

2013 No. 349

NATIONAL HEALTH SERVICE, ENGLAND

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

Made - - - -

14th February 2013

Laid before Parliament -

22nd February 2013

Coming into force - -

1st April 2013



2013 No. 349

NATIONAL HEALTH SERVICE, ENGLAND

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

| | |
|-------------------------------|---------------------------|
| <i>Made</i> - - - - | <i>14th February 2013</i> |
| <i>Laid before Parliament</i> | <i>22nd February 2013</i> |
| <i>Coming into force</i> - - | <i>1st April 2013</i> |

CONTENTS

PART 1

Introductory

1. Citation and commencement
2. Interpretation

PART 2

Pharmaceutical needs assessments

3. Pharmaceutical needs assessments
4. Information to be contained in pharmaceutical needs assessments
5. Date by which the first HWB pharmaceutical needs assessments are to be published
6. Subsequent assessments
7. Temporary extension of Primary Care Trust pharmaceutical needs assessments and access by the NHSCB and HWBs to pharmaceutical needs assessments
8. Consultation on pharmaceutical needs assessments
9. Matters for consideration when making assessments

PART 3

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

10. Pharmaceutical lists and EPS lists
11. Terms of service of NHS chemists: general
12. Routine applications for inclusion in or amendments to a pharmaceutical list
13. Current needs: additional matters to which the NHSCB must have regard
14. Current needs: consequences of additional matters
15. Future needs: additional matters to which the NHSCB must have regard
16. Future needs: consequences of additional matters

17. Improvements or better access to the current service: additional matters to which the NHSCB must have regard
18. Unforeseen benefits applications: additional matters to which the NHSCB must have regard
19. Applications to which regulation 17 or 18 applies: consequences of additional matters
20. Future improvements or better access: additional matters to which the NHSCB must have regard
21. Future improvements or better access: consequences of additional matters
22. Refusal of routine applications that are based on neither a pharmaceutical needs assessment nor unforeseen benefits

PART 4

Excepted applications

23. Applications from NHS chemists in respect of providing directed services
24. Relocations that do not result in significant change to pharmaceutical services provision
25. Distance selling premises applications
26. Change of ownership applications
27. Applications for temporary listings arising out of suspensions
28. Applications from persons exercising a right of return to a pharmaceutical list
29. Temporary arrangements during emergencies or because of circumstances beyond the control of NHS chemists

PART 5

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

30. Refusal: language requirement for some NHS pharmacists
31. Refusal: same or adjacent premises
32. Deferrals arising out of LPS designations

PART 6

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

33. Refusal of applications for inclusion in a pharmaceutical list on fitness grounds
34. Deferral of consideration of applications for inclusion in a pharmaceutical list on fitness grounds
35. Granting applications for inclusion in a pharmaceutical list subject to efficiency conditions and conditions to combat fraud

PART 7

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

36. Determination that an area is a controlled locality
37. Process for determining controlled localities: preliminary matters
38. Process for determining controlled localities: local notification and deferment of routine applications
39. Process of determining controlled localities: formulation of the NHSCB's decision

40. Applications for new pharmacy premises in controlled localities: refusals because of preliminary matters
41. Applications for new pharmacy premises in controlled localities: reserved locations
42. Second and subsequent determinations of reserved location status
43. Determinations of reserved locations: supplemental matters
44. Prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location
45. Appeals against decisions under Part 7

PART 8

Dispensing doctors

46. Dispensing doctor lists
47. Terms of service of dispensing doctors: general
48. Arrangements for the provision of pharmaceutical services by doctors: applications by patients
49. Necessary services for temporary patients
50. Discontinuation of arrangements for the provision of pharmaceutical services by doctors
51. Outline consent and premises approval: applications by doctors
52. Notification of applications for outline consent and premises approval
53. Decisions on outline consent and premises approval applications and the taking effect of grants
54. Premises approval: relocations of practice premises which are not significant before outline consent takes effect
55. Premises approval: relocations of practice premises which are not significant after outline consent has taken effect
56. Taking effect of premises approval where there is no related application for outline consent
57. Gradual introduction of premises approval
58. Temporary provision in cases of relocations or additional premises where premises approval has not taken effect
59. Practice amalgamations
60. Lapse of outline consent and premises approval
61. Temporary arrangements during emergencies or circumstances beyond the control of a dispensing doctor
62. Persons barred from taking part in decision making with regard to applications for outline consent or premises approval
63. Appeals against decisions under Part 8

PART 9

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

64. Distance selling premises: specific conditions
65. Core opening hours conditions
66. Conditions relating to providing directed services
67. Conditions relating to voluntary closure of premises
68. Conditions relating to local resolution of disputes over terms of service

PART 10

Performance related sanctions and market exit

69. Local dispute resolution before serving remedial notices or breach notices
70. Breaches of terms of service: remedial notices
71. Breaches of terms of service: breach notices
72. Payment withholdings: supplementary matters
73. Removal of listings: cases relating to remedial notices and breach notices
74. Removal of listings: cases relating to death, incapacity or cessation of service
75. Voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure
76. Limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing
77. Appeals against decisions under Part 10

PART 11

Enforcement, reviews and appeals relating to fitness matters

78. Extended meaning of “health scheme” in fraud cases
79. Review of decisions to impose fitness conditions originally imposed on grants of applications
80. Removal for breach of fitness conditions imposed under regulation 35 or 79
81. Mandatory removal in suitability cases
82. Fitness cases: procedures for removal or contingent removal from pharmaceutical lists
83. Procedure for suspensions in fitness cases
84. Procedure for reviewing some suspensions and contingent removal conditions
85. General power to revoke suspensions in appropriate circumstances
86. Internal handling of fitness information by the NHSCB or an agent of the NHSCB
87. Review periods for national disqualifications
88. Wider notifications of fitness decisions

PART 12

Remuneration, charges and refunds

89. The Drug Tariff and section 164: general provisions
90. Data to be provided to assist Drug Tariff determinations
91. Remuneration of NHS chemists: instruments of appointment of the NHSCB
92. Dispensing doctor remuneration
93. The taking effect of determinations
94. Overpayments
95. Free supply of drugs, appliances and containers where the drug or appliance is supplied under pharmaceutical services
96. Refunds of prescription charges
97. Reward scheme
98. Payments to suspended chemists

PART 13

Local Pharmaceutical Services

99. Designation of areas, premises or descriptions of premises
100. Review of designations
101. Cancellation of designations
102. Terms of service for LPS schemes: general
103. LPS schemes: health service body status
104. Development of LPS schemes
105. Persons permitted to be parties to LPS schemes: fitness criteria
106. LPS proposals: fitness information to be supplied
107. Notification of proposals
108. Right of return to pharmaceutical lists: LPS contractors
109. LPS pilot schemes: health service body status
110. LPS pilot schemes: termination
111. Emergencies requiring the flexible provision of local pharmaceutical services
112. Sharing of information about LPS chemists and their employees with the General Pharmaceutical Council
113. Directions to the First-tier Tribunal relating to local pharmaceutical services
114. Lists of LPS chemists

PART 14
Miscellaneous

115. Notification by the NHSCB of changes to its lists
116. Authorised persons to apply for services
117. Functions of the Secretary of State to be exercised by the NHS Litigation Authority
118. Proceedings relating to overridden arrangements
119. Transitional provisions
120. Amendments and revocations
121. Review of these Regulations

-
- SCHEDULE 1 — Information to be contained in pharmaceutical needs assessments
- SCHEDULE 2 — Applications in respect of pharmaceutical lists and the procedures to be followed
- PART 1 — Information to be included in routine and excepted applications
 - PART 2 — Preliminary matters
 - PART 3 — Notification of certain applications
 - PART 4 — Determination and deferral of applications
 - PART 5 — Notification, taking effect of decisions and rights of appeal to the Secretary of State
- SCHEDULE 3 — Appeals to the Secretary of State
- PART 1 — Preliminary matters
 - PART 2 — Notification of appeals
 - PART 3 — Determination of appeals
- SCHEDULE 4 — Terms of service of NHS pharmacists
- PART 1 — General
 - PART 2 — Essential services
 - PART 3 — Hours of opening
 - PART 4 — Other terms of service

- SCHEDULE 5 — Terms of service of NHS appliance contractors
- SCHEDULE 6 — Terms of service of dispensing doctors
- SCHEDULE 7 — Mandatory terms for LPS schemes
- SCHEDULE 8 — Service remuneration determined by the NHSCB
- SCHEDULE 9 — Transitional provisions
- SCHEDULE 10 — Amendments and revocations

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7, 8, 126, 128A, 129, 130, 132, 136, 139, 140, 142(b), 143, 145, 148, 150A, 151(5) and (7), 154, 159(9), 160, 161, 162, 163(3), 164, 169(3) and 272(7) and (8) of, and paragraph 1(2)(b) of Schedule 11 and paragraphs 2 and 3 of Schedule 12 to, the National Health Service Act 2006(a).

