secretary of State,

(v) a CCG, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,

(vi) an NHS Trust, or

(vii) an NHS Foundation Trust;

(c) if—

(i) it has been so provided for use by a prescriber in England, and

(ii) a prescription charge may be payable in relation to the prescription or a prescription charge exemption in the Charges Regulations may apply to it,

is in a format that has been approved by the Secretary of State;

(d) has been issued by a prescriber,

(e) indicates that the drugs or appliances ordered may be provided more than once; and

(f) specifies the number of occasions on which they may be provided;

"reserved location" means, unless the context otherwise requires, an area classified as such following a determination (that has not lapsed) under—

(a) regulation 41(2) or 42(1);

(b) regulation 41(2) or 42(1) of the 2012 Regulations (which related to initial, second and subsequent determinations of reserved location status), whether or not by virtue of paragraph 8 of Schedule 9; or

(c) regulation 35 of the 2005 Regulations [M42] (pharmaceutical services in reserved locations), whether or not by virtue of—

(i) paragraph 8 of Schedule 9, or

(ii) paragraph 6 of Schedule 7 to the 2012 Regulations (transitional provisions – 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 [M43], as in force on 31st August 2012;

"Scheduled drug" means a drug specified in Schedule 1 or 2 to the Prescription of Drugs Regulations [M44] (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);

"scheme premises" is to be construed in accordance with regulation 102(1)(b);

"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 [M45] (bodies corporate);

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

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

"supplementary prescriber" means—

(a) a registered pharmacist against whose name in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs and appliances as a supplementary prescriber;

(b) a person—

(i) who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001 [M46] (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;

"transfer scheme" means a property transfer scheme under section 300 of the Health and Social Care Act 2012 (transfer schemes) that transfers the rights and liabilities of a Primary Care Trust under arrangements for the provision of pharmaceutical or local pharmaceutical services to other persons.

(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 (except in the phrase "local pharmaceutical services") 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.

(4) Where reference is made in these Regulations to a decision of the NHSCB 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) For the purposes of these Regulations, "emergency requiring the flexible provision of pharmaceutical services" means an emergency declared by means of directions given by the Secretary of State under section 168A of the 2006 Act [M47] (exercise of functions) 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 directions, the NHSCB must for a specified period—

(a) exercise, or

(b) where a discretion is conferred, consider exercising,

one or more of their functions under regulation 29(2), regulation 61, paragraph 27 of Schedule 4, paragraph 17 of Schedule 5 or paragraph 26(3) of Schedule 7, subject to any conditions or limitations set out in the directions.

(6) Where—

(a) directions of the type mentioned in paragraph (5) are given; and

(b) the Secretary of State issues further directions 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.

(7) Where a word or expression used in Schedule 9 has a different meaning in the 2005 Regulations, the 2006 Regulations or the 2012 Regulations from that given in paragraphs (1) to (3), that word or expression bears the meaning that it bears in the 2005 Regulations, the 2006 Regulations or 2012 the Regulations, or is given in paragraphs (1) to (3), as the context requires.

Marginal Citations

M1 1968 c. 67.

M2 1992/662
; these Regulations were revoked by S.I. 2005/641.

M3 2005/641
; these Regulations were revoked by S.I. 2012/1909.

M4 S.I. 2006/552; these Regulations are revoked by Schedule 10.

M5 2007 c. 28.

M6 S.I. 2012/1909; these Regulations are revoked by Schedule 10.

M7 Section 127 has been amended by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 64.

M8 *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.

M9 2006 c. 52.

M10 Schedule 12A was inserted by the Health and Social Care Act 2012, Schedule 3.

M11 1971 c.80.

M12 S.I. 2000/620.

M13 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).

M14 2000 c.7. The definition of "electronic communication" has been amended by the Communications Act 2003 (c. 21), **Schedule 17**, paragraph 158.

M15 Section 129(2A) was inserted by the Health Act 2009 (c. 21), **section 26(3)**, and has been amended by the Health and Social Care Act 2012 (c. 7), **section 207(4)**, and Schedule 4, paragraph 66(5).

M16 S.I. 2004/291.

M17 S.I. 2010/231.

M18 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)**.
M19 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.
M20 S.I. 2012/1273.
M21 *See* section 194 of the Health and Social Care Act 2012 (c. 7).
M22 Section 222(2A) was inserted by the Health and Social Care Act 2012, section 183(2).
M23 Section 134(2) has been amended by the Health Act 2009 (c. 21), **Schedule 1**, paragraph 8, and by the Health and Social Care Act 2012, Schedule 4, paragraph 71(3).
M24 Section 91 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 35.
M25 Section 159 has been amended by S.I. 2010/22.
M26 S.I. 2005/2414.
M27 S.I. 1995/2800; amended by S.I. 2002/2621, 2005/503 and 1445, 2012/1641 and 2013/235.
M28 S.I. 2012/1916.
M29 S.I. 2002/253; amended by S.I. 2009/1182.
M30 1989 c.44; amended by S.I. 2005/848.
M31 S.I. 2004/906. *See* regulation 2(2) of those Regulations.
M32 S.I. 1976/1213 (N.I. 22).
M33 Section 72A was inserted by the Health Act 2006 (c. 28), **section 30**, and has been amended by S.I. 2006/2407.
M34 S.I. 2004/627.
M35 S.I. 2004/629.
M36 *See* regulation 5(3) of those Regulations.
M37 Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.
M38 Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
M39 2010 c. 15.
M40 2009 c. 1 (N.I.).
M41 S.I. 2003/2382.
M42 Prior to its revocation, regulation 35 was amended by S.I. 2005/1501.
M43 S.I. 1992/664; these Regulations were revoked by S.I. 2012/1909.
M44 Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
M45 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.
M46 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).
M47 Section 168A was inserted by the Health and Social Care Act 2012 (c. 7), **section 49(4)**.

PART 2

Pharmaceutical needs assessments

Pharmaceutical needs assessments

3.—(1) The statement of the needs for pharmaceutical services which each HWB is required to publish by virtue of section 128A of the 2006 Act [M48] (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 the NHSCB 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 the NHSCB with a dispensing doctor).

Marginal Citations

M48 Inserted by the Health Act 2009 (c. 21), **section 25**.

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 HWB 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 HWB pharmaceutical needs assessments are to be published

5. Each HWB must publish its first pharmaceutical needs assessment by 1st April 2015.

Subsequent assessments

6.—(1) After it has published its first pharmaceutical needs assessment, each HWB must publish a statement of its revised assessment within 3 years of its previous publication of a pharmaceutical needs assessment.

(2) A HWB must make a revised assessment as soon as is reasonably practicable after identifying changes since the previous assessment, which are of a significant extent, to the need for pharmaceutical services in its area, having regard in particular to changes to—

(a) the number of people in its area who require pharmaceutical services;

(b) the demography of its area; and

(c) the risks to the health or well-being of people in its area,

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 HWB may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its or a Primary Care Trust's 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 HWB—

(i) is satisfied that making its first or a revised assessment would be a disproportionate response to those changes, or

(ii) is in the course of making its first or 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 Primary Care Trust pharmaceutical needs assessments and access by the NHSCB and HWBs to pharmaceutical needs assessments

7.—(1) Before the publication by an HWB of the first pharmaceutical needs assessment that it prepares for its area, the pharmaceutical needs assessment that relates to any locality within that area is the pharmaceutical needs assessment that relates to that locality of the Primary Care Trust for that locality immediately before the appointed day, read with—

(a) any supplementary statement relating to that assessment published by a Primary Care Trust under the 2005 Regulations or the 2012 Regulations; or

(b) any supplementary statement relating to that assessment published by the HWB under regulation 6(3).

(2) Each HWB must ensure that the NHSCB has access to—

(a) the HWB's pharmaceutical needs assessment (including any supplementary statement that it publishes, in accordance with regulation 6(3), that becomes part of that assessment);

(b) any supplementary statement that the HWB publishes, in accordance with regulation 6(3), in relation to a Primary Care Trust's pharmaceutical needs assessment; and

(c) any pharmaceutical needs assessment of a Primary Care Trust that it holds,

which is sufficient to enable the NHSCB to carry out its functions under these Regulations.

(3) Each HWB must ensure that, as necessary, other HWBs have access to any pharmaceutical needs assessment of a Primary Care Trust that it holds, which is sufficient to enable the other HWBs to carry out their functions under these Regulations.

Consultation on pharmaceutical needs assessments

8.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each HWB (HWB1) must consult the following about the contents of the assessment it is making—

(a) any Local Pharmaceutical Committee for its area (including any Local Pharmaceutical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);

(b) any Local Medical Committee for its area (including any Local Medical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);

(c) any persons on the pharmaceutical lists and any dispensing doctors list for its area;

(d) any LPS chemist in its area with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services;

(e) any Local Healthwatch organisation for its area, and any other patient, consumer or community group in its area which in the opinion of HWB1 has an interest in the provision of pharmaceutical services in its area; and

(f) any NHS trust or NHS foundation trust in its area;

(g) the NHSCB; and

(h) any neighbouring HWB.

(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 HWB is consulted on a draft under paragraph (2), if there is a Local Pharmaceutical Committee or Local Medical Committee for its area or part of its area that is different to a Local Pharmaceutical Committee or Local Medical Committee consulted under paragraph (1)(a) or (b), that HWB—

(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 HWB1 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, HWB1 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 HWB must have regard, in so far as it is practicable to do so, to the following matters—

(a) the demography of its area;

(b) whether in its area there is sufficient choice with regard to obtaining pharmaceutical services;

(c) any different needs of different localities within its area;

(d) the pharmaceutical services provided in the area of any neighbouring HWB 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, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area; and

(e) any other NHS services provided in or outside its area (which are not covered by sub-paragraph (d)) 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, 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 HWB 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, and

(iii) the risks to the health or well-being of people in its area.

PART 3

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

Pharmaceutical lists and EPS lists

10.—(1) In respect of the area of each HWB, the NHSCB must prepare, maintain and publish 2 lists of persons (if there are any), other than medical practitioners or dental practitioners, who undertake to provide pharmaceutical services from premises situated in that area.

(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) Those lists must include—

(a) the address of the premises in the area of the HWB 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) In respect of the area of each HWB but subject to paragraph (5), the NHSCB must—

(a) prepare, maintain and publish a list (to be called an "EPS list") of all the NHS chemists situated in that 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) The NHSCB need not prepare, maintain and publish an EPS list for a HWB area if it is clear from its pharmaceutical lists for that area which NHS chemists situated in that area participate in the Electronic Prescription Service and where in that area the Electronic Prescription Service is provided.

(6) The NHSCB must ensure that each HWB has access to the pharmaceutical lists and any EPS lists that it holds which is sufficient to enable the HWB to carry out its functions under these Regulations.

(7) 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 relevant HWB, 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.

(8) 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 or 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 or obligations relate to NHS pharmacists and are applicable in the case of the NHS pharmacist;

(c) where the NHSCB makes an arrangement with the NHS pharmacist for the provision of any directed services, that are included in that arrangement; and

(d) that are—

(i) included in regulations under section 225 of the 2007 Act [M49] (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and

(ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider,

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 or 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 or obligations relate to NHS appliance contractors and are applicable in the case of the NHS appliance contractor;

(c) where the NHSCB 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—

(i) included in regulations under section 225 of the 2007 Act [M50] (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and

(ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider,

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

Marginal Citations

M49 Section 225 has been amended by the Health and Social Care Act 2012 (c. 7), section 186(6) to (10), **Schedule 14**, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.

M50 Section 225 has been amended by the Health and Social Care Act 2012 (c. 7), section 186(6) to (10), **Schedule 14**, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.

Routine applications for inclusion in or amendments 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 relevant HWB, additional premises from which to provide the same or different pharmaceutical services,

(ii) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services, or

(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 NHSCB must have regard

13.—**[**F1(1) If—

(a) the NHSCB 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 for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the current need has been included in the relevant 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 (regulations as to pharmaceutical services), the NHSCB 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 relevant pharmaceutical needs assessment, there have been changes to the needs for pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;

(e) whether it is satisfied that—

(i) granting the application would only meet the current need mentioned in paragraph (1) in part, and

(ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;

(f) whether—

(i) it is satisfied that granting the application would only meet the current need mentioned in paragraph (1) in part, but

(ii) it considers that, if the application were granted, it would not be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;

(g) whether it is satisfied that—

(i) the current need mentioned in paragraph (1) was for services other than essential services, and

(ii) granting the application would result in an increase in the availability of essential services in the area of the relevant HWB;

(h) whether it is satisfied that, since the publication of the relevant 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 the area of the relevant HWB or in the area of another HWB, NHS services;

(i) whether the application needs to be deferred or refused by virtue of any provision of Parts 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 NHSCB 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 NHSCB, 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.

Textual Amendments

F1 Reg. 13(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **3**

Current needs: consequences of additional matters

14.—(1) If the NHSCB 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 NHSCB 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 NHSCB 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 NHSCB is satisfied as mentioned in regulation 13(2)(d) or (e), it must refuse the application.

(5) If the NHSCB is satisfied as mentioned in regulation 13(2)(f) to (h), it may only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in the area of the relevant HWB.

Future needs: additional matters to which the NHSCB must have regard

15.—**[**[F2](1) If—

(a) the NHSCB 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 for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the future need has been included in the relevant 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 (regulations as to pharmaceutical services), the NHSCB 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 relevant pharmaceutical needs assessment, there have been changes to the needs, or future needs, for pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;

(f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the needs, or future needs, for pharmaceutical services in the area of the relevant HWB 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, or better access, to pharmaceutical services in that area;

(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 relevant HWB;

(j) whether it is satisfied that, since the publication of the relevant 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 the area of the relevant HWB or in the area of another HWB, NHS services;

(k) whether the application needs to be deferred or refused by virtue of any provision of Parts 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 NHSCB 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 NHSCB, 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.

Textual Amendments

F2 Reg. 15(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **4**

Future needs: consequences of additional matters

16.—(1) If the NHSCB 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 NHSCB 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 NHSCB 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 NHSCB 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 NHSCB is satisfied as mentioned in regulation 15(2)(e) to (g), it must refuse the application.