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(b);

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

“the 2005 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005(d), as in force on 31st August 2012;

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

(a) 2006 c.41. Section 7 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), section 21(1) to (4); section 8 has been amended by the 2012 Act, Schedule 4, paragraph 5; section 126 has been amended by the 2012 Act, sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63; section 128A was inserted by the Health Act 2009 (c.21), section 25, and amended by the 2012 Act, section 206(1); section 129 has been amended by the Health Act 2009, sections 26 and 27 and Schedule 6, by the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66, by the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121, and by S.I. 2010/231; section 130 has been amended by the 2012 Act, section 207(10), and by S.I. 2010/22; section 132 has been amended by the 2012 Act, Schedule 4, paragraph 69, by the Protection of Freedoms Act 2012, Schedule 9, paragraph 122, and by S.I. 2007/289 and 2010/22 and 231; section 136 has been amended by the 2012 Act, section 207(11), and Schedule 4, paragraph 72; section 140 has been amended by the 2012 Act, Schedule 4, paragraph 75; section 148 has been amended by the 2012 Act, Schedule 4, paragraph 77, and by S.I. 2010/22; section 150A was inserted by the Health Act 2009, section 28, and amended by the 2012 Act, Schedule 4, paragraph 78; section 151 has been amended by the 2012 Act, Schedule 4, paragraph 80; section 154 has been amended by the 2012 Act, Schedule 4, paragraph 81, and by S.I. 2010/22; section 160 has been amended by the 2012 Act, Schedule 4, paragraph 86; section 161 has been amended by the 2012 Act, Schedule 4, paragraph 87; section 162 has been amended by the 2012 Act, Schedule 4, paragraph 88; 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 2012 Act, Schedule 4, paragraph 89; section 169 has been amended by S.I. 2010/22; paragraph 2 of Schedule 12 has been amended by the Health Act 2009, section 29(12), and by the 2012 Act, section 207(12), and Schedule 4, paragraph 93(3); paragraph 3 of Schedule 12 has been amended by the Health Act 2009, section 29(13) to (15), and by the 2012 Act, Schedule 4, paragraph 93(4). By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England. *See also* section 275(1) of the 2006 Act, which contains definitions of “prescribed” and “regulations” that are relevant to the powers being exercised.

(b) 1968 c. 67.

(c) 1992/662; these Regulations were revoked by S.I. 2005/641.

(d) 2005/641; these Regulations were revoked by S.I. 2012/1909.

“the 2006 Regulations” means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(a), as in force immediately before the appointed day;

“the 2007 Act” means the Local Government and Public Involvement in Health Act 2007(b);

“the 2012 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2012(c), 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(d) (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(e) (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(f) (definitions applying for the purposes of whole Act).

“arrangements for recharging” means arrangements under paragraph 3 of Schedule 12A to the 2006 Act(g) (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(h) (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) S.I. 2006/552; these Regulations are revoked by Schedule 10.
 - (b) 2007 c. 28.
 - (c) S.I. 2012/1909; these Regulations are revoked by Schedule 10.
 - (d) Section 127 has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 64.
 - (e) 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.
 - (f) 2006 c. 52.
 - (g) Schedule 12A was inserted by the Health and Social Care Act 2012, Schedule 3.
 - (h) 1971 c.80.

- (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 subparagraph (d);

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

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

“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(a);

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

“chiroprapist or podiatrist independent prescriber” means a chiroprapist or podiatrist who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(b) (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiroprapist or podiatrist is qualified to order drugs and appliances as a chiroprapist 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(c) (general interpretation);

(a) S.I. 2000/620.

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

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

“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(a) (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(b);

(a) 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).

(b) S.I. 2004/291.

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

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

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

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

“HWB” means a Health and Wellbeing Board(e);

“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(f) (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(g) (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(h) (persons performing primary medical services);

(a) S.I. 2010/231.

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

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

(d) S.I. 2012/1273.

(e) See section 194 of the Health and Social Care Act 2012 (c. 7).

(f) Section 222(2A) was inserted by the Health and Social Care Act 2012, section 183(2).

(g) 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).

(h) Section 91 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 35.

“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^(a) (national disqualification)—

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

“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^(c);

“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) Section 159 has been amended by S.I. 2010/22.

(b) S.I. 2005/2414.

(c) S.I. 1995/2800; amended by S.I. 2002/2621, 2005/503 and 1445, 2012/1641 and 2013/235.

- (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 (INNMod);
- (c) a British Approved Name (BAN);
- (d) a British Approved Name Modified (BANMod); 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^(a) (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;

(a) S.I. 2012/1916.

“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(a) (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(b) (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(c);

“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(d) (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—

(a) S.I. 2002/253; amended by S.I. 2009/1182.

(b) 1989 c.44; amended by S.I. 2005/848.

(c) S.I. 2004/906. *See* regulation 2(2) of those Regulations.

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

- (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^(a) (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^(b);

“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^(c);

“prescription only medicine” has the same meaning as in the Human Medicines Regulations 2012^(d);

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

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

(b) S.I. 2004/627.

(c) S.I. 2004/629.

(d) See regulation 5(3) of those Regulations.

- (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^(a) (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations^(b) (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^(c) (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^(d) (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);

(a) Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.
 (b) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
 (c) 2010 c. 15.
 (d) 2009 c. 1 (N.I.).

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

“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^(b) (pharmaceutical services in reserved locations), whether or not by virtue of—

(i) paragraph 8 of Schedule 9, or

(a) S.I. 2003/2382.

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

(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(a), as in force on 31st August 2012;

“Scheduled drug” means a drug specified in Schedule 1 or 2 to the Prescription of Drugs Regulations(b) (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(c) (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(d) (establishment and maintenance of register) which relates to chiropractors 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

(a) S.I. 1992/664; these Regulations were revoked by S.I. 2012/1909.

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

(c) 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.

(d) 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).

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

- (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.

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^(a) (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).

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.

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

(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 subparagraph (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^(a) (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;

^(a) 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.

- (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^(a) (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.

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.—(1) If 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—

- (a) for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and
- (b) that 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^(b) (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;

(a) 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.

(b) 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).

- (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.

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.—(1) If 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—

- (a) for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and
- (b) that 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^(a) (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

^(a) 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).

- (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.

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.—(1) If 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—

- (a) to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and
- (b) that 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^(a) (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

^(a) 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).

- (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 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.

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^(a) (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^(b) (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^(c) (duty as to reducing inequalities)), and

(a) 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).
 (b) Sections 13I and 13P were inserted by the Health and Social Care Act 2012, section 23(1).
 (c) Sections 13G was inserted by the Health and Social Care Act 2012, section 23(1).

(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^(a) (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).

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.

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

(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.—(1) If 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—

- (a) to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and
- (b) that 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^(a) (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

^(a) 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).

- (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 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.

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 (a) (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.

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;

(a) 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).

- (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 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 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 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^(a) (exemption from the necessary or expedient test) applied, and—

^(a) Prior to its revocation, the heading of regulation 13 was amended by S.I. 2009/2205.

- (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^(a) (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); or
- (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^(b) (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.

Distance selling premises applications

25.—(1) Section 129(2A) of the 2006 Act^(c) (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

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

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

^(c) 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).

- (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Change of ownership applications

26.—(1) Section 129(2A) of the 2006 Act (a) (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) if Y had applied to move to X’s premises, that application would have been granted under regulation 24; and
- (e) if pharmaceutical services—
 - (i) are being provided at Y’s premises, the provision of pharmaceutical services will not be interrupted (except for such period as 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.

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) 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).

- (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(a) (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(b) (right of return to pharmaceutical lists),
 - (ii) regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(c) (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.

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

(a) 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).

(b) S.I. 2002/2016. These Regulations are revoked by Schedule 10.

(c) S.I. 2006/552. These Regulations are revoked by Schedule 10.

- (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.—(1) An application—

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

must be refused where paragraph (2) applies.

(2) This paragraph applies where—

- (a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from—
 - (i) the premises to which the application relates, or

- (ii) adjacent premises; and
- (b) the 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).

Deferrals arising out of LPS designations

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

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

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

(2) This paragraph applies where the relevant premises are premises or part of premises, or are located within an area, designated under—

- (a) regulation 99; or
- (b) regulation 4 of the 2006 Regulations^(a) (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.

PART 6

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

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

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

- (a) A (or where A is a body corporate, any director or superintendent of A) has been convicted in the United Kingdom of murder;
- (b) A (or where A is a body corporate, any director or superintendent of A)—
 - (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

^(a) Prior to its revocation, regulation 4 was amended by S.I. 2009/599 and 2010/914.

- (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 (and where A is a body corporate, any director or superintendent of A), and
 - (ii) considered these and any other facts in its possession relating to fraud involving or relating to A (and where A is a body corporate, any director or superintendent of A),
 considers the outcome of these enquiries justify such refusal;
 - (d) having—
 - (i) checked with the Secretary of State for any facts considered by the Secretary of State to be relevant relating to past or current investigations or proceedings involving or relating to A (and where A is a body corporate, any director or superintendent of A), and
 - (ii) considered these and any other facts in its possession involving or relating to A (and where A is a body corporate, any director or superintendent of A),
 considers the outcome of these enquiries justify such refusal; or
 - (e) considers that granting the application would be prejudicial to the efficiency of the service which A has undertaken to provide.
- (3) Where the 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^(a) (sexual offences) applies, or if it had been committed in England and Wales, would have applied;
 - (g) whether A (and where A is a body corporate, any director or superintendent of A) has been refused inclusion in, conditionally included in, removed, contingently removed or is currently suspended from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, and if so, the facts relating to the matter which led to such action and the reasons given by the NHSCB or another primary care organisation for such action; or
 - (h) whether A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, or has in the preceding 6 months been—

(a) 2003 c. 42.