(6) If the NHSCB is satisfied as mentioned in regulation 15(2)(h) to (j), it may only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in the area of the relevant HWB.

Improvements or better access to the current service: additional matters to which the NHSCB must have regard

17.—[[F3](1) If—

(a) the NHSCB 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, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB 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 relevant pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that 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 relevant 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 the area of the relevant HWB or in the area of another HWB, NHS services;

(g) whether it is satisfied that—

(i) the improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and

(ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB;

(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 NHSCB 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 NHSCB, 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.

Textual Amendments

F3 Reg. 17(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **5**

Unforeseen benefits applications: additional matters to which the NHSCB must have regard

18.—(1) If—

(a) the NHSCB receives a routine application and is required to determine whether it is satisfied that granting the application, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured were or was not included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act [M51] (regulations as to pharmaceutical services), the NHSCB 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 the area of the relevant HWB, or

(ii) the arrangements the NHSCB has in place for the provision of pharmaceutical services in that area;

(b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—

(i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also the NHSCB's duties under sections 13I and 13P of the 2006 Act [M52] (duty as to patient choice and duty as respects variation in provision of health services)),

(ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access (taking into account also the NHSCB's duties under section 13G of the 2006 Act [M53] (duty as to reducing inequalities)), **[**[F4]or**]**

(iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act [M54] (duty to promote innovation)),

granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published;

(c) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access that the applicant is offering to secure;

(d) whether it is satisfied that another application offering to secure the improvements or better access has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;

(e) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;

(f) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.

(3) The NHSCB 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).

Textual Amendments

F4 Word in reg. 18(2)(b)(ii) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **6**

Marginal Citations

M51 Section 129(2A) was inserted by the Health Act 2009 (c. 21), **section 26(3)**, and has been amended by the Health and Social Care Act 2012 (c. 7), **section 207(4)**, and Schedule 4, paragraph 66(5).

M52 Sections 13I and 13P were inserted by the Health and Social Care Act 2012, section 23(1).

M53 Sections 13G was inserted by the Health and Social Care Act 2012, section 23(1).

M54 Sections 13K was inserted by the Health and Social Care Act 2012 (c. 7), **section 23(1)**.

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

19.—(1) If the NHSCB 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 NHSCB 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 NHSCB 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 NHSCB 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 NHSCB is satisfied as mentioned in regulation 17(2)(d) to (g) or 18(2)(a), it must refuse the application.

(6) If the NHSCB 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 the relevant pharmaceutical needs assessment.

Future improvements or better access: additional matters to which the NHSCB must have regard

20.—[F5(1) If—

(a) the NHSCB 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 to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4(b) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB 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 relevant pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;

(f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the profile or future profile of pharmaceutical services in the area of the relevant HWB 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 relevant pharmaceutical needs assessment, the future improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;

(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 relevant HWB;

(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 NHSCB 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 NHSCB, 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.

Textual Amendments

F5 Reg. 20(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **7**

Future improvements or better access: consequences of additional matters

21.—(1) If the NHSCB 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 NHSCB 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 NHSCB 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 NHSCB 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 NHSCB 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.—(1) If the NHSCB receives a routine application to which regulation 19(6) does not apply, the NHSCB 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 the area of the relevant HWB that has been included in the relevant 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 the area of the relevant HWB that have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.

(2) For the purposes of paragraph (1), the relevant pharmaceutical needs assessment is—

(a) the pharmaceutical needs assessment of the relevant HWB that is current at the time that the NHSCB takes its decision to grant or refuse the application, unless in the opinion of the NHSCB (or on appeal the Secretary of State) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment; or

(b) if the relevant HWB has not published a pharmaceutical needs assessment, the pharmaceutical needs assessment of a Primary Care Trust (as extended by regulation 7(1)) that relates to the locality in which the location or premises to which the application relates is or are situated.

PART 4

Excepted applications

Applications from NHS chemists in respect of providing directed services

23. Section 129(2A) of the 2006 Act [M55] (regulations as to pharmaceutical services) does 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.

Marginal Citations

M55 Section 129(2A) was inserted by the Health Act 2009 (c. 21), **section 26(3)**, and has been amended by the Health and Social Care Act 2012 (c. 7), **section 207(4)**, and Schedule 4, paragraph 66(5).

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

24.—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application from a person already included in a pharmaceutical list to relocate to different premises in the area of the relevant HWB (HWB1) 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 NHSCB, 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 the area of HWB1, or

(ii) in a controlled locality in the area of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;

(c) the NHSCB **[**F6is not of the opinion that granting the application would cause**]** significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB1;

(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 NHSCB chooses to commission them); and

(e) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow).

(2) Section 129(2A) of the 2006 Act does not apply to an application from a person already included in a pharmaceutical list for the area of a HWB (HWB2) for inclusion in the pharmaceutical list for the area of a neighbouring HWB (HWB3), or inclusion in the pharmaceutical list for the area of HWB3 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 the NHSCB, 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 HWB3's area; or

(ii) in a controlled locality in the area of a neighbouring HWB (including HWB2), where that controlled locality is within 1.6 kilometres of P2;

(d) the NHSCB **[**F7is not of the opinion that granting the application would cause**]** significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB3;

(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, the NHSCB chooses to commission them);

(f) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow); and

(g) the applicant consents to—

(i) where the applicant has only one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of the applicant's name from that pharmaceutical list, or

(ii) where the applicant has more than one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of P1 from being listed in relation to the applicant in that 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 [M56] (exemption from the necessary or expedient test) applied, and—

(i) P3 are located in an area that, immediately before the 2012 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;

(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 regulation 16 of the 2005 Regulations [M57] (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); [F8]...

(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 regulation 24 of the 2012 Regulations (relocations that do not result in significant change to pharmaceutical services provision), or

(bb) to which regulation 6 or 7 of the 2005 Regulations [M58] (which related to minor relocations) applied, and

(iii) the applicant is unable to satisfy the NHSCB that relocation from P3 is necessary for reasons that the NHSCB accepts are good cause **[**[F9]; or**]**

[[F10](d) are distance selling premises, unless—

(i) the premises to which the applicant is seeking to relocate are also distance selling premises, and

(ii) if the application was one to which regulation 25(1) applied, it would not be refused pursuant to regulation 25(2).**]**

Textual Amendments

F6 Words in reg. 24(1)(c) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **8(a)**

F7 Words in reg. 24(2)(d) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **8(b)**

F8 Word in reg. 24(3)(b) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **8(c)(i)**

F9 Word in reg. 24(3)(c) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **8(c)(ii)**

F10 Reg. 24(3)(d) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **8(c)(iii)**

Marginal Citations

M56 Prior to its revocation, the heading of regulation 13 was amended by S.I. 2009/2205.

M57 Prior to its revocation, regulation 16 was amended by S.I. 2005/1501.

M58 Prior to their revocation, regulations 6 and 7 were both amended by S.I. 2005/1501 and 2006/3373.

Distance selling premises applications

25.—(1) Section 129(2A) of the 2006 Act [M59] (regulations as to pharmaceutical services) does 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 NHSCB 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 NHSCB 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.

Marginal Citations

M59 Section 129(2A) was inserted by the Health Act 2009 (c. 21), **section 26(3)**, and has been amended by the Health and Social Care Act 2012 (c. 7), **section 207(4)**, and Schedule 4, paragraph 66(5).

Change of ownership applications

26.—(1) Section 129(2A) of the 2006 Act [M60] (regulations as to pharmaceutical services) does not apply to an application from a person who is not included in a pharmaceutical list 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 NHSCB may for good cause allow).

(2) Section 129(2A) of the 2006 Act does not apply to an application from a person who is not included in a pharmaceutical list for the area of a HWB (HWB1) 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 HWB1 or a neighbouring HWB, or

(ii) has provided at Y's premises but Y is no longer able to provide pharmaceutical services at those premises for reasons that the NHSCB 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) **[**F11had Y**]** applied to move to X's premises, that application would have been granted under regulation 24; and

(e) **[**F12in a case where**]** pharmaceutical services—

(i) are being provided at Y's premises, the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB 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 the NHSCB considers is an acceptable period for the interruption of the provision of pharmaceutical services by the business that X is taking over.

[F13(3) An application pursuant to paragraph (1) must be refused if it relates to distance selling premises, unless the application, if made pursuant to regulation 25(1), would not be refused pursuant to regulation 25(2).

(4) An application pursuant to paragraph (2) must be refused if the existing pharmacy premises from which the applicant is seeking to relocate are distance selling premises, unless the premises to which the applicant is seeking to relocate are also distance selling premises (and this is in addition to the requirement that arises by virtue of paragraph (2)(d) that the application, if made pursuant to regulation 25(1), would not be refused pursuant to regulation 25(2)).**]**

Textual Amendments

F11 Words in reg. 26(2)(d) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **9(a)(i)**

F12 Words in reg. 26(2)(e) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **9(a)(ii)**

F13 Reg. 26(3)(4) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **9(b)**

Marginal Citations

M60 Section 129(2A) was inserted by the Health Act 2009 (c. 21), **section 26(3)**, and has been amended by the Health and Social Care Act 2012 (c. 7), **section 207(4)**, and Schedule 4, paragraph 66(5).

Applications for temporary listings arising out of suspensions

27.—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

(a) for temporary inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for temporary inclusion in that list in respect of services, or services and premises, other than those already listed in relation to that person,

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

(2) The NHSCB 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, or

(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;

(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; or

(d) if Y is a partnership and X—

(i) is or has been a member or employee of Y,

(ii) is a body corporate of which a member or employee of Y is or has been a director, superintendent or majority shareholder, or

(iii) is a partnership of which X, or a member or employee of X, is or has been a member.

(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 NHSCB, 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) of the 2006 Act [M61] (regulations as to pharmaceutical services) does not apply to an application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person,

in the circumstances set out in paragraph (2).

(2) Those circumstances are—

(a) it has been determined in accordance with—

(i) regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002 [M62] (right of return to pharmaceutical lists),

(ii) regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 [M63] (right of return to pharmaceutical lists), or

(iii) regulation 108,

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 NHSCB 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 NHSCB may for good cause allow); and

(b) any conditions in the relevant determination of the right of return are satisfied.

Marginal Citations

M61 Section 129(2A) was inserted by the Health Act 2009 (c. 21), **section 26(3)**, and has been amended by the Health and Social Care Act 2012 (c. 7), **section 207(4)**, and Schedule 4, paragraph 66(5).

M62 S.I. 2002/2016. These Regulations are revoked by Schedule 10.

M63 S.I. 2006/552. These Regulations are revoked by Schedule 10.

Temporary arrangements during emergencies or because of circumstances beyond the control of NHS chemists

29.—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application for a temporary amendment to a pharmaceutical list in the following circumstances—

(a) there is an emergency requiring the flexible provision of pharmaceutical services; or

(b) there is a temporary suspension in the provision of pharmaceutical services at listed chemist premises (P1) for a reason (for example, fire or flooding) that is beyond the control of the NHS chemist (C) listed in relation to P1.

(2) In the circumstances described in paragraph (1)(a), the NHSCB may make a temporary amendment to an entry in a 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 NHSCB 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 NHSCB, on giving the NHSCB at least 24 hours notice.

(3) In the circumstances described in paragraph (1)(b), the NHSCB may make a temporary amendment to the entry of C in the relevant pharmaceutical list in order to allow C to provide the services that C ordinarily provided at P1 at other premises nearby (P2), at the days on which and times at which those services were ordinarily provided at P1, for a period specified by the NHSCB.

(4) A period specified under paragraph (3) must not be longer (initially) than 6 months, and the NHSCB may under that paragraph—

(a) if it has good cause to do so, extend the period specified under that paragraph (but not beyond 12 months from the date on which C starts to provide the services in question from P2); or

(b) curtail the period specified,

in appropriate circumstances.

(5) For the period specified under paragraph (3), but subject to paragraph (6) and regulation 118, P2 instead of P1 are to be treated as listed in relation to C for the purposes of these Regulations (albeit that the premises actually listed in relation to C are P1).

(6) The applicant may revert to the applicant's overridden entry in the pharmaceutical list before the end of the period specified by under paragraph (3), on giving the NHSCB at least 24 hours notice.

(7) Planned refurbishment is not a "reason beyond the control" of C for the purposes of paragraph (1)(b).

(8) There is no right of appeal under these Regulations in respect of a decision of the NHSCB under this regulation.

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 NHSCB 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 relevant HWB.

Refusal: same or adjacent premises

31.—**[**[F14](1) A routine or excepted application 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 NHSCB 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).

Textual Amendments

F14 Reg. 31(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **10**

Deferrals arising out of LPS designations

32.—**[**[F15](1) A routine application must be refused 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—

(a) regulation 99; or

(b) regulation 4 of the 2006 Regulations [M64] (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 NHSCB 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.

Textual Amendments

F15 Reg. 32(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **11**

Marginal Citations

M64 Prior to its revocation, regulation 4 was amended by S.I. 2009/599 and 2010/914.

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.—**[**F16(A1) In this regulation, "A" means, where an application for inclusion in a pharmaceutical list is made by a person who is—

(a) an individual, the individual making the application;

(b) a partnership, any partner in the partnership making the application; or

(c) a body corporate—

(i) except for the purposes of paragraphs (1)(a) and (b) and (3)(h)(i), the body corporate making the application, and

(ii) except for the purposes of paragraph (2)(b) and (e), any director or superintendent of the body corporate making the application.**]**

(1) An application for inclusion in a pharmaceutical list by a person F17... who is not already included in it must be refused if the NHSCB is satisfied that—

(a) A F18...has been convicted in the United Kingdom of murder;

(b) A F18...—

(i) has been convicted in the United Kingdom of a criminal offence, other than murder, 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 NHSCB 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 NHSCB—

(a) having contacted the referees mentioned in paragraph 3(8) of Schedule 2, is not satisfied with the references given;

(b) considers that A is unsuitable to be included in the list;

(c) having—

(i) checked with the NHS BSA for any facts that it considers relevant relating to past or current fraud investigations involving or related to A [F19]..., and

(ii) considered these and any other facts in its possession relating to fraud involving or relating to A [F19]...,

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 [F20]..., and

(ii) considered these and any other facts in its possession involving or relating to A [F20]...,

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 NHSCB 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 [M65] (sexual offences) applies, or if it had been committed in England and Wales, would have applied;

(g) whether A [F21]... 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 NHSCB or another primary care organisation for such action; or

(h) whether A [F21]...was, at the time of the originating events, or has in the preceding 6 months been—

(i) a director or superintendent of a body corporate which has been refused inclusion in, conditionally included in, removed or contingently removed from a relevant list, or

(ii) is currently suspended from a relevant list,

for a reason relating to unsuitability, fraud or efficiency of service provision, and if so, what the facts were in each such case and the reasons given by the NHSCB or another primary care organisation in each case.