- (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.

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

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

- (a) there are, in respect of A (or where A is a body corporate, in respect of A or a director or superintendent of A)—
 - (i) criminal proceedings in the United Kingdom, or
 - (ii) proceedings elsewhere relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,
 which, if they result in a conviction, or the equivalent of a conviction, would be likely to lead to A's removal from its pharmaceutical list, if A were to be included in it;
- (b) in respect of a body corporate of which A is, or has in the preceding 6 months been, or was at the time of the originating events, a director or superintendent, there are—
 - (i) criminal proceedings in the United Kingdom, or
 - (ii) proceedings elsewhere relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,
 which, if they resulted in a conviction, or the equivalent of a conviction, would be likely to lead to A's removal from its pharmaceutical list, if A were to be included in it;
- (c) there is an investigation anywhere in the world—
 - (i) by A's (or where A is a body corporate, any director or superintendent of A's) licensing or regulatory body, or
 - (ii) relating to A (or where A is a body corporate, any director or superintendent of A) in A's professional capacity (including one by the NHSCB or another primary care organisation),
 which, if the outcome were adverse, would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
- (d) A (and where A is a body corporate, any director or superintendent of A) is suspended from a relevant list;
- (e) a body corporate of which A (or where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent, is suspended from a relevant list;

- (f) the First-tier Tribunal is considering an appeal by A (or where A is a body corporate, by A or any director or superintendent of A) against a decision of 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 A from the pharmaceutical list if A were to be included in it;
 - (g) the First-tier Tribunal is considering an appeal by a body corporate of which A (or where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, or has in the preceding 6 months been, a director or superintendent, against a decision of 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 A from the pharmaceutical list if A were to be included in it;
 - (h) A (and where A is a body corporate, any director or superintendent of A) is being investigated by the NHS BSA in relation to any fraud, where the result, if adverse, would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
 - (i) a body corporate, of which A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent, is being investigated by the NHS BSA in relation to any fraud, where the result if adverse would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
 - (j) the First-tier Tribunal is considering an application from the NHSCB or a Local Health Board for a national disqualification of A (and where A is a body corporate, any director or superintendent of A);
 - (k) the First-tier Tribunal is considering an application from the NHSCB or a Local Health Board for a national disqualification of a body corporate of which A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent; or
 - (l) 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 A 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.

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(a), the application notice must be sent to the Tribunal if an appeal is to be brought; and
 - (d) the effect of paragraph (5).
- (5) If P issues a notice of commencement before the First-tier Tribunal has determined an appeal against a condition imposed under paragraph (1), P is to be included in the pharmaceutical list subject to the condition, but only pending the outcome of the appeal if the appeal is successful.
- (6) The appeal is to be by way of redetermination of—
- (a) the decision of the 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.

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

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

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.

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^(a) (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.

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

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

- (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^(a) (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—

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

- (i) included in regulations under section 225 of the 2007 Act^(a) (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.

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

^(a) 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.

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^(a) (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,

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

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.

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^(a) (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.

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.

^(a) Prior to its revocation, regulation 65 was amended by S.I. 2006/3373.

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

Gradual introduction of premises approval

57.—(1) Where a dispensing doctor (D) has outline consent but 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^(a) (imposition of conditions) or by virtue of regulation 57.

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

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

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

- (a) to which regulation 25(1) applies is granted;
- (b) to which regulation 25(1) of the 2012 Regulations (distance selling premises applications) applied was granted; or
- (c) to which regulation 13(1)(d) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted,

paragraph (2) applies.

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

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

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

(3) Those conditions are—

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

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

Core opening hours conditions

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

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

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

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

(3) 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^(a) (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

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

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).

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^(a) (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—

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

- (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.

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 (a)(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.

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,

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

- (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 subparagraph (ii)); or
- (b) by or on behalf of the government of a country or territory outside the United Kingdom.

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

79.—(1) Where 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(a), the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (d) the continuing application of the condition that applied prior to the review, if there is an appeal, pending the outcome of the appeal.

(6) If the outcome of the review is that the condition is to be varied or a different decision is to be imposed, that decision is to take effect—

- (a) if no appeal is brought against the decision, once the period for bringing an appeal has elapsed; or
- (b) if an appeal is brought against the decision, and the decision of 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).

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

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

- (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^(a) (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^(b).

(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

^(a) 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.

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

- (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^(a) (appeals), and
 - (ii) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008^(b), the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (c) if the NHSCB has decided to contingently remove C, the arrangements for review of the conditions under section 157(1) of the 2006 Act^(c) (review of decisions).

(4) If 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).

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^(d) (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) Section 158 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 84, and by S.I. 2010/22.
(b) S.I. 2008/2699 (L 16); *see* rule 19 of those Rules.
(c) Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.
(d) 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.

- (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^(a) (review of decisions).

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^(b) (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^(c), the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (c) if C has been or remains suspended or contingently removed, the arrangements for review of the suspension or the conditions under section 157(1) of the 2006 Act.

General power to revoke suspensions in appropriate circumstances

85.—(1) If an NHS chemist is suspended from a pharmaceutical list, in addition to the NHSCB’s powers to terminate suspensions under section 157(3)(b) of the 2006 Act^(d) (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.

(a) Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.
 (b) 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.
 (c) See rule 19 of those Rules.
 (d) 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 subparagraphs (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 (a) (national disqualification) is to have effect as if the reference to “two years” were a reference to “five years”, if the First-tier Tribunal determines, when it imposes the national disqualification, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a review being successful if held within five years.

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

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

- (a) in a case where—
 - (i) a national disqualification has been imposed as a consequence of a criminal conviction, and
 - (ii) on appeal, the conviction has been quashed or the penalty imposed by the court has been reduced; or
- (b) in a case where—
 - (i) a national disqualification has been imposed as a consequence of an adverse decision of a licensing body, and
 - (ii) on appeal, the decision of the licensing body has been quashed or the penalty imposed by it has been reduced,

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

Wider notifications of fitness decisions

88.—(1) Where the NHSCB—

- (a) refuses an application from a person (P) by virtue of regulation 33;

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

- (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^(a) (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^(b) (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

(a) 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.

(b) 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.

(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.

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 (a) (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

(a) 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.

(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.

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^(a) (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.

^(a) 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..

- (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).

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^(a) (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)).

The taking effect of determinations

93.—(1) A determination of remuneration under section 164 of the Act^(b) (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

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

^(b) 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.

- (b) if no such date is specified, in relation to remuneration in respect of the period beginning on the date that the determination is published.

(2) A date before the date a determination is published may only be specified under paragraph (1)(a) if, taking the determination as a whole, it is not detrimental to the persons to whose remuneration it relates.

Overpayments

94.—(1) Where 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^(a) (repayment of charges); or
- (b) on an equivalent form issued in Scotland, Wales or Northern Ireland.

Reward scheme

97.—(1) An NHS chemist who is presented with or receives an order under paragraph 5(2) or (3) of Schedule 4, or paragraph 4(2) or (3) of Schedule 5, is eligible to claim a payment from the NHSCB, in accordance with the Drug Tariff, if—

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

- (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^(a) (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.

(a) 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).

(5) A designation under this regulation, and any designation by a Primary Care Trust under regulation 4 of the 2006 Regulations^(a) (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.

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).

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

- (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^(a) (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.

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^(b) (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.

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

^(b) 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.

(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.

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^(a) (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^(b) (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^(c) (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^(d) or Schedule 2A of the Insolvency (Northern Ireland) Order 1989^(e) (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

(a) 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.

(b) 1995 c. 46.

(c) 1986 c. 45; Part 7A was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), Schedule 17.

(d) 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.

(e) S.I. 1989/2405 (N.I. 19); Schedule 2A was inserted by S.I. 2005/1455 (N.I. 10).

- (ii) an administration order under Schedule B1 to the Insolvency Act 1986(a) (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(b) (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(c) (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(d) or the Company Directors Disqualification (Northern Ireland) Order 2002(e), or
 - (ii) an order made under section 429(2) of the Insolvency Act 1986(f) (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.

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) Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), Schedule 16.
 - (b) 1990 c.40; section 7 was repealed by the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), Schedule 4, paragraph 7(b).
 - (c) 2005 asp 10; section 34(5) has been amended by the section the Public Services Reform (Scotland) Act 2010 (asp 8), section 122.
 - (d) 1986 c.46.
 - (e) S.I. 2002/3150 (N.I. 4); relevant amendments were made by S.I. 2005/1454 (N.I. 9).
 - (f) Section 429(2) was amended by the Enterprise Act 2002 (c.40), Schedule 23, paragraph 15.

- (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(a) (admonition and absolute discharge) discharging R absolutely;
- (e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995(b) (fixed penalty: conditional offer by procurator fiscal);
- (f) has agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(c) (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.

(a) 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.

(b) 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).

(c) 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.

(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.

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(a), by a person duly authorised by that authority, or
 - (ii) in the care of a voluntary organisation, by that organisation or a person duly authorised by them;
- (c) on behalf of any adult who is incapable of making such an application or authorising such an application to be made on their behalf, by a relative or the primary carer (who may be an adult or an organisation) of that person; or
- (d) on behalf of any other person by a duly authorised person.

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

(a) 1989 c. 41.

- (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
Parliamentary Under-Secretary of State,
Department of Health

14th February 2013

SCHEDULE 1

Regulation 4(1)

Information to be contained in pharmaceutical needs assessments

Necessary services: current provision

1. A statement of the pharmaceutical services that the HWB has identified as services that are provided—

- (a) in the area of the HWB and which are necessary to meet the need for pharmaceutical services in its area; and
- (b) outside the area of the HWB but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the HWB has identified such services).

Necessary services: gaps in provision

2. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied—

- (a) need to be provided (whether or not they are located in the area of the HWB) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;
- (b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the HWB) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Other relevant services: current provision

3. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are provided—

- (a) in the area of the HWB and which, although they are not necessary to meet the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access, to pharmaceutical services in its area;
- (b) outside the area of the HWB and which, although they do not contribute towards meeting the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access, to pharmaceutical services in its area;
- (c) in or outside the area of the HWB and, whilst not being services of the types described in sub-paragraph (a) or (b), or paragraph 1, they nevertheless affect the assessment by the HWB of the need for pharmaceutical services in its area.

Improvements and better access: gaps in provision

4. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied—

- (a) would, if they were provided (whether or not they were located in the area of the HWB), secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area,
- (b) would, if in specified future circumstances they were provided (whether or not they were located in the area of the HWB), secure future improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Other NHS services

5. A statement of any NHS services provided or arranged by a local authority, the NHSCB, a CCG, an NHS trust or an NHS foundation trust to which the HWB has had regard in its assessment, which affect—

- (a) the need for pharmaceutical services, or pharmaceutical services of a specified type, in its area; or
- (b) whether further provision of pharmaceutical services in its area would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area.

How the assessment was carried out

6. An explanation of how the assessment has been carried out, and in particular—

- (a) how it has determined what are the localities in its area;
- (b) how it has taken into account (where applicable)—
 - (i) the different needs of different localities in its area, and
 - (ii) the different needs of people in its area who share a protected characteristic; and
- (c) a report on the consultation that it has undertaken.

Map of provision

7. A map that identifies the premises at which pharmaceutical services are provided in the area of the HWB.

SCHEDULE 2

Regulation 10(7)

Applications in respect of pharmaceutical lists and the procedures to be followed

PART 1

Information to be included in routine and excepted applications

Information to be included in all routine and excepted applications

1.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications.

- (2) The name of the relevant HWB.

(3) The type of application being made (for example, the application is for inclusion in a pharmaceutical list and a change of ownership application), including a statement of whether the application is a routine or an excepted application.

(4) The name and address of the applicant (A).

(5) If A is an individual or a partnership carrying on a retail pharmacy business, A or each partner's registration number in the GPhC register.

(6) If A is a body corporate carrying on a retail pharmacy business, the name and registration number in the GPhC register of A's superintendent.

(7) If A is seeking the listing of premises not already listed in relation to A (whether or not A is already listed)—

(a) either—

(i) the address of the premises, or

(ii) if the address is not known and it is a routine application, A's best estimate of where the proposed premises will be;

(b) whether the applicant is currently in possession of the premises;

(c) the proposed core opening hours in respect of the premises; and

(d) the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).

(8) If A is seeking to provide directed services—

(a) details of the directed services to be provided;

(b) confirmation that A is accredited to provide the services, where that accreditation is a prerequisite for the provision of those services;

(c) confirmation that the premises are accredited in respect of the provision of the services, where that accreditation is a prerequisite for the provision of those services; and

(d) a floor plan showing the consultation area where A proposes to offer directed services (where relevant, unless one cannot be provided for reasons that are good cause).

(9) A is not entitled to ask for a routine application to be considered, in the alternative, as an excepted application, or for an excepted application to be considered, in the alternative, as a routine application.

(10) An estimate of the location of premises is only a "best estimate" for the purposes of subparagraph (7)(a)(ii) if the NHSCB is satisfied that—

(a) it is the best estimate that A can reasonably make at the time of the application of the location of the premises; and

(b) its reasons for granting or refusing the application would be essentially the same if the applicant located, if the application was granted, at any location within the range of possible locations covered by the estimate.

Information to be included in all routine and excepted applications for inclusion in a pharmaceutical list

2.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

(2) If the applicant (A) is an individual or a partnership—

(a) A's or each partner's full name;

(b) A's or each partner's sex;

(c) A's or each partner's date of birth;

(d) A's or each partner's private address and telephone number;

(e) a declaration that A or each partner is a registered pharmacist, if A is seeking entry in the list mentioned in regulation 10(2)(a);

- (f) if A is a partnership, a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act^(a) (general provisions), if A is seeking entry in the list mentioned in regulation 10(2)(a); and
 - (g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register, if A is seeking entry in the list mentioned in regulation 10(2)(a).
- (3) If A is a body corporate—
- (a) A's registered name and any other name under which A trades;
 - (b) A's company registration number;
 - (c) A's registered office and any fixed line telephone number relating to that office;
 - (d) the private address and date of birth of A's superintendent (if A is seeking entry in the list mentioned in regulation 10(2)(a));
 - (e) the name and date of birth of each director of A (who is not A's superintendent), and if any director of A (who is not A's superintendent) is a registered pharmacist, that director's registration number in the GPhC register;
 - (f) a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act, if A is seeking entry in the list mentioned in regulation 10(2)(a); and
 - (g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register, if A is seeking entry in the list mentioned in regulation 10(2)(a).
- (4) If the services that A undertakes to provide consists of or includes the supply of appliances, the appliances A undertakes to supply.

Fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list

3.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list, as regards any person (P) who is—

- (a) the individual who is making the application;
 - (b) a partner in the partnership that is making the application; or
 - (c) a director or (if A is seeking entry in the list mentioned in regulation 10(2)(a)) superintendent of the body corporate that is making the application.
- (2) Details of whether P—
- (a) has been convicted of any criminal offence in the United Kingdom;
 - (b) has been bound over following a criminal conviction in the United Kingdom;
 - (c) has accepted a police caution in the United Kingdom;
 - (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging P absolutely (without proceeding to conviction); or
 - (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995^(b) (fixed penalty: conditional offer by

^(a) Section 69 has been amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1, Part 12, and by S.I. 1976/1213, 2007/289 and 3101 and 2010/231.

^(b) 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).

procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(a) (penalty as alternative to prosecution).

(3) Details of whether P has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which P is currently subject—

- (a) in the United Kingdom; or
- (b) elsewhere than the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's fitness to practise by a licensing body—

- (a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or
- (b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(6) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's professional conduct by an employer—

- (a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or
- (b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(7) If P is a pharmacist, details of P's—

- (a) pharmaceutical qualifications (including where obtained); and
- (b) professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why P was dismissed from any post (if not already covered by the details provided pursuant to sub-paragraph (6)(b)).

(8) If P is a pharmacist, names and addresses of 2 referees who are willing to provide references in respect of 2 recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, details of why and the names and addresses of alternative referees who are acceptable to the NHSCB.

(9) If P is, to P's knowledge, or has been subject to any investigation or proceedings that could lead or could have led to P's removal from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(10) If P is, to P's knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(11) If P has been refused inclusion in, or conditionally included in, or contingently removed or suspended from, any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of same.

(12) If P is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

- (a) any deferment of that application; or

(a) 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.

- (b) refusal or conditional inclusion where the refusal or conditional inclusion has not yet reached its final outcome.

(13) If P—

- (a) is the person making the application; and
- (b) qualified as a pharmacist in Switzerland or an EEA State other than the United Kingdom, details that demonstrate that P has the level of knowledge of English which, in the interests of P and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the relevant HWB.

Fitness information about corporate bodies: routine and excepted applications for inclusion in a pharmaceutical list

4.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list by a body corporate (C1)—

- (a) as regards C1; or
- (b) as regards any other body corporate (C2) of which a director or superintendent of C1—
 - (i) is a director or superintendent or has been a director or superintendent in the 6 months prior to the date of the application, or
 - (ii) has been a director or superintendent for more than 6 months prior to the date of the application, where they were a director or superintendent of C2 at the time of the originating events to which the information relates.

(2) Details of any convictions that C1 or C2 has for offences committed in the United Kingdom that are not spent convictions.

(3) Details of whether C1 or C2 (being corporate bodies registered within the United Kingdom) has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which C1 or C2 is currently subject—

- (a) in the United Kingdom; or
- (b) elsewhere than in the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) Details of any investigation to which C1 or C2—

- (a) is, to its knowledge, subject by the General Pharmaceutical Council in relation to an entry in Part 3 of the GPhC register; or
- (b) has been subject by the General Pharmaceutical Council, the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland in relation to an entry in the register required to be kept under section 75 of the 1968 Act^(a) (registration of premises), the outcome of which was adverse.