(4) When the NHSCB 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 NHSCB 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.

Textual Amendments

F16 Reg. 33(A1) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **12(a)**

F17 Word in reg. 33(1) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **12(b)(i)**

F18 Words in reg. 33(1)(a)(b) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **12(b)(ii)**

F19 Words in reg. 33(2)(c)(i)(ii) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **12(c)**

F20 Words in reg. 33(2)(d)(i)(ii) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **12(c)**

F21 Words in reg. 33(3)(g)(h) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **12(c)(d)**

Marginal Citations

M65 2003 c. 42.

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

34.—[[F22](A1) In this regulation, "A" means, where an application for inclusion in a pharmaceutical list is made by a person who is—

(a) an individual, the individual making the application;

(b) a partnership, any partner in the partnership making the application; or

(c) a body corporate—

(i) except for the purposes of paragraph (1)(b), (c)(ii), (e), (g), (i) and (k), the body corporate making the application, and

(ii) any director or superintendent of the body corporate making the application.**]**

(1) An application for inclusion in a pharmaceutical list by a person F23...who is not already included in it may be deferred if the NHSCB is satisfied that—

(a) there are, in respect of A F24...—

(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 **[**F25the person's removal from the pharmaceutical list, if the person**]** 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 **[**F26the person's removal from the pharmaceutical list, if the person**]** were to be included in it;

(c) there is an investigation anywhere in the world—

(i) by A's F27... licensing or regulatory body, or

(ii) relating to A F28... in A's professional capacity (including one by the NHSCB or another primary care organisation),

which, if the outcome were adverse, would be likely to lead to the removal of **[**F29the person from the pharmaceutical list if the person**]** were to be included in it;

(d) A F30...is suspended from a relevant list;

(e) a body corporate of which A F31... 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 F32... against a decision of the NHSCB 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 NHSCB would be likely to remove **[**F33the person from the pharmaceutical list if the person**]** were to be included in it;

(g) the First-tier Tribunal is considering an appeal by a body corporate of which A F34... was, at the time of the originating events, or has in the preceding 6 months been, a director or superintendent, against a decision of the NHSCB 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 NHSCB would be likely to remove **[**F35the person from the pharmaceutical list if the person**]** were to be included in it;

(h) A [F36]... 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 **[**[F37]the person from the pharmaceutical list if the person**]** were to be included in it;

(i) a body corporate, of which A [F38]...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 **[**[F39]the person from the pharmaceutical list if the person**]** were to be included in it;

(j) the First-tier Tribunal is considering an application from the NHSCB or a Local Health Board for a national disqualification of A [F40]...;

(k) the First-tier Tribunal is considering an application from the NHSCB or a Local Health Board for a national disqualification of a body corporate of which A [F41]... was, at the time of the originating events, a director or superintendent; or

(l) the NHSCB or another 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 **[**[F42]the applicant**]** from a relevant list but that decision has yet to take effect.

(2) The NHSCB 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.

Textual Amendments

F22 Reg. 34(A1) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(a)**

F23 Word in reg. 34(1) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(i)**

F24 Words in reg. 34(1)(a) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(ii)(aa)**

F25 Words in reg. 34(1)(a) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(ii)(bb)**

F26 Words in reg. 34(1)(b) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(iii)**

F27 Words in reg. 34(1)(c)(i) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(iv)(aa)**

F28 Words in reg. 34(1)(c)(ii) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(iv)(bb)**

F29 Words in reg. 34(1)(c) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(iv)(cc)**

F30 Words in reg. 34(1)(d) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(v)**

F31 Words in reg. 34(1)(e) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(vi)**

F32 Words in reg. 34(1)(f) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(vii)(aa)**

F33 Words in reg. 34(1)(f) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(vii)(bb)**

F34 Words in reg. 34(1)(g) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(viii)(aa)**

F35 Words in reg. 34(1)(g) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(viii)(bb)**

F36 Words in reg. 34(1)(h) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(ix)(aa)**

F37 Words in reg. 34(1)(h) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(ix)(bb)**

F38 Words in reg. 34(1)(i) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(x)(aa)**

F39 Words in reg. 34(1)(i) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(x)(bb)**

F40 Words in reg. 34(1)(j) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(v)**

F41 Words in reg. 34(1)(k) omitted (1.4.2014) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(v)**

F42 Words in reg. 34(1)(l)(ii) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **13(b)(xi)**

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 NHSCB and which the NHSCB decides to impose with regard to P.

(2) The NHSCB 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 the NHSCB 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 [M66], 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 NHSCB 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 NHSCB; or

(b) imposes a different condition,

P must, within 30 days of P being notified of the First-tier Tribunal's decision, notify the NHSCB 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 NHSCB within that 30 days that P does not wish to withdraw P's application, the grant of P's application lapses.

Marginal Citations

M66 S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.

PART 7

Areas that are controlled localities or 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 2012 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), the NHSCB may at any time consider and determine whether or not any locality, 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 the NHSCB, a Primary Care Trust or on appeal (whether under these Regulations, the 2012 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 NHSCB or the Primary Care Trust, or if that determination was appealed, the date of the decision on appeal;

(b) unless the NHSCB 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 the NHSCB for it to determine whether or not an area specified in the application (which must be all or part of the Committee's area) is to be, or is to be part of, a controlled locality.

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

(3) If the NHSCB 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 the NHSCB is considering making a determination that an area (A1) 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 whose area includes all or part of A1;

(b) any Local Medical Committee whose area includes all or part of A1;

(c) any person on a pharmaceutical list or dispensing doctors list who, in the opinion of the NHSCB, may be affected by the determination;

(d) any LPS chemist who, in the opinion of the NHSCB, may be affected by the determination;

(e) any provider of primary medical services who, in the opinion of the NHSCB, may be affected by the determination;

(f) where it is considering making a determination as a consequence of a routine application, the person making that application; and

(g) any HWB whose area includes all or part of A1.

(2) The NHSCB 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 NHSCB expects to make its determination, which must be no later than 6 months after the day on which the NHSCB first gives notice to any person in respect of the proposed determination under paragraph (1) or (2).

(4) Once the NHSCB 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 NHSCB's decision

39.—(1) When it is determining whether or not an area is or is part of a controlled locality, the NHSCB must have regard to whether the provision of—

(a) primary medical services by a provider of primary medical services;

(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, the NHSCB 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,

(ii) publish that map, and

(iii) make that map available as soon as is practicable to any HWB that has all or part of that controlled locality in its area;

(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.

(4) A HWB to which a map is made available under paragraph (2)(a)(iii) must—

(a) publish that map alongside its pharmaceutical needs assessment map (once it has one); or

(b) include the boundary of the controlled locality (in so far as it is in, or part of the boundary of, the HWB's area) in its pharmaceutical needs assessment map (once it has one).

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 included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, 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 the NHSCB 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, the 2012 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 the 2012 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 NHSCB 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 NHSCB 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.

[[F43](4) Paragraph (2)(b) does not apply where the NHSCB is satisfied that there are reasonable grounds for believing the person making the refused application was motivated (wholly or partly) by a desire for that application to be refused.

(5) The refusal of an application pursuant to paragraph (2)(b), or regulation 40(2)(b) of the 2012 Regulations (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters), is to be ignored for the purposes of the calculation of a 5 year period pursuant to paragraph (2)(b).**]**

Textual Amendments

F43 Reg. 40(4)(5) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **14**

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 included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, 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 NHSCB 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 NHSCB 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 NHSCB 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 NHSCB, 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 NHSCB 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 NHSCB must—

(a) notify the persons notified under Part 3 of Schedule 2 about A1 that the NHSCB 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 NHSCB 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 NHSCB 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 paragraph (1), regulation 44(1) of the 2012 Regulations (prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location) or regulation 18ZA of the 2005 Regulations [M67] (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),

(ii) regulation 44(3) of the 2012 Regulations, or

(iii) regulation 18ZA(2) of the 2005 Regulations; and

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

unless the NHSCB 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 NHSCB 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.

Marginal Citations

M67 Prior to its revocation, regulation 18ZA was inserted by S.I. 2005/1501.

Second and subsequent determinations of reserved location status

42.—(1) Where the NHSCB has made D1, or a reserved location determination has been made in accordance with the 2012 Regulations or 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 NHSCB may determine (subject to paragraph (3) and regulation 43(2))—

(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 NHSCB, 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 NHSCB, there is no longer—

(i) a reserved location, or

(ii) in the case of a determination of a reserved location that has not yet taken effect, a determination of a reserved location,

with regard to the premises proposed for listing (which may have become pharmacy premises) because the relevant location no longer meets (or does not meet) the criteria for being a reserved location in regulation 41(3).

(2) Before making D2, the NHSCB 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 NHSCB 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 NHSCB with regard to that determination.

(3) The NHSCB 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 the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB.

(4) Where the NHSCB makes D2—

(a) D1 lapses as soon as D2 is made; and

(b) the NHSCB may (in accordance with regulation 50) postpone the termination of the arrangements that it has with the provider of primary medical services or dispensing doctor that would otherwise take place as a consequence of D2.

(5) Where—

(a) the NHSCB 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 the NHSCB 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 NHSCB must—

(a) delineate precisely the boundary of the reserved location on a map;

(b) publish that map; and

(c) make that map available as soon as is practicable to any HWB that has all or part of that reserved location in its area.

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 included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services.

(2) As regards any application to which paragraph (1) applies, the NHSCB 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 NHSCB must refuse the application if granting it would, in the opinion of the NHSCB, prejudice the proper provision of relevant NHS services in the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB.

(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 NHSCB 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 the NHSCB—

(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) In respect of the area of each HWB, the NHSCB must prepare and publish a list (a "dispensing doctor list") of the names of any "dispensing doctors" in that area, that is to say—

(a) providers of primary medical services who provide pharmaceutical services from medical practice premises in that area; and

(b) general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in that area (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 include—

(a) the address of any premises in the area of the relevant HWB 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 (which may be in the area of a neighbouring HWB).

(3) The NHSCB must remove a dispensing doctor from a 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 at or from (what were) the relevant listed dispensing premises;

(b) in the case of a listed general practitioner, that person is no longer on the medical performers list or no longer performs primary medical services within the area of the relevant HWB; or

(c) all the arrangements that the dispensing doctor has with the NHSCB to perform or provide pharmaceutical services at or from (what were) the relevant listed dispensing premises 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 member of 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 the NHSCB lists that provider instead of them as the dispensing doctor (or doctors) on a dispensing doctors list.

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

(a) the NHSCB must agree to that request;

(b) the arrangements that the NHSCB 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 that individual general practitioner or 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 NHSCB—

(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 and when, in the case of a general practitioner who has been so notified, 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 NHSCB must include the names of any general practitioner notified under sub-paragraph (a)(i), unless the NHSCB 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 or 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 [M68] (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 or obligations are applicable in the case of the dispensing doctor; and

(d) are—

(i) included in regulations under section 225 of the 2007 Act [M69] (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and

(ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider.

(2) The NHSCB must ensure that those terms of service—

(a) if the dispensing doctor has arrangements with the NHSCB 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, are terms of service of, and so are enforceable under, the arrangements that the NHSCB 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.

Marginal Citations

M68 Prior to its revocation, regulation 20 was amended by S.I. 2006/552.

M69 Section 225 has been amended by the Health and Social Care Act 2012 (c. 7), section 186(6) to (10), **Schedule 14**, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.

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 (E) by whom D is employed or engaged.

(2) Condition 1 is that P satisfies the NHSCB 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 for the area in which P resides, 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 2012 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 whilst residing in the area of the relevant HWB,

(bb) has been so included but now resides at a different address in the area of the relevant HWB, 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 in the area of the relevant HWB under arrangements with the NHSCB, 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 the NHSCB, enclosing P's request, the NHSCB 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, the NHSCB 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) The NHSCB must not, under paragraph (5)(b), require D to undertake to provide services to P, if D satisfies the NHSCB 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 the NHSCB 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 the NHSCB 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, the general practitioner or any other general practitioner who performs primary medical services on behalf of that provider.

(9) To be valid, a notification under paragraph (5)(b) by the NHSCB 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 the NHSCB has arrangements (whether they were made under these Regulations or were made under or continued by virtue of the 2012 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 NHSCB 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 NHSCB determines that Condition 3 in regulation 48(4) does not apply in respect of P, or

(ii) the NHSCB determines that Condition 3 in regulation 48(4) does apply in respect of P, but P informs the NHSCB that P wishes 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);

(e) P is resident in a reserved location, and—

(i) had previously informed the NHSCB (or a Primary Care Trust) that P wished to be provided with pharmaceutical services by D, but

(ii) P has since informed the NHSCB 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 NHSCB in accordance with paragraphs (2) to (6).

(2) The NHSCB 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) the NHSCB grants a routine or excepted application, the result of which is the inclusion in a 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 NHSCB, 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 the NHSCB is required to terminate the provision of pharmaceutical services pursuant to paragraph (1)(f) but the NHSCB is satisfied that the determination that led to the decision to terminate has adversely affected D.

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

(6) The NHSCB must postpone the discontinuation—

(a) while it is forming the opinion mentioned in paragraph (3)(c); or

(b) for such period as the NHSCB considers necessary in order to give the doctor reasonable notice (in any case to which paragraph (1) applies) of the discontinuation.