(6) If C1 or C2, to its knowledge, is or has been subject to any investigation or proceedings that could lead or could have led to its removal from a relevant list, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(7) If C1 or C2 is, to its knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(8) If C1 or C2 has been refused inclusion in, or conditionally included in (other than by reason of a condition imposed under Part 9), a relevant list, details of that refusal or conditional inclusion.

^(a) Amended by S.I. 1968/1699 and 2010/231.

(9) If C1 or C2 is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

- (a) any deferment of that application; or
- (b) any refusal or conditional inclusion, where the refusal or conditional inclusion has not yet reached its final outcome.

Fitness information that has already been provided under pharmaceutical or local pharmaceutical services

5.—(1) If information mentioned in paragraph 3 or 4 has already been provided to the NHSCB (or a home Primary Care Trust) on a previous occasion pursuant to regulations under Part 7 of the 2006 Act, an applicant need not provide that information again to the NHSCB in relation to the current application.

(2) An applicant relying on paragraph (1) must, when making its application—

- (a) confirm to the NHSCB that the NHSCB already has all the information required under paragraphs 3 and 4; or
- (b) if there is any missing information required under those paragraphs—
 - (i) confirm to the NHSCB what information the NHSCB already has, and
 - (ii) provide the missing information.

Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises

6. If, as regards a routine or excepted application—

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

the premises which the applicant (A) is seeking to be listed in relation to A are already listed chemist premises or are adjacent to or in close proximity to such premises, A must include with the application details that explain why A believes the application should not be refused pursuant to regulation 31.

Additional information to be included with routine applications

7.—(1) If an applicant (A) is making a routine application and is seeking to satisfy the NHSCB that granting that application would meet a need for pharmaceutical services, or secure improvements to or better access to pharmaceutical services, in circumstances where—

- (a) that need, those improvements or that better access has or have been identified in the pharmaceutical needs assessment of the relevant HWB (or Primary Care Trust), A must include in that application details that explain how A intends to meet that need, or secure those improvements or that better access (in whole or in part); or
- (b) that need, those improvements or that better access has or have not been identified in the pharmaceutical needs assessment of the relevant HWB (or Primary Care Trust), A must include in that application, details that explain A's belief that regulation 18(1)(b) is satisfied in relation to that application.

(2) Where an applicant includes information in an application pursuant to paragraph (a) but not paragraph (b) of sub-paragraph (1), the NHSCB must not consider whether regulation 18(1)(b) applies in relation to that application when it determines that application.

Additional information to be included with excepted applications

8. If the applicant (A) is making an excepted application, A must include in that application details that explain—

- (a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) of the 2006 Act^(a) (regulations as to pharmaceutical services) are not to apply in relation to that application; and
- (b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Undertakings

9. An applicant (A) must provide the following undertakings—

- (a) an undertaking to notify the NHSCB within 7 days of any material changes to the information provided in the application that occur before—
 - (i) the application is withdrawn,
 - (ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
 - (iii) if the application is granted, A commences the provision of the services to which the application relates,whichever is the latest of these events to take place;
- (b) an undertaking to notify the NHSCB if A is included, or applies to be included, in any other relevant list of another primary care organisation before—
 - (i) the application is withdrawn,
 - (ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
 - (iii) if the application is granted, A commences the provision of the services to which the application relates,whichever is the latest of these events to take place;
- (c) if A is seeking inclusion in a pharmaceutical list or (if A is already listed in that list) the listing of premises in relation to A that are not already listed in relation to A, an undertaking—
 - (i) to comply with all the obligations that are to be their terms of service under regulation 11 if the application is granted, and
 - (ii) in particular, in relation to any proposed pharmacy premises, to provide all the services and perform all the activities at those premises that are required under the terms of service to be provided or performed as or in connection with essential services; and
- (d) if A is seeking to provide directed services an undertaking—
 - (i) that A will provide the directed services mentioned in the application, if the NHSCB does commission the services from A within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates,
 - (ii) if the services are commissioned by the NHSCB, that A will provide the services in accordance with an agreed service specification, and
 - (iii) A's agreement to a service specification will not be unreasonably withheld.

(a) 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).

Nature of details to be supplied

10. Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy the NHSCB, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.

PART 2

Preliminary matters

Relevant information or documentation

11.—(1) As regards any routine or excepted application, if the NHSCB considers that relevant information or documentation is missing—

- (a) it may request the missing relevant information or documentation from the applicant; and
- (b) the applicant must, within the period reasonably specified by the NHSCB in the request under paragraph (a)—
 - (i) provide any information or documentation reasonably requested,
 - (ii) notify the NHSCB that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or
 - (iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the NHSCB of that and seek a review by the NHSCB of the reasonableness of the request.

(2) If an applicant refuses to comply with a request under sub-paragraph (1)(a)—

- (a) within the period—
 - (i) reasonably specified by the NHSCB under paragraph (1)(b), or
 - (ii) ending on the date specified by the applicant in accordance with paragraph (1)(b)(ii), if the NHSCB is satisfied that a delay beyond the period it specified, and the length of the delay, are for good cause,unless paragraph (b) applies, the application is to be treated as withdrawn;
- (b) in circumstances where the applicant has, in accordance with sub-paragraph (1)(b)(iii), sought a review by the NHSCB of the reasonableness of the request, if the review determines that any or all of the information or documentation requested—
 - (i) must after all, be provided, the application is to be treated as withdrawn unless the information or documentation that must still be provided is provided within a new period reasonably specified by the NHSCB for the provision of that information or documentation,
 - (ii) need not be provided by the applicant, the request of the NHSCB is to be treated as withdrawn to the extent that it relates to information or documentation that need not be provided.

(3) The NHSCB may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application, but it must consider whether or not it needs to request information or documentation under this paragraph prior to notifying an application (where it is required to do so) under Part 3.

Failure to provide undertakings or fees

12.—(1) If, when an applicant (A) submits an application, A fails to provide with the application—

- (a) the undertakings referred to in paragraph 9 that are relevant to the application, the NHSCB must, if the application is notifiable prior to notifying the application under Part 3, request that A provide the relevant undertakings within a specified period; or
- (b) any fee payable in respect of that application by virtue of directions under section 131 of the 2006 Act (power to charge), the NHSCB must, if the application is notifiable prior to notifying the application under Part 3, request that A provide the fee (or any missing part of the fee) within a specified period.

(2) If A fails to comply with a request under sub-paragraph (1) within a period reasonably specified by the NHSCB under that sub-paragraph, the application is to be treated as withdrawn.

Functions of the NHSCB in relation to fitness information relevant to applications from bodies corporate

13. Where an applicant (A) is relying on paragraph 5(1), the NHSCB must ensure that the information that it holds about A is aggregated in such a way that it is able to make a reasonable determination as to whether the application should be refused or deferred under regulation 33 or 34.

Deferral of notifiable applications prior to notification

14.—(1) The NHSCB, having received—

- (a) a routine application, consideration of which may or must be deferred under regulation 14(1) to (3), 16(1) to (4), 19(1) to (4), 21(1) to (4) or 38(4); or
- (b) a notifiable application, consideration of which may be deferred under regulation 32 or 34,

must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not to defer consideration of that application under those provisions.

(2) If consideration of the application is deferred prior to notification, once the NHSCB no longer has grounds for deferring the application, it must proceed as soon as is practicable with the notification of the application, unless the application has been withdrawn or the NHSCB is required to treat it as withdrawn.

Refusal of notifiable applications prior to notification because of the language requirement for some NHS pharmacists

15. The NHSCB, having received a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list, may without notifying that application under Part 3 (or if no notification is required, as soon as is practicable) decide to refuse that application under regulation 30.

Refusal of notifiable applications on fitness grounds prior to notification

16. The NHSCB, having received a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list, may without notifying that application under Part 3 decide to refuse that application under regulation 33(1).

Proposed new pharmacy premises in controlled localities: refusal of routine applications because of preliminary matters prior to notification

17. The NHSCB, having received a routine application where the applicant is seeking the listing of pharmacy premises, must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not the application needs to be refused under regulation 40(2).

PART 3

Notification of certain applications

Applications requiring notifications

18. An application is a “notifiable application” for the purposes of this Schedule if—

- (a) it is a routine application; or
- (b) it is an excepted application pursuant to regulation 24, 25 or 26(2),

and the NHSCB has not decided to dispense with the notification pursuant to paragraphs 15 to 17.

Notification procedure for notifiable applications

19.—(1) As soon as is practicable (having regard to its functions under Part 2), the NHSCB must give notice of a notifiable application to—

- (a) any Local Pharmaceutical Committee—
 - (i) whose area includes the premises or location to which the application relates, or
 - (ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;
- (b) any Local Medical Committee—
 - (i) whose area includes the premises or location to which the application relates, or
 - (ii) any part of whose area is within 2 kilometres of the premises or location 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) if the applicant is seeking to locate premises in, or within 1.6 kilometres of, a controlled locality in the area of the relevant HWB—
 - (i) any provider of primary medical services, or
 - (ii) 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 premises or location to which the application relates; and
- (h) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the application relates.

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

(3) If any part (PA) of the area of a notified HWB (HWB2) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also give notice of the application to—

- (a) any Local Pharmaceutical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (1)(a);
- (b) any Local Medical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (1)(b);
- (c) 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;
- (d) 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;
- (e) 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
- (f) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in the area of HWB2—
 - (i) any provider of primary medical services, or
 - (ii) 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) Those notified under sub-paragraphs (1) to (3) may make representations in writing about the application that is the subject of the notification to the NHSCB, provided they do so within 45 days of the date on which notice of the application was given to them.

Parallel notifications

20.—(1) If the NHSCB is considering, as a consequence of a notifiable application, making (including revising) a determination as to whether or not an area is or is not to be part of a controlled locality, it must give notice under this Part at the same time that it gives notice under regulation 38(1).

(2) If, as a consequence of a notifiable application, the NHSCB is required, by virtue of regulation 41 to determine whether or not an area is a reserved location, the NHSCB must consider giving notice under this Part at the same time that it gives notice under regulation 41(4).

Content of notifications

21.—(1) A person notified under paragraph 19 (P)—

- (a) must be informed—

- (i) of P’s right to make representations under paragraph 19(4);
 - (ii) of the circumstances in which notified persons would be permitted, pursuant to paragraph 25, to make oral representations at any oral hearing relating to the application, and
 - (iii) if the NHSCB intends to consider the application together and in relation to any other application, of that intention;
- (b) need not be given the same information as other persons notified under paragraph 19 but, subject to sub-paragraphs (2) to (4), P must be provided with sufficient information, from the information supplied by the applicant, to enable P to make informed representations with regard to whether or not the application should be granted, having regard to P’s interest in the matter.
- (2) P need not be provided with any information that is published as part of the relevant pharmaceutical needs assessment.
- (3) P must not be provided with—
- (a) information supplied by the applicant (A) under paragraphs 2 to 4, or which A is exempt from supplying by virtue of paragraph 5; and
 - (b) any private addresses, private telephone numbers or dates of birth supplied by A.
- (4) 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.
- (5) The “full disclosure principle” is that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application, unless it is fair and proper for that information to be withheld from that individual.
- (6) If information is being withheld from P under paragraph (4), P must be informed of the nature of the information that is being withheld from P.

PART 4

Determination and deferral of applications

Flexibility with regard to determining or deferring applications

22.—(1) Except in so far as these Regulations provide to the contrary, the NHSCB is to determine or defer routine and excepted applications in such manner (including with regard to procedures) as it sees fit.

(2) The NHSCB may determine a routine or excepted application without hearing any oral representations, if it considers that oral representations are unnecessary.

(3) Where appropriate, the NHSCB may if it thinks fit consider 2 or more applications together and in relation to each other, but where it does so, it must give notice to the applicants of its intention to do so (if it has not already done so under Part 3).

Additional matters for consideration in relation to applications for inclusion in a pharmaceutical list

23.—(1) In the case of a routine or excepted application by a person (A) for inclusion in a pharmaceutical list who is not already included in it, the NHSCB must, prior to determining the application—

- (a) check with the NHS BSA whether A, and if A is a body corporate whether any director or superintendent of A, has any record of, or is under investigation for, fraud;

- (b) check with the Secretary of State whether the Secretary of State holds any information about A, and if A is a body corporate about any director or superintendent of A, that is relevant to its consideration of whether—
 - (i) the application should be refused or deferred under regulations 33 or 34, or
 - (ii) conditions should be imposed under regulation 35;
 - (c) take up references from, and check the references provided by, the referees whose details A is required to provide pursuant to paragraph 3(8).
- (2) In such a case, having considered whether—
- (a) the application should be refused or deferred under regulations 33 or 34; or
 - (b) conditions should be imposed under regulation 35,

if it is minded to impose conditions under regulation 35, it must notify A at least 7 days in advance of determining that it is to impose such conditions and consider any representations (which may be at an oral hearing) that A makes prior to the determination with regard to the notification.

Action following deferrals

24.—(1) Where the NHSCB receives a routine or excepted application, consideration or determination of which may be deferred, if it does decide to defer consideration or determination of that application (whether before or after the application is notified, in the case of a notifiable application), it must—

- (a) notify the applicant (A) of its decision and the reasons for it; and
 - (b) where possible, notify A of the period for which the application is being deferred (if necessary by reference to a future event rather than a period of time).
- (2) If the application is—
- (a) a routine application, consideration of which may be deferred under regulation 14(1)(a), 16(1)(a), 19(2)(a) or 21(1)(a), it must proceed as soon as is practicable to invite other applications under regulation 14(1)(b), 16(1)(b), 19(2)(b) or 21(1)(b), in such manner as it sees fit;
 - (b) a routine application, consideration of which may be deferred under regulation 14(2), 16(3), 19(3) or 21(3), it must make arrangements that enable it to consider the other applications at the same time as A's application, as soon as is practicable;
 - (c) a routine application, consideration of which may be deferred under regulation 14(3), 16(4), 19(4) or 21(4), it must, once the appeal relating to the other application has reached its final outcome, notify A of that outcome and that A must within a specified period (of not less than 30 days)—
 - (i) update A's application, and
 - (ii) notify the NHSCB as to whether or not A still wishes to proceed with the application;
 - (d) a routine application, consideration of which may be deferred under regulation 16(2) or 21(2), it must keep under regular review the issue of whether the future circumstances that gave rise to the deferral have arisen;
 - (e) a routine application, consideration of which may be deferred under regulation 32, it must—
 - (i) send A a copy of the designation that led to the decision,
 - (ii) review that decision once the designation that led to the decision has been cancelled or is varied in a manner which means the application may no longer be deferred under regulation 32,
 - (iii) notify A of the cancellation or variation, and
 - (iv) require A within a specified period (of not less than 30 days)—
 - (aa) to update A's application, and

- (bb) to notify the NHSCB as to whether or not A still wishes to proceed with the application;
 - (f) a routine or excepted application, consideration of which may be deferred under regulation 34, once the outcome of the cause for the deferral is known, the NHSCB must notify A that A must within a specified period (of not less than 30 days)—
 - (i) update A’s application, and
 - (ii) notify the NHSCB as to whether or not A still wishes to proceed with the application; and
 - (g) a routine application, consideration of which must be deferred under regulation 38(4), it must proceed, as soon as is practicable, with the determination of whether the relevant area is or is not to be part of a controlled locality.
- (3) If A informs the NHSCB within the period specified under sub-paragraph (2)(c), (e)(iv) or (f) that A does not wish to proceed with the application, or fails to respond in the required manner to the notification within the specified period, the application is to be treated as withdrawn.

Oral hearings

- 25.—**(1) If the NHSCB does decide to hear oral representations, it must—
- (a) give the applicant and any additional presenters not less than 14 days notice of the time and place at which the oral representations are to be heard; and
 - (b) in the case of the applicant, advise the applicant of who apart from the applicant (including other applicants, where the hearing relates to more than one application), has been invited to make representations at the hearing.
- (2) For these purposes, a person (P) is an “additional presenter” if—
- (a) the application to which the oral hearing relates is a notifiable application;
 - (b) P was given notice of the application under Part 3 and made representations about the application in accordance with paragraph 19(4), which—
 - (i) indicated that, if there were to be an oral hearing in relation to the application, P would wish to make oral representations at that hearing, and
 - (ii) identified a matter about which the NHSCB considers it would be desirable to hear further evidence from P at the oral hearing; and
 - (c) the NHSCB is satisfied that P made a reasonable attempt to express P’s views on the application adequately in P’s written representations.
- (3) If the NHSCB decides at or after an oral hearing that an application is to be deferred, it may (but need not) hold a further oral hearing once the period for which the application is deferred expires.

Persons barred from taking part in decision making on routine and excepted applications

- 26.—**(1) No person is to take part in determining or deferring any routine or excepted application who—
- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
 - (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
 - (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
 - (d) is a provider of primary medical services;
 - (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
 - (f) is employed or engaged by a primary medical services provider; or

- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

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

(2) No other person is to take part in determining or deferring a particular routine or excepted application if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

Timetable for determining applications

27. As regards any routine or excepted application—

- (a) the NHSCB must endeavour to determine it as soon as is practicable; and
- (b) unless consideration of it is deferred in accordance with these Regulations or there is other good cause for delay, in the case of—
 - (i) a notifiable application, the NHSCB must determine it within 4 months of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it, or
 - (ii) an application which is not a notifiable application, the NHSCB must determine it within 30 days of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it.