(7) The NHSCB 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 NHSCB;

(c) any Local Pharmaceutical Committee whose area includes the listed dispensing premises at or from which D has been providing pharmaceutical services to P; and

(d) any Local Medical Committee whose area includes the listed dispensing premises at or from which D has been providing pharmaceutical services to P.

(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, who wishes to be granted the right to provide pharmaceutical services to patients on their own list or the provider's list (if the patients apply under regulation 48(1) on the basis of Condition 2 or 3) may apply in writing to the NHSCB 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, 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, the NHSCB is to determine applications for outline consent and premises approval in such manner (including with regard to procedures) as it sees fit.

(5) The NHSCB 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) The NHSCB 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 the NHSCB 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), the NHSCB 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 the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB.

(9) If the NHSCB 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 the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB,

it may grant the application in respect of that smaller area.

(10) The NHSCB 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,

(ii) under regulation 51 of the 2012 Regulations (outline consent and premises approval: applications by doctors), or

(iii) by virtue of regulation 18(2) of the 2005 Regulations [M70] (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 NHSCB 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.

Marginal Citations

M70 Prior to its revocation, 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 the NHSCB receives an application for outline consent or premises approval (including an application for premises approval to which regulation 54 or 55 applies, but not an application for temporary premises approval to which regulation 58 or 61 applies), as soon as is practicable, it must give notice of that application to—

(a) any Local Pharmaceutical Committee—

(i) whose area includes the medical practice premises or all or part of the area to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the medical practice premises to which the application relates;

(b) any Local Medical Committee—

(i) whose area includes the medical practice premises or all or part of the area to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the medical practice premises to which the application relates;

(c) any person—

(i) included in a pharmaceutical list for the area of the relevant HWB, or

(ii) who is entitled to be included in that 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 the NHSCB, be significantly affected if the application were granted;

(d) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted;

(e) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in that area which, in the opinion of the NHSCB, has a significant interest in the outcome of the application;

(f) any provider of primary medical services, or any other person on the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services), who in the opinion of the NHSCB has a significant interest in the outcome of the application;

(g) any Local Health Board any part of whose area is within 2 kilometres of the medical practice premises to which the application relates; and

(h) the relevant HWB and any other HWB (HWB2) any part of whose area—

(i) is within 2 kilometres of the medical practice premises to which the application relates, or

(ii) in the case of an application for outline consent, is part of the area specified in the application;

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

(3) If a HWB is notified under paragraph (1)(h), the NHSCB must also give notice of the application to—

(a) any person—

(i) included in a pharmaceutical list for the area of HWB2, or

(ii) who is entitled to be included in that 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 the NHSCB, be significantly affected if the application were granted;

(b) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB2, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted,

(c) any Local Healthwatch organisation for the area of HWB2, and any other patient, consumer or community group in that area which, in the opinion of the NHSCB, has a significant interest in the outcome of the application; and

(d) any provider of primary medical services, or any other person on the dispensing doctors list for the area of HWB2 if there is one (being a performer but not a provider of primary medical services), who in the opinion of the NHSCB has a significant interest in the outcome of the application.

(4) A person (P) notified under paragraphs (1) to (3) may make representations in writing about the application that is the subject of the notification to the NHSCB, provided P does so within 45 days of the date on which notice of the application was given to them.

(5) If the NHSCB 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) 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) 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 the relevant 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 NHSCB 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 NHSCB 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 the NHSCB 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) to (3) in relation to the application.

(2) Each notification under paragraph (1) 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.

(3) When outline consent is granted, subject to paragraphs (11) and (13)(b), the NHSCB must determine when the outline consent is to take effect.

(4) 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).

(5) 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.

(6) 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.

(7) 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 the relevant HWB), or

(ii) from a person included in a pharmaceutical list—

(aa) to relocate to different premises in the area of the relevant HWB, or

(bb) to open, within the area of that HWB, 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.

(8) In a case where outline consent is not to take effect on the date on which it is granted, the NHSCB 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.

(9) That provisional date, subject to paragraph (10), is the day after the end of the period of one year beginning on the day of—

(a) the determination by the NHSCB 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.

(10) The NHSCB 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 (8).

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

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

(13) Where the NHSCB receives a request under paragraph (12), 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 (11),

and it must inform D accordingly.

(14) The NHSCB must notify the applicant for outline consent of its determination under paragraph (10) or (13) 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 NHSCB to change the premises from which D wishes to dispense to other premises in the area of the relevant HWB.

(2) The NHSCB 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 the NHSCB 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 NHSCB.

(4) The NHSCB 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 NHSCB for premises approval for the new medical practice premises from which D wishes to dispense.

(2) Subject to paragraph (3), the NHSCB must grant that application if it is of the type described in this paragraph, that is to say if the NHSCB 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 the area of the relevant HWB, or

(ii) in a controlled locality in the area of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate; and

(c) the NHSCB is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB.

(3) The NHSCB must, unless it has good cause not to do so, refuse an application under paragraph (1) if an application under—

(a) that paragraph;

(b) regulation 55(1) of the 2012 Regulations (premises approval: relocations of practice premises which are not significant after outline consent has taken effect); or

(c) regulation 65(4)(a) of the 2005 Regulations [M71] (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 NHSCB 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.

Marginal Citations

M71 Prior to its revocation, regulation 65 was amended by S.I. 2006/3373.

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

56.—(1) Where—

(a) premises approval is granted in relation to additional medical practice premises, or in relation to medical practice premises to which a dispensing doctor (D) is relocating; and

(b) the application for premises approval had no related application for outline consent,

paragraph (2) applies.

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

(a) on the date the determination of the application takes effect, and that date is—

(i) if no appeal is made against the decision within the period for bringing an appeal, the date on which that period expires, or

(ii) if the decision is appealed within that period, the date on which the appeal reaches its final outcome; or

(b) if on the day before that day within 1.6 kilometres of the relevant medical practice premises there are premises which are the subject of an outstanding pharmacy application, on the date which is—

(i) the day after the end of a period of one year from the date on which that outstanding pharmacy application reaches its final outcome, or

(ii) such longer period (not exceeding 3 months) as the NHSCB 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 the NHSCB 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), the NHSCB 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 NHSCB 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 NHSCB 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 whose area includes the medical practice premises to which the decision relates; and

(d) any Local Medical Committee whose area includes the medical practice premises to which the decision relates.

(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 NHSCB 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 the NHSCB 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 whose area includes the medical practice premises for which temporary premises approval has been granted; and

(d) any Local Medical Committee whose area includes the medical practice premises for which temporary premises approval has been granted;

(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.

(4) If the NHSCB refuses an application to grant temporary premises approval under paragraph (1), the NHSCB 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 providers of primary medical services.

(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 providers of primary medical services 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(11) and (13)(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 NHSCB 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 NHSCB 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 one of the provisions mentioned in paragraph (6).

(6) Those provisions are—

(a) regulation 57;

(b) regulation 57 of the 2012 Regulations (gradual introduction of premises approval); and

(c) regulation 20(2) of the 2005 Regulations [M72] (imposition of conditions) or by virtue of regulation 57.

Marginal Citations

M72 Prior to its revocation, regulation 20 was amended by S.I. 2006/552.

Temporary arrangements during emergencies or circumstances beyond the control of a dispensing doctor

61.—(1) During an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may require a dispensing doctor 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 the area of the relevant HWB, the NHSCB considers that, in order to secure continuing adequate provision of

pharmaceutical services in that 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 NHSCB may extend or curtail in appropriate circumstances.

(2) The NHSCB 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) The NHSCB 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,

because there is 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 NHSCB 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 NHSCB, on giving the NHSCB at least 24 hours notice.

(5) The NHSCB may grant temporary premises approval if there is a temporary suspension in the provision of dispensing services at listed dispensing premises (P1) for a reason (for example, fire or flooding) that is beyond the control of the dispensing doctor (D) listed in relation to P1.

(6) In the circumstances described in paragraph (5), the NHSCB may make a temporary amendment to the entry of D in the relevant dispensing list in order to allow D to provide the services that D ordinarily provided at P1 at other premises nearby (P2), at the days on which and times at which those services were ordinarily provided at P1, for a period specified by the NHSCB.

(7) A period specified under paragraph (6) must not be longer (initially) than 6 months, and the NHSCB may under that paragraph—

(a) if it has good cause to do so, extend the period specified under that paragraph (but not beyond 12 months from the date on which D starts to provide the services in question from P2); or

(b) curtail the period specified,

in appropriate circumstances.

(8) For the period specified under paragraph (6), but subject to paragraph (9) and regulation 118, P2 instead of P1 are to be treated as listed in relation to D for the purposes of these Regulations (albeit that the premises actually listed in relation to D are P1).

(9) D may revert to the overridden premises approval before the end of the period specified under paragraph (6), on giving the NHSCB at least 24 hours notice.

(10) Planned refurbishment is not a "reason beyond the control" of D for the purposes of paragraph (5).

(11) There is no right of appeal under these Regulations in respect of a decision of the NHSCB under this regulation.

(12) If the NHSCB grants an application for temporary premises approval under this regulation, it must notify that decision to the persons who would have been notified about the application had the application been an application to which regulation 55 applies.

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

(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 the NHSCB—

(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 by the NHSCB;

(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(10), or

(ii) whether outline consent is to come into effect under regulation 53(13),

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 the NHSCB was required to notify about the relevant application for outline consent or premises approval by virtue of P1 being—

(i) included in a pharmaceutical list,

(ii) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but not (yet) included,

(iii) an LPS chemist with whom the NHSCB 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 the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services),

and a person whose interests might, in the opinion of the NHSCB, 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), the NHSCB 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 the relevant pharmaceutical needs assessment, or to the fairness of the process by which that assessment was undertaken, and

(bb) are not vexatious or frivolous.

(4) If the NHSCB considers that a person notified under regulation 52(1) to (3) 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 NHSCB that they are person with third party appeal rights may appeal to the Secretary of State against the

determination (D2) by the NHSCB 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 the NHSCB'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.—**[**[F44](1) Paragraph (2) applies where—

(a) an application in respect of distance selling premises is granted under these Regulations; or

(b) an application was granted under the 2005 Regulations or 2012 Regulations in respect of premises which were, for the purposes of the Regulations under which the application was granted, distance selling premises.**]**

(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) The NHSCB may not vary or remove the conditions set out in paragraph (3).

Textual Amendments

F44 Reg. 64(1) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **15**

Modifications etc. (not altering text)

C1 Reg. 64(3)(c) excluded (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **16**

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) The NHSCB 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 relevant HWB, 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),

(ii) the NHS pharmacist and the NHSCB 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 a pharmaceutical list, the NHSCB 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; or

(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 relevant HWB, 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),

(ii) the NHS appliance contractor and the NHSCB 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 a pharmaceutical list, the NHSCB 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 the NHSCB 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 NHSCB 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), the NHSCB may only vary a direction given under paragraph (4) or (5), or regulation 65(4) or (5) of the 2012 Regulations (core opening hours conditions), 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), or regulation 65(4) or (5) of the 2012 Regulations, 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 [M73] (variation of directed services in respect of exempted premises) or regulation 66(2) and (3) of the 2012 Regulations (conditions relating to providing directed services), it is a condition of the inclusion in the pharmaceutical list of the person listed in relation to those premises—

(a) if, before these Regulations came into force, C1 had not been requested by a 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 NHSCB unless thereafter the NHSCB ceases to commission those services; or

(b) if, before these Regulations came into force, C1 was providing, or had been requested by a 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 unless the NHSCB does not continue to commission those services.

(2) The person listed in relation to the premises may apply to the NHSCB 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 neither a Primary Care Trust nor the NHSCB has requested that the services be provided at the premises in respect of which the condition was imposed,

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

(3) If, pursuant to an application under paragraph (2), the NHSCB 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—

(i) if the NHSCB commissions the services within 3 years of the date on which the condition is imposed by virtue of these Regulations, and

(ii) unless thereafter the NHSCB ceases to commission the services; and

(b) not withhold agreement to a service specification for those services unreasonably.

(4) Where, in the course of making a routine or excepted application under these Regulations or the 2012 Regulations, an NHS chemist undertook—

(a) to provide the directed services mentioned in the application, if a Primary Care Trust or the NHSCB 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;

(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 withhold agreement to a service specification for those services unreasonably,

if the Primary Care Trust or the NHSCB 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, unless thereafter the NHSCB ceases to commission the services (if it has commissioned them) or does not continue to commission services (that is, if only the Primary Care Trust, and not the Board, has commissioned them).

(6) Where a Primary Care Trust or the NHSCB 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) The NHSCB may not vary or remove the condition imposed by virtue of paragraphs (3) to (5).

Marginal Citations

M73 Prior to its revocation, regulation 14 was amended by S.I. 2006/3373.

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 NHSCB 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 NHSCB that C wishes to withdraw from the pharmaceutical list within a shorter period of not less than 30 days,

unless either it is impracticable for C to do so, in which case C must notify the NHSCB as soon as it is practicable for C to do so, or the NHSCB agrees to a shorter notification period.

(3) If C has consented to—

(a) particular listed chemist premises no longer being listed in relation to C by the NHSCB; or

(b) being removed from the pharmaceutical list for the area of a HWB,

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, when C gives notice to the NHSCB 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 the NHSCB 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 the NHSCB that C makes every reasonable effort to communicate and co-operate with the NHSCB with a view to resolving any dispute between C and the NHSCB relating to C's compliance with the terms of service under which C provides pharmaceutical services for the NHSCB.

(2) The NHSCB 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, the NHSCB must make every reasonable effort to communicate and co-operate with an NHS chemist (C) with a view to resolving any dispute between C and the NHSCB relating to C's compliance with C's terms of service.

(2) Where an NHS pharmacist invites a Local Pharmaceutical Committee to participate in the attempts to resolve the dispute, the NHSCB 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 the NHSCB is satisfied—

(a) the dispute relates to a matter that has already been the subject of dispute resolution between the NHSCB (or a Primary Care Trust) 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 the NHSCB 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 NHSCB 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 the NHSCB, 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 the NHSCB 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 the NHSCB 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, the NHSCB 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(6);

(b) pending C taking the steps that C must take, to the satisfaction of the NHSCB, in order to remedy the breach, the NHSCB is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(6), 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 the NHSCB, 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(6), 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(6) 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 the NHSCB 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 NHSCB 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, the NHSCB is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(6) 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(6) 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 NHSCB 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 NHSCB 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 NHSCB 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.