PART 5

Notification, taking effect of decisions and rights of appeal to the Secretary of State

Notification of decisions on routine and excepted applications

28.—(1) As regards any routine application, once it has determined the application, the NHSCB must, as soon as is practicable, give notice of its decision to—

- (a) the applicant;
- (b) any Local Pharmaceutical Committee—
 - (i) whose area includes the premises or location to which the application relates, or
 - (ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;
- (c) any Local Medical Committee—
 - (i) whose area includes the premises or location to which the application relates, or
 - (ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;
- (d) 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 by the decision;
- (e) 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 by the decision;

- (f) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision;
 - (g) if the applicant is seeking to locate premises in or within 1.6 kilometres of a controlled locality in the area of the relevant HWB—
 - (i) any provider of primary medical services, or
 - (ii) 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 decision;
 - (h) any person—
 - (i) whom the NHSCB notified under paragraph 19(2), and
 - (ii) who made representations in writing about the application under paragraph 19(4);
 - (i) any Local Health Board any part of whose area is within 2 kilometres of the premises or location to which the decision relates; and
 - (j) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the decision relates.
- (2) If any part (PA) of the area of a notified HWB (HWB2) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also, as soon as is practicable, give notice of the decision to—
- (a) any Local Pharmaceutical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (1)(b);
 - (b) any Local Medical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (1)(c);
 - (c) 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 by the decision;
 - (d) 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 by the decision;
 - (e) any Local Healthwatch organisation for the area of HWB2, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision; and
 - (f) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in the area of HWB2—
 - (aa) any provider of primary medical services, or
 - (bb) 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 decision.
- (3) As regards any excepted application, once it has determined the application, the NHSCB must, as soon as is practicable, give notice of its decision to—

- (a) in the case of an application pursuant to regulation 23, the applicant;
- (b) in the case of an application pursuant to regulation 24, 25 or 26(2)—
 - (i) the applicant,
 - (ii) any Local Pharmaceutical Committee whose area includes the premises or location to which the application relates,
 - (iii) any Local Medical Committee whose area includes the premises or location to which the application relates,
 - (iv) the relevant HWB, and if the applicant is relocating to different premises in the area of another HWB, the other HWB, and
 - (v) any (other) person whom the NHSCB notified under paragraph 19 and who made representations in writing about the application under paragraph 19(4);
- (c) in the case of an application pursuant to regulation 26(1) or 27 to 29—
 - (i) the applicant,
 - (ii) any Local Pharmaceutical Committee whose area includes the premises or location to which the application relates,
 - (iii) any Local Medical Committee whose area includes the premises or location to which the application relates,
 - (iv) any person—
 - (aa) included in a pharmaceutical list for the area of the relevant HWB, or
 - (bb) 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 by the decision;
 - (v) any LPS chemist—
 - (aa) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and
 - (bb) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision,
 - (vi) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision,
 - (vii) any Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates, and
 - (viii) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the decision relates.

(4) If, in the case of an application pursuant to regulation 26(1) or 27 to 29, any part (PA) of the area of a HWB (HWB3) notified under sub-paragraph (3)(c) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also, as soon as is practicable, give notice of the decision to—

- (a) any Local Pharmaceutical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (3)(c)(ii);
- (b) any Local Medical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (3)(c)(iii);
- (c) any person—
 - (i) included in a pharmaceutical list for the area of HWB3, 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 by the decision;
- (d) any LPS chemist—
 - (i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB3, and
 - (ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision; and
- (e) any Local Healthwatch organisation for the area of HWB3, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision.

(5) Where the NHSCB has decided to consider 2 or more applications together pursuant to paragraph 22(3), it must give notice to each applicant of the decision taken with regard to each other application considered together with their application.

(6) Each notification of a decision under this paragraph must include a statement by the NHSCB of the reasons for the decision.

Template notice of commencement to be included with a notice of decision

29. The NHSCB must send with a notice of decision under paragraph 28 in respect of the grant of an application a template of a notice of commencement, for the applicant to send to it under paragraph 34, in which the applicant is to provide the following information (some of which the NHSCB may have included in the template that it sends)—

- (a) the address of the premises to which the application relates;
- (b) the services that are to be provided from those premises;
- (c) the date of the grant of the application;
- (d) a declaration with regard to when the applicant intends to commence the provision of those services at those premises;
- (e) in the case of pharmacy premises, the registration number for those premises with the General Pharmaceutical Council; and
- (f) a signature on behalf of the applicant and the date of the notice.

Third party rights of appeal to the Secretary of State where an application is granted

30.—(1) A person with third party rights (as provided for in this paragraph) may appeal to the Secretary of State against a decision of the NHSCB to grant a notifiable application, or an application to which regulation 26(1), 27 or 28 applies, provided that the person notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which that person was notified of the NHSCB's decision under paragraph 28.

- (2) For the purposes of this Schedule, a person (P1) is a person with third party rights if—
 - (a) P1 is a person to whom sub-paragraph (3) applies; or
 - (b) P1 was entitled to receive notification of the decision to grant the application by virtue of paragraph 28(5).
- (3) P1 is a person to whom this sub-paragraph applies if—
 - (a) P1 was a person whom the NHSCB was required to notify about the decision on the application by virtue of P1 being a person whose interests might, in the opinion of the NHSCB, be significantly affected by the decision, and also 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 who is not (yet) included,

- (iii) an LPS chemist, or
- (iv) either—
 - (aa) a provider of primary medical services, or
 - (bb) another person on the dispensing doctor list for the area of the relevant HWB if there is one (P1 being a performer but not a provider of primary medical services),

but only if the application is in respect of premises in a controlled locality and it was granted partly on the basis that, having regard to regulation 44(3), in the opinion of the NHSCB granting the application would not prejudice the proper provision of relevant NHS services in the area of the relevant HWB or of a neighbouring HWB of the relevant HWB;

- (b) in the case of a notifiable application, P1 made representations in writing about the application under paragraph 19(4); and
- (c) in the case of a notifiable application but subject to sub-paragraph (6), the NHSCB is satisfied, having regard to those representations in writing and any oral representations made in accordance with paragraph 25, that P1—
 - (i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and
 - (ii) has grounds for opposing the application, which—
 - (aa) do not amount to a challenge to the legality or reasonableness of a pharmaceutical needs assessment, or to the fairness of the process by which a HWB or Primary Care Trust undertook that assessment, and
 - (bb) are not vexatious or frivolous.

(4) If the NHSCB considers that a person notified under paragraph 28 is a person with third party appeal rights, it must notify that person of that fact when it notifies that person of the determination.

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

(6) A person to whom sub-paragraph (3)(a) and (b) applies (P2) who is not notified by the NHSCB that they are person with third party appeal rights may appeal to the Secretary of State against the determination (D1) 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 under paragraph 28 (D2) that P2 wishes to appeal against D1 and D2; and
- (b) includes within that notification concise and reasoned statements of P2's grounds of appeal against both D1 and D2,

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

Conditional grant of applications where the address of the premises is unknown

31.—(1) As regards any routine application, sub-paragraph (2) applies where—

- (a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and
- (b) prior to the determination of the application, A was only able to provide a best estimate of where the proposed listed chemist premises would be (not the address of those premises).

(2) Where this sub-paragraph applies, it is a condition of the grant of that application that A notifies to the NHSCB the address of the premises to be listed within 6 months of—

- (a) the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3);

- (b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, the date on which the appeal is determined by the Secretary of State; or
- (c) in a case of an application which is subject to a condition imposed by virtue of paragraph 33(2), the date on which that condition becomes spent,

whichever is the latest.

(3) A notification under sub-paragraph (2) is only valid if the NHSCB is satisfied that the premises are at a location that is within the range of possible locations covered by the estimate referred to in sub-paragraph (1)(b).

(4) If the NHSCB receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

- (a) notify A of whether or not it is satisfied that it is a valid notification;
- (b) if it is satisfied that it is a valid notification, notify the address to the persons notified of the decision to grant the application; and
- (c) if the NHSCB is not satisfied that it is a valid notification, it must include with that notification—
 - (i) the reasons for its decision, and
 - (ii) an explanation of how A’s rights of appeal under paragraph 36(1)(b) may be exercised.

(5) The NHSCB may not vary or remove a condition imposed by virtue of this paragraph.

(6) If A breaches a condition imposed by virtue of this paragraph, the grant of the application lapses.

Changes to the premises specified in an application after its grant but before the listing of the premises

32.—(1) As regards any routine application, sub-paragraph (2) applies where—

- (a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and
- (b) prior to the determination of the application, A provided the address of where the proposed listed chemist premises would be.

(2) Where this sub-paragraph applies, A may notify to the NHSCB a different address (“new address”) as the address to which the application relates within—

- (a) 4 months of the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3); or
- (b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, 4 months of the date on which the appeal is determined by the Secretary of State.

(3) A notification under sub-paragraph (2) is only valid if the NHSCB is satisfied that accepting the notification as valid would neither—

- (a) result in a significant change to the arrangements that are in place (having regard to the grant of A’s application) for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
 - (i) in any part of the area of the relevant HWB, or
 - (ii) in a controlled locality that is part of the area of a neighbouring HWB of the relevant HWB, where that controlled locality is within 1.6 kilometres of the new address; nor
- (b) cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB.

(4) If the NHSCB receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

- (a) notify A of whether or not it is satisfied that it is a valid notification, together with the reasons for its decision;
- (b) if the NHSCB is not satisfied that it is a valid notification, it must include with that notification—
 - (i) the reasons for its decision, and
 - (ii) an explanation of how A's rights of appeal under paragraph 36(1)(b) may be exercised.
- (c) if it is satisfied that it is a valid notification, notify the new address to the persons notified of the decision to grant the application, and must include with that notification—
 - (i) the reasons for its decision, and
 - (ii) if the person has a right of appeal under sub-paragraph (5), an explanation of how that right of appeal may be exercised.