(4) For the purposes of regulations 70(4) and 71(3), remuneration determined by the Secretary of State, or by the NHSCB acting as determining authority pursuant to regulation 91(1), is remuneration due to C under the Drug Tariff.

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

73.—(1) The NHSCB may remove an NHS chemist (C) from a 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 NHSCB, in order to remedy the breach, and the NHSCB is satisfied that it is necessary to remove C from the 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 the NHSCB 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 the NHSCB 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 the NHSCB 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), the NHSCB may only remove—

(a) particular chemist premises from C's listing in a pharmaceutical list if the relevant breaches all relate to those particular chemist premises; or

(b) C from a particular pharmaceutical list if the relevant breaches all relate to listed chemist premises which are the only chemist premises listed in that pharmaceutical list in relation to C.

(3) The NHSCB may only remove C, or chemist premises listed in relation to C, from a 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) the NHSCB, when it notifies C of the decision, includes in the notice its duly justified reasons for the decision.

(4) The NHSCB 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) The NHSCB must not remove C, or chemist premises listed in relation to C, from a 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 the NHSCB is considering removing C, or removing the listing of particular chemist premises listed in relation to C, from a pharmaceutical list under paragraph (1), it must—

(a) give notice to C, at least 30 days in advance of taking the decision, that the NHSCB is minded to remove C or the premises from a pharmaceutical list;

(b) as part of that notification, advise C that C may make—

(i) written representations to the NHSCB with regard to that action, provided C notifies the NHSCB with those representations within 30 days beginning with the date of the notification by the NHSCB, and

(ii) oral representations to the NHSCB with regard to that action, provided—

(aa) C notifies the NHSCB of C's wish to do so within 30 days beginning with the date of the notification by the NHSCB, and

(bb) C (or a representative of C) attends the hearing that the NHSCB arranges for the purpose of hearing those representations, which the NHSCB must give C reasonable notice of; and

(c) consult any Local Pharmaceutical Committee whose area includes the particular listed chemist premises or C's only chemist premises on that pharmaceutical list.

(7) If the NHSCB does decide to remove C, or to remove the listing of particular chemist premises listed in relation to C, from a 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 NHSCB must remove C from the relevant pharmaceutical lists.

(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 [M74] (representative of pharmacist in case of death or disability)) is carrying on the retail pharmacy business of C that is included in the relevant 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 the NHSCB determines that C has not, during the preceding 6 months, provided pharmaceutical services at chemist premises ("the particular premises") listed in a particular pharmaceutical list—

(a) if there are other chemist premises listed in that pharmaceutical list in relation to C, the NHSCB must remove the listing of the particular premises from that list; or

(b) if there are no other chemist premises listed in that pharmaceutical list in relation to C, the NHSCB must remove C from that 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 a relevant 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 a pharmaceutical list under paragraph (1) or (3), the NHSCB must—

(a) give notice to C (or, in appropriate circumstances, a person whom the NHSCB reasonably believes is representing C or is an executor of C) of the decision that the NHSCB 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 the NHSCB with regard to that action, provided they notify the NHSCB with those representations within 30 days beginning with the date of the notification by the NHSCB, and

(ii) oral representations to the NHSCB with regard to that action, provided—

(aa) they notify the NHSCB of their wish to do so within 30 days beginning with the date of the notification by the NHSCB, and

(bb) C (or the representative or executor, or someone representing the representative or executor) attends the hearing that the NHSCB arranges for the purpose of hearing those representations, which the NHSCB must give C reasonable notice of; and

(c) consult any Local Pharmaceutical Committee whose area includes the chemist premises that the NHSCB is minded to remove from the pharmaceutical list.

(6) If the NHSCB does decide to remove C, or chemist premises listed in relation to C, from a 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.

Marginal Citations

M74 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.

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 a pharmaceutical list in relation to particular pharmacy premises—

(a) if there are other chemist premises listed in that pharmaceutical list in relation to C, the NHSCB must remove the listing of the particular premises in relation to C from that list; or

(b) if there are no other chemist premises listed in that pharmaceutical list in relation to C, subject to regulation 76, the NHSCB must remove C from that pharmaceutical list.

(2) If C is relocating from existing chemist premises listed in a particular pharmaceutical list to new chemist premises—

(a) if—

(i) there are other chemist premises listed in that pharmaceutical list in relation to C, or

(ii) there are no other chemist premises so listed, but the existing chemist premises and the new chemist premises are in the area of the same HWB,

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

(b) if—

(i) there are no other premises listed in that pharmaceutical list in relation to C, and

(ii) the new chemist premises are in the area of another HWB,

subject to regulation 76, the NHSCB must remove C from that pharmaceutical list with effect from the date that C is required to notify to the NHSCB under regulation 67(4)(a)(ii).

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

(a) other chemist premises are listed by the NHSCB in that pharmaceutical list in relation to C, the NHSCB 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 the NHSCB in that pharmaceutical list in relation to C, the NHSCB must remove C from that 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 the relevant pharmaceutical list in relation to C, the NHSCB must remove the listing of the particular premises in relation to C from that list; or

(b) if there are no other chemist premises listed in the relevant pharmaceutical list in relation to C, subject to regulation 76, the NHSCB must remove C from that list.

(6) If the NHSCB decides not to remove C from a 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 the NHSCB would otherwise remove an NHS chemist (C) from a pharmaceutical list under regulation 75, but—

(a) is investigating 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 [M75](which relate to disqualification of practitioners, contingent removal and suspension), or regulation 80;

(b) has decided to—

(i) remove C from a 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 that pharmaceutical list under regulation 75 until the relevant investigation or proceedings have been concluded.

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

(a) as regards C, the NHSCB 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 that pharmaceutical list under regulation 75.

Marginal Citations

M75 Section 154 has been amended by S.I. 2010/22.

Appeals against decisions under Part 10

77.—(1) An NHS chemist (C) may appeal against the following decisions by the NHSCB—

(a) the issuing of a remedial notice under regulation 70, including—

(i) the specified steps that C must take that are in the notice,

(ii) the duration of the notice period in the notice,

(iii) any decision to provide for a withholding of remuneration that is included in the notice, and

(iv) the amount of any withholding;

(b) a decision not to restore remuneration to C, as provided for in a remedial notice in accordance with regulation 70(4)(b)(ii), or to restore a smaller amount than the amount that C considers should be restored;

(c) the issuing of a breach notice under regulation 71, including—

(i) any decision to provide for a withholding of remuneration that is included in the notice, and

(ii) the amount of any withholding;

(d) a decision to remove C from a 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 a 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 NHSCB must not remove C or the listing of particular listed chemist premises in relation to C (as the case may be) from a 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 the NHSCB has imposed a condition on an NHS chemist (C) under regulation 35 (or thereafter under this regulation), or a Primary Care Trust has imposed a condition on C under regulation 35 or 79 of the 2012 Regulations (which relate to fitness conditions and conditions to combat fraud), the NHSCB 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 relevant pharmaceutical list, or

(ii) thereafter, until at least 6 months have elapsed since the NHSCB (or a Primary Care Trust) determined the outcome of the previous review.

(2) If the NHSCB 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), the NHSCB must afford C an opportunity to make representations to it in writing.

(4) As a result of the review, the NHSCB 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) The NHSCB 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 [M76], 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 the NHSCB 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 the NHSCB, that decision takes effect upon the taking of that decision, unless the First-tier Tribunal directs otherwise).

Marginal Citations

M76 S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.

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, the NHSCB determines that an NHS chemist has failed to comply with a condition imposed under—

(a) regulation 35 or 79, or as varied under regulation 79; or

(b) regulation 35 or 79 of the 2012 Regulations (which relate to fitness conditions and conditions to combat fraud), or as varied under regulation 79 of those Regulations,

it may remove that NHS chemist from the relevant pharmaceutical list.

Mandatory removal in suitability cases

81. In unsuitability cases, the NHSCB must remove an NHS chemist (C) from a 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)—

(i) has been convicted in the United Kingdom of a criminal offence, other than murder, 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 the NHSCB is considering—

(a) removing an NHS chemist (C) from a pharmaceutical list under section 151 or 152(3)(b) of the 2006 Act [M77] (which relate to disqualification of practitioners and contingent removal);

(b) removing C from a pharmaceutical list under regulation 80; or

(c) contingently removing C from a pharmaceutical list under section 152(1) of the 2006 Act [M78].

(2) Where paragraph (1) applies, before reaching its decision, the NHSCB must—

(a) notify C of the action the NHSCB 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 the NHSCB with regard to that action, provided C notifies the NHSCB with those representations within 30 days beginning with the date of the notification by the NHSCB, and

(bb) oral representations to the NHSCB with regard to that action, provided C notifies the NHSCB of C's wish to do so within 30 days beginning with the date of the notification by the NHSCB and C (or a representative of C) attends the hearing that the NHSCB arranges for the purpose of hearing those representations, which the NHSCB 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 the NHSCB will not remove C from the relevant 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 the NHSCB, and

(ii) within that period, C notifies the NHSCB 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 the NHSCB 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 the NHSCB has decided to remove or contingently remove C from a pharmaceutical list—

(i) C's rights of appeal in relation to that decision under section 158 of the 2006 Act [M79] (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 [M80], the application notice must be sent to the Tribunal if an appeal is to be brought; and

(c) if the NHSCB has decided to contingently remove C, the arrangements for review of the conditions under section 157(1) of the 2006 Act [M81] (review of decisions).

(4) If the NHSCB has decided to remove or contingently remove C from a 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 the NHSCB (if the First-tier Tribunal takes a different decision to the decision taken by the NHSCB, that decision takes effect upon the taking of that decision, unless the First-tier Tribunal directs otherwise).

Marginal Citations

M77 Section 151 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 79. Section 152(3) has been amended by the 2012 Act, Schedule 4, paragraph 80.

M78 Section 152(1) has been amended by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 80.

M79 Section 158 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 84, and by S.I. 2010/22.

M80 S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.

M81 Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.

Procedure for suspensions in fitness cases

83.—(1) Where the NHSCB is considering suspending an NHS chemist (C) from a pharmaceutical list under section 154(1) or section 155(2) of the 2006 Act [M82] (which relate to suspension and suspension pending appeal), before reaching its decision, it must—

(a) notify C of the action the NHSCB is considering taking and its grounds for considering taking that action; and

(b) as part of that notification—

(i) where the NHSCB 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 the NHSCB with regard to the possible suspension on a specified day, provided C notifies the NHSCB 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 the NHSCB that C wishes to make oral representations to the NHSCB on the specified day, thereafter the NHSCB may suspend C with immediate effect; or

(b) C does advise the NHSCB that C wishes to make oral representations to the NHSCB on the specified day, the NHSCB must not suspend C until after the oral hearing, but may then do so with immediate effect.

(3) Once the NHSCB 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 the NHSCB has decided to suspend C under section 154(1), the arrangements for review of the suspension under section 157(1) of the 2006 Act [M83] (review of decisions).

Marginal Citations

M82 Section 154 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 81, and by S.I. 2010/22. Section 155 has been amended by the 2012 Act, Schedule 4, paragraph 82, and by S.I. 2010/22.

M83 Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.

Procedure for reviewing some suspensions and contingent removal conditions

84.—(1) This paragraph applies where the NHSCB—

(a) is required to review a contingent removal or a suspension under section 157(1) of the 2006 Act (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, the NHSCB must afford the NHS chemist who has been contingently removed or is suspended (C) the opportunity to make—

(a) written representations to the NHSCB, provided C notifies the NHSCB with those representations within 30 days beginning with the date of the notification by the NHSCB; and

(b) oral representations to the NHSCB with regard to that action, provided—

(i) C notifies the NHSCB of C's wish to do so within 30 days beginning with the date of the notification by the NHSCB, and

(ii) C (or a representative of C) attends the hearing that the NHSCB arranges for the purpose of hearing those representations, which the NHSCB must give C reasonable notice of.

(3) Once the NHSCB has taken its decision under section 157(3) of the 2006 Act, 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 [M84] (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 [M85], 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.

Marginal Citations

M84 Section 158 has been amended by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 84, and by S.I. 2010/22.

M85 *See* rule 19 of those Rules.

General power to revoke suspensions in appropriate circumstances

85.—(1) If an NHS chemist is suspended from a pharmaceutical list, in addition to the NHSCB's powers to terminate suspensions under section 157(3)(b) of the 2006 Act [M86] (review of decisions) on a review, the NHSCB may terminate the suspension at any time, in appropriate circumstances.

(2) If the NHSCB terminates a suspension under paragraph (1), it must notify the NHS chemist that it has done so.

Marginal Citations

M86 Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.

Internal handling of fitness information by the NHSCB or an agent of the NHSCB

86.—(1) The NHSCB must ensure that the records it maintains relating to the fitness of NHS chemists and LPS chemists to be NHS chemists or LPS chemists are only accessible to persons whom the NHSCB employs in circumstances where the NHSCB is satisfied that they—

(a) should have access to the information on a need-to-know basis; and

(b) fully understand the confidential nature of the information and the purposes for which they are being permitted access to it.

(2) Where functions of the NHSCB relating to the fitness of NHS chemists or LPS chemists are carried out on behalf of the NHSCB by an agent of the NHSCB—

(a) the reference in paragraph (1) to persons whom the NHSCB employs includes reference to persons whom the agent employs to perform functions under the agency arrangement (about whom the agent must be satisfied on the NHSCB's behalf as mentioned in sub-paragraphs (a) and (b) of paragraph (1)); and

(b) the NHSCB must ensure that the terms of the agency arrangement are such that the information the agent holds relating to the fitness of NHS chemists and LPS chemists to be NHS chemists or LPS chemists as a consequence of the arrangement is not further processed by the agent in a manner which is incompatible with the confidential nature of the information and the purposes for which it has been obtained.

Review periods for national disqualifications

87.—(1) Section 159(8)(a) of the 2006 Act [M87] (national disqualification) is to have effect as if the reference to "two years" were a reference to "five years", if the First-tier Tribunal determines, when it imposes the national disqualification, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a review being successful if held within five years.

(2) Section 159(8)(b) of the 2006 Act is to have effect as if the reference to "one year" were a reference to "three years", if the First-tier Tribunal determines, on a review, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a further review being successful if held within three years.

(3) Section 159(8) of the 2006 Act is to have effect as if the references to "two years" and "one year"—

(a) in a case where—

(i) a national disqualification has been imposed as a consequence of a criminal conviction, and

(ii) on appeal, the conviction has been quashed or the penalty imposed by the court has been reduced; or

(b) in a case where—

(i) a national disqualification has been imposed as a consequence of an adverse decision of a licensing body, and

(ii) on appeal, the decision of the licensing body has been quashed or the penalty imposed by it has been reduced,

were a reference to a period equal to the period between the date on which that appeal was determined and the date on which the national disqualification was imposed or last reviewed.

Marginal Citations

M87 Section 159 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 85, and by S.I. 2010/22.

Wider notifications of fitness decisions

88.—(1) Where the NHSCB—

(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 a pharmaceutical list by virtue of section 151 or 152(3)(b) of the 2006 Act [M88] (which relate to disqualification of practitioners and contingent removal);

(e) contingently removes P from a 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 [M89] (which relate to suspension and suspension pending appeal),

the NHSCB 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 the NHSCB, any other primary care organisation that—

(i) has included P, or a body corporate of which P is a director or superintendent, in a relevant list, or

(ii) is considering including P, or a body corporate of which P is a director or superintendent, in a relevant list;

(c) the Scottish Ministers;

(d) the Welsh Ministers;

(e) the Northern Ireland Executive;

(f) the General Pharmaceutical Council;

(g) any Local Pharmaceutical Committee for the area of the relevant HWB (including any Local Pharmaceutical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);

(h) in a case that is or may be a fraud case, the NHS BSA; and

(i) 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)(i) if Q establishes to the satisfaction of the NHSCB (or before the appointed day the relevant Primary Care Trust) 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 the NHSCB who is in a position to respond to further enquiries.

(5) The NHSCB 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), the NHSCB notifies that person with further documentation (including documentation in an electronic form) that relates to P, the NHSCB must also notify P with—

(a) that documentation; and

(b) details of the person to whom it has been sent.

(7) If the NHSCB 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 (i).

(8) If—

(a) having notified a person under paragraph (1) of a suspension or a condition (including a condition imposed on contingent removal); or

(b) after a Primary Care Trust notified a person under regulation 88(1) of the 2012 Regulations (wider notifications of fitness decisions) of a suspension or a condition (including a condition imposed on contingent removal),

the NHSCB terminates the suspension or removes the condition, the NHSCB must notify that person with the notification given to P of the decision to terminate the suspension or remove the condition.

Marginal Citations

M88 Section 151 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 79. Section 152 has been amended by the 2012 Act, Schedule 4, paragraph 80.

M89 Section 154 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 81, and by S.I. 2010/22. Section 155 has been amended by the 2012 Act, Schedule 4, paragraph 82, and by S.I. 2010/22.

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 [M90] (remuneration for persons providing pharmaceutical services), but not of the remuneration of dispensing doctors;

(b) the determinations of remuneration made by the NHSCB, acting as a determining authority, pursuant to regulation 91(1); and

(c) 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 or the NHSCB 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 (whether the amounts are determined by the Secretary of State or the NHSCB), and—

(a) claims by NHS chemists for payments under the Drug Tariff must be made in accordance with those arrangements;

(b) payments under the Drug Tariff must be made—

(i) by the NHSCB (or a person exercising its functions), and

(ii) in accordance with those arrangements, subject as appropriate to any deduction that may or must be made in accordance either with those arrangements or with any provision of, or made under, the 2006 Act (including the Drug Tariff); and

(c) the arrangements may include arrangements for auditing, monitoring or analysing the making of payments.

Marginal Citations

M90 Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), **section 141(1)**, and Schedule 15, Part 4, and by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 89.

Data to be provided to assist Drug Tariff determinations

90.—(1) The data which the Secretary of State and the NHSCB may take into account prior to making a determination under section 164 of the 2006 Act [M91] (remuneration for persons providing pharmaceutical services) may include information obtained pursuant to paragraph (3) by—

(a) the Secretary of State or a person appointed by the Secretary of State under this paragraph; or

(b) the NHSCB or a person appointed by the NHSCB under this paragraph,

and a person appointed under this paragraph is referred to in this regulation as "a nominee".

(2) Before appointing a person to be a nominee, the Secretary of State or the NHSCB must consult, as they consider 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—

(a) the Secretary of State or a nominee of the Secretary of State 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; or

(b) the NHSCB or a nominee of the NHSCB with information (for example invoices) which the NHSCB considers to be relevant to the matters the NHSCB may take into account prior to making a determination under section 164 of the 2006 Act.

(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 of the Secretary of State under paragraph (3)(a) to be obtained; and

(b) information processed or handled by a nominee of the Secretary of State under paragraph (4) to be processed or handled,

in such manner as the Secretary of State may reasonably specify.

(6) The NHSCB may require—

(a) information obtained by a nominee of the NHSCB under paragraph (3)(b) to be obtained; and

(b) information processed or handled by a nominee of the NHSCB under paragraph (4) to be processed or handled,

in such manner as the NHSCB may reasonably specify.

(7) The Secretary of State and the NHSCB may share with each other information which they or their nominees have obtained under this regulation (for purposes related to the determination of pharmaceutical remuneration).

Marginal Citations

M91 Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), **section 141(1)**, and Schedule 15, Part 4, and by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 89..

Remuneration of NHS chemists: instruments of appointment of the NHSCB

91.—(1) The NHSCB is appointed by the Secretary of State as a determining authority in relation to the following remuneration to be paid to NHS chemists for providing pharmaceutical services—

(a) the remuneration listed in Schedule 8 (which has effect); and

(b) remuneration in respect of advanced services.

(2) Before making determinations as provided for by paragraph (1), the NHSCB must consult—

(a) the Secretary of State in such manner as the Secretary of State may reasonably request; and

(b) a body appearing to it to be representative of persons to whose remuneration the determination would relate.

(3) In making determinations as provided for by paragraph (1), the NHSCB must—

(a) co-operate with the Secretary of State over seeking to ensure that resource use in respect of pharmaceutical remuneration is compatible with any objectives agreed between the Secretary of State and the NHSCB in respect of the total resource to be available for pharmaceutical remuneration;

(b) ensure that those determinations are compatible with the Secretary of State's arrangements for the claiming and making of payments, and making deductions from payments, that are included in the Drug Tariff (which may relate to pharmaceutical remuneration determined by the NHSCB as well as to pharmaceutical remuneration determined by the Secretary of State);

(c) ensure that those determinations are signed by a member of the senior management of the NHSCB, and for these purposes a person is a member of the senior management of the NHSCB if that person plays a significant role in—

(i) the making of decisions about how the whole or a substantial part of its activities are to be managed or organised, or

(ii) the actual managing or organising of the whole or a substantial part of those activities; and

(d) act in a manner that ensures that any amendments which, as a consequence, need to be made to the Drug Tariff, are made in a manner that is compatible with the Secretary of State's arrangements for the publication of the Drug Tariff (or the arrangements of a person publishing the Drug Tariff on the Secretary of State's behalf).

(4) The Secretary of State must, before making a determination which could by virtue of paragraph (1) be made by the NHSCB, notify the NHSCB of the Secretary of State's intention to make the determination.

(5) Before determining the remuneration payable by it in respect of an enhanced service, the NHSCB must consult any Local Pharmaceutical Committee for the area in which the service is to be provided.

(6) Where the NHSCB makes a determination of the remuneration payable in respect of an enhanced service, it must publish the determination in such manner as it thinks appropriate for bringing it to the attention of persons included in the relevant pharmaceutical lists.

(7) The arrangements for claiming and paying any remuneration in respect of an enhanced service thus determined must allow for the making for any deduction that may or must be made from that remuneration by virtue of any provision of, or made under, the 2006 Act (for example, a deduction that may or must be made by virtue of regulations 70 to 72).

Dispensing doctor remuneration

92.—(1) As regards the pharmaceutical services provided by dispensing doctors—

(a) if a drug, appliance or related additional service is provided by a dispensing doctor in circumstances where the dispensing doctor could provide it under pharmaceutical services or related arrangements for the provision of primary medical services, the remuneration in respect of providing that drug, appliance or service is to be the remuneration payable in respect of that drug, appliance or service under the related arrangements; and

(b) in all other cases, the remuneration payable to a dispensing doctor in respect of those pharmaceutical 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 [M92] (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 NHSCB) in such manner as the NHS BSA determines.

(3) The making of payments by the NHSCB 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 NHSCB 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, that the NHSCB 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,

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)).

Marginal Citations

M92 Section 87 has been amended by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 33.

The taking effect of determinations

93.—(1) A determination of remuneration under section 164 of the Act [M93] (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.

Marginal Citations

M93 Section 164 has been amended by the Health and Social Care Act 2008 (c. 14), **section 141(1)**, and Schedule 15, Part 4, and by the Health and Social Care Act 2012, Schedule 4, paragraph 89.

Overpayments

94.—(1) Where the NHSCB considers that a payment has been made to an NHS chemist pursuant to the arrangements mentioned in regulation 89(5) or 91(7) in circumstances where it was not due, it must (except to the extent that the Secretary of State, on the application of the NHSCB, directs otherwise) draw the overpayment to the attention of the NHS chemist, and—

(a) where the NHS chemist admits the overpayment; or

(b) if the NHS chemist does not admit there has been an overpayment, where the final outcome of an investigation or appeal is that there has been an overpayment,

the amount overpaid shall be recoverable by deduction from other remuneration payable to the NHS chemist in respect of pharmaceutical services or as a civil debt.

(2) Where the NHSCB 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 NHSCB, 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 the NHSCB 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 [M94] (repayment of charges); or

(b) on an equivalent form issued in Scotland, Wales or Northern Ireland.

Marginal Citations

M94 Regulation 10 has been amended by S.I. 2000/3189, 2002/2352 and 2004/696.

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 NHSCB, 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 NHSCB 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 NHSCB 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 NHSCB.

(2) Where the NHSCB establishes that an order about which it has been notified in accordance with paragraph (1) was not a genuine order, the NHSCB must make such payment as is due to the NHS chemist under the Drug Tariff.

(3) In this regulation, "order" includes a purported order.

Payments to suspended chemists

98.—(1) If an NHS chemist (C) is suspended from a pharmaceutical list, the NHSCB 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 NHSCB, 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 the NHSCB—

(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

Local Pharmaceutical Services

Designation of areas, premises or descriptions of premises

99.—(1) The NHSCB may designate relevant areas, premises or descriptions of premises for the purposes of paragraph 2 of Schedule 12 to the 2006 Act [M95] (LPS schemes – designation of priority neighbourhoods or premises).

(2) Any designation made is to be of an area in which, or premises or descriptions of premises at which, local pharmaceutical services are to be provided under a proposed or approved LPS scheme (referred to in this regulation as the "relevant scheme"), but a designation is not necessary in respect of every such scheme.

(3) Any designation made must—

(a) be made in writing and be dated;

(b) include a map showing the location of the area, premises or description of premises designated; and

(c) include an outline of the services to be provided under the relevant scheme.

(4) The NHSCB must give notice of the designation to—

(a) the HWB (HWB1) for the area to which the designation relates, or (as the case may be) for the area in which the premises or descriptions of premises are situated;

(b) any Local Pharmaceutical Committee whose area includes the premises, descriptions of premises, or all or part of the area to which the designation relates;

(c) any Local Medical Committee whose area includes the premises, descriptions of premises, or all or part of the area to which the designation relates;

(d) any NHS chemist whose listed chemist premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the designation;

(e) any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list—

(i) for the area of HWB1, or

(ii) for the area of a neighbouring HWB, if their interests are likely, in the opinion of the NHSCB, to be affected by the designation,

but who is not (yet) included;

(f) any LPS chemist whose chemist premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the designation;

(g) any dispensing doctor whose listed dispensing premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the designation; and

(h) any Local Healthwatch organisation for the area of HWB1.

(5) A designation under this regulation, and any designation by a Primary Care Trust under regulation 4 of the 2006 Regulations [M96] (designation of priority neighbourhoods or premises), may be varied by the NHSCB where—

(a) if it relates to an area, the LP services to be provided under the relevant scheme are to be provided in or from part only of that area;

(b) if it relates to premises, the LP services to be provided under the relevant scheme are to be provided at or from part only of those premises;

(c) if it relates to a description of premises, the LP services to be provided under the relevant scheme are to be provided at or from parts only of the premises described.

(6) Where a designation is varied under paragraph (5), that designation must—

(a) satisfy the requirements of paragraph (3) (the date of the designation becoming the date on which it is varied); and

(b) be notified in accordance with paragraph (4).

(7) The NHSCB must—

(a) publish—

(i) all its (current) designations, including designations it has varied, under this regulation, and

(ii) all the (current) designations of Primary Care Trusts, including their varied designations, under regulation 4 of the 2006 Regulations; and

(b) ensure that each HWB has access to those designations which is sufficient to enable the HWB to carry out its functions under these Regulations.

Marginal Citations

M95 Paragraph 2 has been amended by: the Health Act 2009 (c. 21), **section 29(12)**; and the Health and Social Care Act 2012 (c. 7), **section 207(12)**, and Schedule 4, paragraph 93(3).

M96 Prior to its revocation, regulation 4 was amended by S.I. 2009/599 and 2010/914.

Review of designations

100.—(1) The NHSCB must regularly review—

(a) all its designations, including designations it has varied, under regulation 99; and

(b) all the designations of Primary Care Trusts, including their varied designations, under regulation 4 of the 2006 Regulations (designation of priority neighbourhoods or premises),

and in any event must review each of those designations before the end of 6 months beginning with either the date of the designation or (if later) the date it concluded its last review of the designation.

(2) When conducting a review under paragraph (1), the NHSCB must take into account any responses it or a Primary Care Trust received when the designation was last notified.

(3) In a case where a designation is not varied or cancelled as a result of a review, the NHSCB must give notice of the outcome of the review to the persons who would have been notified under regulation 99(6)(b) if the designation had been varied.

Cancellation of designations

101.—(1) The NHSCB may at any time cancel—

(a) any of its designations, including designations it has varied, under regulation 99; and

(b) any of the designations of Primary Care Trusts, including their varied designations, under regulation 4 of the 2006 Regulations (designation of priority neighbourhoods or premises).

(2) The NHSCB must cancel a designation—

(a) if required to do so by a direction given by the Secretary of State under section 168A of the 2006 Act [M97] (exercise of functions);

(b) within 12 months of the date of the decision to make the designation, disregarding any subsequent decision to vary the designation, if in the case of designation for a proposed LPS scheme, no proposal to enter into an LPS scheme has been received by the NHSCB (or before the appointed day by a Primary Care Trust) for approval;

(c) if, in the case of a designation for a proposed LPS scheme, the only (or only remaining) proposal to enter into an LPS scheme that relates to the designation has been refused;

(d) if there has been a significant change to the area in which, or to the premises from which, LP services are to be provided, other than a change which leads to a variation of the designation under regulation 99(5); or

(e) if or when an LPS contractor commences the provision of LP services at the designated location.

(3) The NHSCB must give notice of the cancellation to the persons who would have been notified under regulation 99(6)(b) if the designation had instead been varied.

(4) If a designation has been cancelled under this regulation or regulation 6 of the 2006 Regulations (cancellation of designations by a Primary Care Trust), the NHSCB may only designate the same area, premises or description of premises under regulation 99 within 6 months of that cancellation if the reason for the cancellation was the refusal by the NHSCB or a Primary Care Trust of a proposal to enter into an LPS scheme.

Marginal Citations

M97 Section 168A was inserted by the Health and Social Care Act 2012 (c. 7), **section 49(4)**.

Terms of service for LPS schemes: general

102.—(1) Each LPS scheme must specify—

(a) the LP services to be provided under the scheme, which must include the dispensing of drugs; and

(b) the address of the premises at or from which those services are to be provided ("the scheme premises").

(2) If the provider of services under an LPS scheme is a health service body, the scheme must state that it is an NHS contract.

(3) Each LPS scheme must contain the terms, or terms which make provision that has the same effect as the terms, set out in Schedule 7.

LPS schemes: health service body status

103.—(1) Subject to paragraph (3), an LPS contractor (C) is to be treated as a health service body for the purposes of section 9 of the 2006 Act [M98] (NHS contracts) unless—

(a) as regards an LPS scheme established by a Primary Care Trust before the appointed day, either—

(i) before the LPS scheme was entered into, the proposed provider (or providers) under the scheme objected to that by a notice in writing to the Primary Care Trust, or

(ii) before the appointed day, the LPS scheme was varied under regulation 10(4) of the 2006 Regulations (health service body status), as a consequence of which the scheme ceased to be treated as an NHS contract; or

(b) before the LPS scheme is entered into, the proposed provider (or providers) under the scheme object to that by a notice in writing to the NHSCB.

(2) Where C is to be treated as a health service body for the purposes of section 9 of the 2006 Act, subject to paragraph (3), any variation of the LPS scheme which changes a party to the scheme does not affect the health service body status of the provider (or providers) of goods and services under the scheme.

(3) C may at any time request a variation of an LPS scheme so as to provide that the scheme is to become, or is to cease to be, an NHS contract, and if C does so—

(a) if—

(i) C is the only other party to the scheme, the NHSCB must agree to the variation, or

(ii) if all the parties to the scheme other than the NHSCB are together making the request, the NHSCB must agree to the variation; and

(b) the procedure in paragraph 26 of Schedule 7 is to apply.

(4) Where, pursuant to paragraph (3), the NHSCB agrees to a variation of an LPS scheme, C is (as the case may be)—

(a) to be treated as a health service body; or

(b) subject to paragraph (6), to cease to be treated as a health service body,

for the purposes of section 9 of the 2006 Act from the date on which the variation takes effect.

(5) Subject to paragraph (6), a person who has been both a provider under an LPS scheme and treated as a health service body for the purposes of that scheme is to cease to be treated as a health service body for the purposes of that scheme where—

(a) the scheme is varied so that person is no longer a provider under that scheme; or

(b) the scheme, or the agreement that is part of the scheme to which that person is a party, is terminated.

(6) Where a person ceases to be treated as a health service body pursuant to—

(a) paragraph (4), C is to be bound (as is the NHSCB) by any adjudication which was referred to an adjudicator pursuant to paragraph 22 of Schedule 7 before the variation took effect; or

(b) paragraph (5)(b), C is to continue to be treated as a health service body for the purposes of the resolution of any dispute that falls to be resolved in accordance with the terms of the terminated agreement or scheme notwithstanding its termination.

Marginal Citations

M98 Section 9 has been amended by the Health and Social Care Act 2008 (c. 14), **Schedule 5**, paragraph 82, and by the Health and Social Care Act 2012, Schedule 4, paragraph 6, Schedule 7, paragraph 18, Schedule 14, paragraph 4, Schedule 17, paragraph 10, Schedule 19, paragraph 9, and Schedule 21, paragraph 6.

Development of LPS schemes

104.—(1) The NHSCB may make payments of financial assistance in respect of the development of LPS schemes.

(2) If a proposal for an LPS scheme is submitted to the NHSCB, it must consider whether or not to select that proposal for development, unless the proposal is vexatious or frivolous.

Persons permitted to be parties to LPS schemes: fitness criteria

105.—(1) The NHSCB may only be a party to an LPS scheme with the following—

(a) an individual who does not fall within paragraph (2);

(b) a partnership (other than a limited liability partnership) where each partner does not fall within paragraph (2);

(c) a body corporate where—

(i) the body corporate, and

(ii) any director, chief executive, superintendent or company secretary of the body corporate,

do not fall within paragraph (2).

(2) A person (P) falls within this paragraph if—

(a) P is the subject of a national disqualification;

(b) Subject to paragraph (3), P is disqualified or suspended (other than by an interim suspension order or a direction pending investigation) from practising by a licensing or regulatory body anywhere in the world;

(c) P has, within 5 years of the date on which either P would be due to start participating in the LPS scheme, or (if earlier) commits to participating in the scheme, been refused admission to a relevant list for a reason that amounts to inefficiency, fraud or unsuitability (as understood by reference to the conditions in section 151(2) to (4) of the 2006 Act) (disqualification of practitioners), unless P has subsequently been included in a relevant list;

(d) P has been convicted in the United Kingdom of murder;

(e) P has been convicted in the United Kingdom of a criminal offence other than murder—

(i) which was committed on or after 1st April 2006, and

(ii) for which P has been sentenced to a term of imprisonment of over 6 months;

(f) subject to paragraph (4), P has elsewhere than the United Kingdom been convicted of an offence which, if committed in England or Wales—

(i) would constitute murder, or

(ii) would constitute a criminal offence, and

(aa) which was committed on or after 1st April 2006, and

(bb) for which P has been sentenced to a term of imprisonment of over 6 months;

(g) P has been convicted of an offence referred to in—

(i) Schedule 1 to the Children and Young Persons Act 1933 [M99] (offences against children and young persons with respect to which special provisions of the Act apply), or

(ii) Schedule 1 to the Criminal Procedure (Scotland) Act 1995 [M100] (offences against children under the age of 17 years to which special provisions apply),

which was committed on or after 1st April 2006;

(h) P—

(i) has been adjudged bankrupt and has not been discharged from the bankruptcy,

(ii) is a person in relation to whom a moratorium period under a debt relief order under Part 7A of the Insolvency Act 1986 [M101] (debt relief orders) applies,

(iii) is the subject of a bankruptcy restrictions order, an interim bankruptcy restrictions order, a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4A or 4ZB to the Insolvency Act 1986 [M102] or Schedule 2A of the Insolvency (Northern Ireland) Order 1989 [M103] (which relate to bankruptcy and debt relief restrictions orders and undertakings),

(iv) if P is a body corporate, has been wound up under Part 4 of the Insolvency Act 1986;

(v) has made a composition or arrangement with, or granted a trust deed for, P's creditors and P has not been discharged in respect of it;

(i) in respect of P there is—

(i) an administrator, administrative receiver or receiver appointed, or

(ii) an administration order under Schedule B1 to the Insolvency Act 1986 [M104] (administration);

(j) P has, within 5 years of the date on which either P would be due to start participating in the LPS scheme or (if earlier) commits to participating in the scheme, been removed—

(i) from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners, the Charity Commission, the Charity Commission for Northern Ireland or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity—

(aa) for which the person was responsible or to which the person was privy, or

(bb) which the person by their conduct contributed to or facilitated, or

(ii) under—

(aa) section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990 [M105] (powers of Court of Session to deal with management of charities), or

(bb) section 34(5)(e) or (ea) of the Charities and Trustee Investment (Scotland) Act 2005 [M106] (powers of the Court of Session),

from being concerned with the management or control of any body;

(k) P has, within 5 years of the date on which either P would be due to start participating in the LPS scheme or (if earlier) commits to participating in the scheme, been subject to—

(i) a disqualification order or disqualification undertaking under the Company Directors Disqualification Act 1986 [M107] or the Company Directors Disqualification (Northern Ireland) Order 2002 [M108], or

(ii) an order made under section 429(2) of the Insolvency Act 1986 [M109] (disabilities on revocation of a county court administration order); or

(l) P has, in the case of an individual, refused to comply with a request from the NHSCB for P to be medically examined on the grounds that the NHSCB is concerned that P is incapable of adequately providing services under the scheme.

(3) A person does not fall within paragraph (2)(b) if the NHSCB is satisfied that the disqualification or suspension imposed by a licensing or regulatory body outside the United Kingdom does not make P unsuitable to be—

(a) a party to an LPS scheme; or

(b) in the case of an LPS scheme made with a body corporate, a director, chief executive, superintendent or company secretary of a party to an LPS scheme.

(4) A person does not fall within paragraph (2)(f) where the NHSCB is satisfied that the conviction does not make P unsuitable to be—

(a) a party to an LPS scheme; or

(b) in the case of an LPS scheme with a body corporate, a director, chief executive, superintendent or company secretary of a party to an LPS scheme.

Marginal Citations

M99 1933 c. 12. Schedule 1 has been amended by: the Sexual Offences Act 1956 (c. 69), **Schedule 4**; the Criminal Justice Act 1988 (c. 33), **Schedule 15**, paragraph 8, and Schedule 16; the Sexual Offences Act 2003 (c. 42), **Schedule 6**, paragraph 7; the Domestic Violence, Crime and Victims Act 2004 (c. 28), **Schedule 10**, paragraph 2; the Coroners and Justice Act 2009 (c. 25), **Schedule 21**, paragraph 53; and the Protection of Freedoms Act 2012 (c. 9), **Schedule 9**, paragraph 136.

M100 1995 c. 46.

M101 1986 c. 45; Part 7A was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), **Schedule 17**.

M102 Schedule 4A was inserted by Schedule 20 to the Enterprise Act 2002 (c.40). Schedule 4ZB was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), **Schedule 19**.

M103 S.I. 1989/2405 (N.I. 19); Schedule 2A was inserted by S.I. 2005/1455 (N.I. 10).

M104 Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), **Schedule 16**.

M105 1990 c.40; section 7 was repealed by the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), **Schedule 4**, paragraph 7(b).

M106 2005 asp 10; section 34(5) has been amended by the section the Public Services Reform (Scotland) Act 2010 (asp 8), **section 122**.

M107 1986 c.46.

M108 S.I. 2002/3150 (N.I. 4); relevant amendments were made by S.I. 2005/1454 (N.I. 9).

M109 Section 429(2) was amended by the Enterprise Act 2002 (c.40), **Schedule 23**, paragraph 15.

LPS proposals: fitness information to be supplied

106.—(1) A person (P) proposing to become a party to an LPS scheme with the NHSCB must supply to the NHSCB, with their proposal, the information listed in paragraph (2) about the following relevant persons—

(a) if P is an individual, about P;

(b) if P a partnership, about each partner;

(c) if P is a body corporate, about—

(i) the body corporate, and

(ii) any director, chief executive, superintendent or company secretary of the body corporate.

(2) That information is whether a relevant person (R)—

(a) has any criminal convictions in the United Kingdom;

(b) has accepted a police caution in the United Kingdom;

(c) has been convicted elsewhere than in the United Kingdom of an offence which would, if committed in England or Wales, constitute a criminal offence;

(d) has been subject to an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995 [M110] (admonition and absolute discharge) discharging R absolutely;

(e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995 [M111] (fixed penalty: conditional offer by procurator fiscal);

(f) has agreed to pay a penalty under section 115A of the Social Security Administration Act 1992 [M112] (penalty as alternative to prosecution);

(g) is the subject of any proceedings which might lead to a conviction and which have not yet been notified to the NHSCB;

(h) has been subject to any investigation into R's professional conduct by a licensing or regulatory body, the outcome of which was adverse;

(i) is, to R's knowledge, the subject of an investigation into R's professional conduct by a licensing or regulatory body;

(j) is, to R's knowledge, or where the outcome was adverse has been, the subject of an investigation into R's professional conduct in respect of any current or previous employment;

(k) is, to R's knowledge, the subject of an investigation by another primary care organisation, which might lead to removal from a relevant list;

(l) is, to R's knowledge, or where the outcome was adverse has been, the subject of an investigation by the NHS BSA in relation to fraud;

(m) on fitness grounds—

(i) has had an application for inclusion in a relevant list refused,

(ii) has been conditionally included in a relevant list,

(iii) has been removed or contingently removed from a relevant list,

(iv) is suspended from a relevant list,

and if so, the name of the relevant primary care organisation; or

(n) is or ever has been the subject of a national disqualification,

and if so, P must give details of the relevant investigation or proceedings, including the nature of the investigation or proceedings, where and when (if known) they took place, and any outcome.

(3) If information mentioned in paragraph (2) has already been provided to the NHSCB on a previous occasion pursuant to regulations under Part 7 of the 2006 Act, P need not provide that information again to the NHSCB, but if P is relying on this paragraph, P must, when supplying their proposal—

(a) confirm to the NHSCB that the NHSCB already has all the information required under paragraph (2); or

(b) if there is any missing information required under that paragraph—

(i) confirm to the NHSCB what information the NHSCB already has, and

(ii) provide the missing information.

(4) If the NHSCB determines that P may not become a party to the LPS scheme by virtue of regulation 105, the NHSCB must notify P of its determination, the reasons for its determination, and of P's right of appeal under paragraph (5).

(5) P may appeal against a determination mentioned in paragraph (4) to the First-Tier Tribunal, provided P does so within 30 days of the date on which P was notified of the determination.

Marginal Citations

M110 1995 c. 46; section 246(2) and (3) have been amended by the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), **Schedule 2**, paragraph 26.

M111 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), **Schedule 17**, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), **Schedule 7**, paragraph 16; the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), **section 50(1)**; and the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), **section 70(3)**.

M112 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), **section 15**, and amended by the Social Security Fraud Act 2001 (c. 11) ("the 2001 Act"), section 14. The amendments made by the 2001 Act are to be repealed by, and other amendments to section 115A are to be made by, the Welfare Reform Act 2012 (c. 5), **sections 113 to 115**, and Schedule 14, Part 1.

Notification of proposals

107. If the NHSCB decides to select a proposal for an LPS scheme for development, it must give notice of that decision and provide such details of the proposed LPS scheme as it considers appropriate to—

(a) the HWB (HWB1) for the area in which are situated the premises at or from which local pharmaceutical services are to be provided under the proposal;

(b) any Local Pharmaceutical Committee for the area in which are situated the premises at or from which local pharmaceutical services are to be provided under the proposal;

(c) any Local Medical Committee for the area in which are situated the premises at or from which local pharmaceutical services are to be provided under the proposal;

(d) any NHS chemist whose listed chemist premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the proposal;

(e) any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list—

(i) for the area of HWB1, or

(ii) for the area of a neighbouring HWB, if their interests are likely, in the opinion of the NHSCB, to be affected by the proposal,

but who is not (yet) included;

(f) any LPS chemist whose scheme premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the proposal;

(g) any dispensing doctor whose listed dispensing premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the proposal; and

(h) any Local Healthwatch organisation for the area of HWB1.

Right of return to pharmaceutical lists: LPS contractors

108.—(1) Before the NHSCB becomes a party to an LPS scheme with any person, it must determine whether that person is to be given a right of return to a pharmaceutical list if that person makes an application under regulation 28 and satisfies the conditions for a grant of an application under that regulation.

(2) If an LPS scheme is varied so as to—

(a) relocate the provision of local pharmaceutical services under the scheme to different scheme premises; or

(b) change a party (other than the NHSCB) to the scheme,

the NHSCB must review any right of return granted under this regulation or regulation 15 of the 2006 Regulations (right of return to pharmaceutical lists) arising under that scheme in order to determine whether or not the right of return is to be varied or rescinded.

(3) If an LPS scheme is varied as mentioned in paragraph (2)(b), the right of return of the person who is no longer a party to the LPS scheme is extinguished (whether or not the right of return is maintained in respect of the new provider under the LPS scheme).

(4) The NHSCB may review any right of return granted under this regulation or regulation 15 of the 2006 Regulations (right of return to pharmaceutical lists) in order to determine whether or not the right of return is to be varied or rescinded—

(a) at any time an LPS scheme is varied other than in order to give effect to an amendment to these Regulations (in addition to those occasions on which it is required to review a right of return under paragraph (2)); or

(b) if asked to do so by an LPS contractor.

(5) The NHSCB must publish the principles by reference to which it makes determinations under this regulation and may amend those principles from time to time.

(6) Where the NHSCB makes, varies or rescinds a determination under this regulation, it must give notice of that decision to—

(a) the HWB (HWB1) for the area in which are situated the scheme premises for the relevant LPS scheme;

(b) any Local Pharmaceutical Committee for the area in which are situated the scheme premises for the relevant LPS scheme;

(c) any Local Medical Committee for the area in which are situated the scheme premises for the relevant LPS scheme;

(d) any NHS chemist whose listed chemist premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the decision;

(e) any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list—

(i) for the area of HWB1, or

(ii) for the area of a neighbouring HWB, if their interests are likely, in the opinion of the NHSCB, to be affected by the decision,

but who is not (yet) included;

(f) any LPS chemist whose scheme premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the decision;

(g) any dispensing doctor whose listed dispensing premises—

(i) are in the area of HWB1, or

(ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the decision; and

(h) any Local Healthwatch organisation for the area of HWB1.

LPS pilot schemes: health service body status

109.—(1) Where a provider (P) of piloted services under an LPS pilot scheme is or has become a health service body for the purposes of section 9 of the 2006 Act (NHS contracts), subject to paragraph (2), any variation of the LPS pilot scheme which changes a party to the scheme does not affect the health service body status of the provider of piloted services under that scheme.

(2) If P is a health service body for the purposes of an LPS pilot scheme, P may at any time request a variation by the NHSCB of the scheme so as to provide that the scheme is to cease to be an NHS contract, and if P does—

(a) the NHSCB must agree to the variation; and

(b) subject to paragraph (4), P is to cease to be a health service body for the purposes of section 9 of the 2006 Act from the date on which the variation takes effect.

(3) Subject to paragraph (4), a person who has been both the provider of piloted services under an LPS pilot scheme and a health service body for the purposes of that scheme is to cease to be a health service body for the purposes of that scheme where the scheme—

(a) is varied so that person is no longer the provider of piloted services under that scheme; or

(b) is terminated.

(4) Where a person ceases to be a health service body for the purposes of an LPS pilot scheme agreement pursuant to—

(a) paragraph (2), P is to be bound (as is the NHSCB) by any adjudication which was referred to an adjudicator in accordance with the terms of the scheme before the variation took effect; or

(b) paragraph (3)(b), C is to continue to be a health service body for the purposes of the resolution of any dispute that falls to be resolved in accordance with the terms of the terminated scheme notwithstanding its termination.

(5) Piloted services and pharmaceutical services must not be provided from the same premises.

LPS pilot schemes: termination

110. On the date (D1) on which an LPS pilot scheme terminates because of a term of that scheme provided for in directions under section 138 of, or paragraph 7(1) of Schedule 11 to, the 2006 Act (which relate to terms of LPS pilot schemes) which requires that the scheme is to terminate—

(a) for a reason that relates to the fitness of P to be a provider of piloted services, P does not have a right of return to a pharmaceutical list; or

(b) either—

(i) because listed chemist premises, other than distance selling premises, of an NHS pharmacist have opened less than a kilometre by the nearest practical route available to the public on foot from the premises specified in the LPS pilot scheme,

(ii) for a reason relating to the requisite amount of items dispensed at those premises during a financial year,

(iii) because the NHSCB (or before it the Primary Care Trust that was party to the scheme) or P has given the other party to the scheme a period of notice of not less than 6 months of their intention to terminate the scheme, or

(iv) because all LPS pilot schemes terminate on that date,

the NHSCB must include those premises, and if P is not already so included P, in the pharmaceutical list for the area of the HWB in which the premises are situated with effect from D1.

Emergencies requiring the flexible provision of local pharmaceutical services

111.—(1) Nothing in these Regulations prevents the NHSCB from making a temporary amendment to an LPS scheme or an LPS pilot scheme which the NHSCB 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 NHSCB may make a temporary variation to an LPS scheme or an LPS pilot scheme, but—

(a) only for a specified period (which must be no longer than the specified period of the emergency given by the Secretary of State), which the NHSCB may extend or curtail in appropriate circumstances; and

(b) the provider under the scheme may revert to their overridden arrangements before the end of the period specified by the NHSCB, on giving the NHSCB 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 extend or curtail the duration of, a temporary amendment under this regulation.

Sharing of information about LPS chemists and their employees with the General Pharmaceutical Council

112. Where the NHSCB has concerns about the fitness of an LPS chemist, or a pharmacist or pharmacy technician employed by an LPS chemist, to provide local pharmaceutical services, it must where appropriate pass on those concerns and any relevant supporting evidence to the General Pharmaceutical Council.

Directions to the First-tier Tribunal relating to local pharmaceutical services

113.—(1) The Secretary of State directs the First-tier Tribunal to exercise the functions of the Secretary of State under the terms of an LPS scheme which—

(a) give effect to paragraphs 21, 22 and 29 of Schedule 7; and

(b) relate to the determination of appeals to the Secretary of State, but only in so far as those functions require a determination by the Secretary of State—

(i) as to whether a person falls within paragraph 29(2) of Schedule 7 during the existence of the scheme, or

(ii) in respect of a decision by the NHSCB under paragraph 29(3) or (4) of Schedule 7.

(2) The Secretary of State directs the First-tier Tribunal to exercise the functions of the Secretary of State under the terms of an LPS pilot scheme that relate to the determination of appeals to the Secretary of State, but only in so far as those functions require a determination by the Secretary of State in respect of the fitness of a provider of piloted services to be a provider of piloted services.

Lists of LPS chemists

114.—(1) In respect of the area of each HWB, the NHSCB must prepare, maintain and publish a list of the LPS chemists (if there are any) who provide local pharmaceutical services at or from premises situated in that area.

(2) The lists must include—

(a) the addresses of the premises at or from which the local pharmaceutical services are provided;

(b) the days on which and times at which, at those premises, the LPS chemist is to provide those services;

(c) a description of the services the LPS chemist is to provide.

(3) The NHSCB must ensure that each HWB has access to the lists of LPS chemists that it holds which is sufficient to enable the HWB to carry out its functions under these Regulations.

PART 14

Miscellaneous

Notification by the NHSCB of changes to its lists

115. Where, in accordance with the provisions of these Regulations, or the 2012 Regulations or the 2005 Regulations as they continue to have effect by virtue of Schedule 9, or the 2006 Act, the NHSCB—

(a) removes a person from a pharmaceutical list, dispensing doctor list or list of LPS chemists; or

(b) removes the listing of premises in relation to a person on a pharmaceutical list or dispensing doctor list,

it must notify the person of the change to its list that has taken place.

Authorised persons to apply for services

116. An application to an NHS chemist for pharmaceutical services, or an application to an LPS chemist for local pharmaceutical services, may be made (other than by the 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 [M113], by a person duly authorised by that authority, or

(ii) in the care of a voluntary organisation, by that organisation or a person duly authorised by them;

(c) on behalf of any adult who is incapable of making such an application or authorising such an application to be made on their behalf, by a relative or the primary carer (who may be an adult or an organisation) of that person; or

(d) on behalf of any other person by a duly authorised person.

Marginal Citations

M113 1989 c. 41.

Functions of the Secretary of State to be exercised by the NHS Litigation Authority

117.—(1) The NHS Litigation Authority must exercise the following functions of the Secretary of State—

(a) the functions relating to receiving and determining any appeal in relation to which Schedule 3 has effect, including all of the functions of the Secretary of State under that Schedule (which include determining whether certain persons have rights of appeal);

(b) the functions relating to being contacted about, and providing, information under—

(i) regulation 33(2),

(ii) regulation 86(2), and

(iii) paragraph 23(1)(b) of Schedule 2;

(c) the function of providing consent under regulation 76(1);

(d) the function of receiving notifications under regulation 88(2)(a);

(e) the functions relating to receiving and determining an appeal under—

(i) paragraph 25(7) to (9) of Schedule 4,

(ii) paragraph 26(9) to (11) of Schedule 4,

(iii) paragraph 15(7) to (9) of Schedule 5, and

(iv) paragraph 16(9) to (11) of Schedule 5;

(f) subject to paragraph (2), the functions under the terms of LPS schemes that give effect to the following provisions—

(i) paragraph 21 of Schedule 7,

(ii) paragraph 22 of Schedule 7, and

(iii) paragraph 23 of Schedule 7;

(g) the functions under the terms of LPS pilot schemes which relate to receiving and determining appeals by providers of piloted services with regard to the determination of premises opening hours;

(h) subject to paragraph (2), the functions under the terms of LPS pilot schemes which relate to dispute resolution; and

(i) the functions relating to—

(i) receiving and determining any appeal which, by virtue of Schedule 9, the Secretary of State is required to determine, and

(ii) dispute resolution which, by virtue of Schedule 9, the Secretary of State is required to perform,

under the 2005 Regulations, the 2012 Regulations or the terms of an LPS scheme, including the incidental functions of the Secretary of State relating to such appeals or dispute resolution (for example, determining whether certain persons have rights of appeal and applying the continuity principles as appropriate).

(2) The NHS Litigation Authority must not, pursuant to paragraph (1)(f) or (h), exercise the Secretary of State's functions that the First-tier Tribunal is required to exercise by virtue of regulation 113.

(3) The NHS Litigation Authority is to exercise the powers of the Secretary of State under section 2 of the 2006 Act (Secretary of State's general power) to do anything that is calculated to facilitate, or is conducive or incidental to, the discharge of any function of the Secretary of State that the NHS Litigation Authority is exercising by virtue of paragraph (1), but only to the extent that it is necessary for the proper exercise of that function.

Proceedings relating to overridden arrangements

118. Where, during an emergency requiring the flexible provision of pharmaceutical services, or a period specified under regulation 29(3), 61(6) or 111(2), arrangements for the provision of pharmaceutical services or local 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 or the specified period 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 or the specified period ends, the reversion to overridden arrangements is to be to the original overridden arrangements as amended as a result of those proceedings.

Transitional provisions

119. The transitional provisions set out in Schedule 9 have effect.

Amendments and revocations

120. The amendments to and revocations of enactments set out in Schedule 10 have effect.

Review of these Regulations

121. Before the end of 31st August 2017, 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
Department of Health — Parliamentary Under-Secretary of State,

Status:
Point in time view as at 01/04/2014.

Changes to legislation:
The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 is up to date with all changes known to be in force on or before 06 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.