(5) A person (X) who—

- (a) is notified under sub-paragraph (4)(c); and
- (b) was entitled to be notified of the decision to grant the application—
 - (i) by virtue of paragraph 28(5), or
 - (ii) as a person whom the NHSCB was required to notify about the application by virtue of X being—
 - (aa) an LPS chemist,
 - (bb) included in a pharmaceutical list, or
 - (cc) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,and a person whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

may appeal against a decision by the NHSCB to accept the purported notification as a valid notification, provided X notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which X was notified under sub-paragraph (4)(c).

(6) A notice of appeal under sub-paragraph (5) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

Conditional grant in cases relating to future needs or future improvements or better access

33.—(1) Where the NHSCB grants a routine application because doing so—

- (a) will meet a future need for pharmaceutical services, or pharmaceutical services of a specified type in its area; or
- (b) will secure future improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type, in its area,

sub-paragraph (2) applies.

(2) Where this sub-paragraph applies, the NHSCB may grant the application subject to a condition that pharmaceutical services are not provided at the listed chemist premises to which the application relates (or at any premises to which the business relocates) until—

- (a) some or all of the future circumstances, as a consequence of which the application was granted, have arisen; or
- (b) a specified date (having regard to when some or all of the future circumstances, as a consequence of which the application was granted, are likely to arise).

(3) The NHSCB may vary or remove a condition imposed by virtue of sub-paragraph (2), but if it varies the condition, the revised condition (which becomes a condition imposed by virtue of sub-paragraph (2)) must be a condition that it also meets the requirements of that paragraph.

(4) The condition imposed by virtue of sub-paragraph (2) becomes spent once—

- (a) where a date has been specified, that date passes; or
- (b) where the condition relates to future circumstances arising, the NHSCB notifies the successful applicant (P) that the future circumstances have arisen.

(5) P may by a notice request a determination from the NHSCB as to whether the future circumstances have arisen at any time (but only once in any 60 days), and the NHSCB must give notice of that determination within 30 days of that request.

Taking effect of listing decisions: general

34.—(1) As regards any application—

- (a) for inclusion in a pharmaceutical list by a person who is not already included in it; or
- (b) by a person 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,

if the application is granted, paragraph (2) applies.

(2) Subject to paragraph 35, the NHSCB may only change a pharmaceutical list to give effect to that decision if the successful applicant (P) gives the NHSCB a valid notice of commencement, in the correct form, informing the NHSCB that P is to commence the provision of the services in respect of which the application was made and at the premises to which the application related in the next 14 days.

(3) A notice of commencement is in the correct form if it—

- (a) includes the information required under paragraph 29; and
- (b) is in the same format as the version of the notice sent by the NHSCB with the notice of decision under paragraph 28.

(4) A notice of commencement is invalid unless it is sent to the NHSCB within—

- (a) if, prior to the NHSCB determining the application—
 - (i) P undertook to commence the provision of the services in respect of which the application was made within a period of less than 6 months, and
 - (ii) that undertaking was not withdrawn, that period;
- (b) 6 months of—
 - (i) unless paragraph (a) applies, the date on which P was sent the notice of the NHSCB’s decision under paragraph 28 granting the application,
 - (ii) if the grant was appealed by a person with third party appeal rights, the date on which that appeal is determined by the Secretary of State,
 - (iii) if, in the course of granting the application, a decision is taken to impose a condition in accordance with regulation 35 and that condition is appealed by P, the date on which that appeal is determined by the First-tier Tribunal (unless regulation 35(8) applies),
 - (iv) if the grant of the application was subject to a condition imposed by virtue of paragraph 31, the date on which—

- (aa) P validly notifies to the NHSCB under a condition imposed by virtue of paragraph 31 of the address of the premises, or
- (bb) if P appeals successfully against a decision of the NHSCB that a notification under a condition imposed by virtue of paragraph 31 is invalid, that appeal is determined by the Secretary of State,
- (v) if P, pursuant to paragraph 32—
 - (aa) notifies the NHSCB of a new address,
 - (bb) the NHSCB does not accept the validity of the notification, and
 - (cc) P appeals successfully against that decision,
 the date on which that appeal is determined by the Secretary of State, or
- (vi) if the grant of the application was subject to a condition imposed by virtue of paragraph 33, the date on which the condition imposed by virtue of that paragraph becomes spent or is removed on appeal, or
whichever is the latest; or
- (c) such longer period—
 - (i) not exceeding a further 3 months as the NHSCB may allow, or
 - (ii) if—
 - (aa) the grant is appealed by a person with third party appeal rights,
 - (bb) a decision to accept a notification pursuant to paragraph 32 is appealed by a third party,
 - (cc) P appeals successfully against a notice under paragraph 35, or
 - (dd) if P appeals successfully against a decision not to allow a longer period under sub-paragraph (i),
 as the Secretary of State may allow when the appeal is determined,

and so once a valid notice of commencement can no longer be sent in relation to an application (having regard also to paragraph 10(2) of Schedule 3), the grant of that application lapses.

(5) A notice of commencement ceases to have effect if the Secretary of State receives a valid notice of appeal—

- (a) from a person with third party appeal rights relating to the grant to which the notice of commencement relates; or
- (b) from a third party, in a case to which sub-paragraph (4)(c)(ii)(bb) applies.

Notice requiring the commencement of pharmaceutical services

35.—(1) The NHSCB, having granted a routine application—

- (a) for inclusion in a pharmaceutical list by a person (P) not already included; or
- (b) if P is already included in a particular pharmaceutical list, for inclusion in that list also in relation to premises not already listed in relation to P,

may, if the grant has not lapsed and is not under appeal to the Secretary of State, give notice to P requiring P to commence the provision of pharmaceutical services by a date specified in the notice.

(2) If the NHSCB gives notice under sub-paragraph (1) but afterwards a valid notice of appeal is given against the grant, the notice under sub-paragraph (1) lapses.

(3) A notice under sub-paragraph (1) may not specify a date that is—

- (a) earlier than 30 days from the date of the notice under that paragraph; or
- (b) later than 9 months after the date on which the grant of the application was notified to P.

(4) The NHSCB may change its pharmaceutical list to give effect to that notice—

- (a) on the specified date, unless the decision to give notice under sub-paragraph (1) is appealed; or
- (b) if the notice under paragraph (1) is appealed and the appeal is unsuccessful or discontinued—
 - (i) if the appeal is discontinued, 30 days after P discontinues the appeal,
 - (ii) if the appeal is unsuccessful, 30 days after the appeal is determined, or
 - (iii) on the specified date,
 whichever is the latest.

Appeals to the Secretary of State by the applicant

36.—(1) As regards any routine or excepted application, other than an application pursuant to regulation 29, the applicant (A) may appeal to the Secretary of State against a decision by the NHSCB—

- (a) to refuse the application on grounds set out in Parts 3 to 5 or 7 of these Regulations;
- (b) that a notification pursuant to a condition imposed by virtue of paragraph 31 is invalid;
- (c) to refuse to accept that a notification under paragraph 32(2) is a valid notification;
- (d) to impose or vary a condition imposed pursuant to paragraph 33;
- (e) to refuse to allow A an extension period under paragraph 34(4)(c)(i); or
- (f) to give notice under paragraph 35,

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

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

SCHEDULE 3 Regs 10(8), 45(3), 63(6), 77(4), 98(9)

Appeals to the Secretary of State

PART 1

Preliminary matters

Determination of third party appeal rights in certain cases

1.—(1) If the Secretary of State has received a notification under paragraph 30(6) of Schedule 2 from a person (P1), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P1 is to have third party appeal rights on the basis that—

- (a) P1 is a person to whom paragraph 30(3)(a) and (b) of Schedule 2 applies; and
- (b) in relation to P1, the NHSCB should have been satisfied as mentioned in paragraph 30(3)(c) of Schedule 2.

(2) If the Secretary of State has received a notification under regulation 63(5) from a person (P2), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P2 is to have third party appeal rights on the basis that—

- (a) P2 is a person to whom regulation 63(3)(a) and (b) applies; and
- (b) in relation to P2, the NHSCB should have been satisfied as mentioned in regulation 63(3)(c).

(3) Once the Secretary of State has made a determination under paragraph (1) or (2), the Secretary of State must notify the NHSCB and P1 or P2 of that determination and the reasons for it.

Misconceived appeals

2. If the Secretary of State, after considering a valid notice of appeal under regulation 45, 63 or 77, or paragraph 30, 32(5) or 36 of Schedule 2 against a decision, is of the opinion that the notice—

- (a) contains no valid grounds of appeal (for example, because it amounts to a challenge to the legality or reasonableness of a HWB's or Primary Care Trust's pharmaceutical needs assessment, or to the fairness of the process by which the HWB or a Primary Care Trust undertook that assessment); or
- (b) contains no reasonable grounds for appeal (for example, where it is vexatious or frivolous),

the Secretary of State may determine the appeal by dismissing it (without proceeding to notify the appeal under Part 2).

PART 2

Notification of appeals

Notification of appeals notices under paragraph 30, 32(5) or 36 of Schedule 2

3.—(1) Unless the Secretary of State determines the appeal under paragraph 2, or the appeal relates to an application pursuant to regulation 23, the Secretary of State must send a copy of a valid notice of appeal sent under paragraph 30, 32(5) or 36 of Schedule 2 to—

- (a) the NHSCB;
- (b) in the case of an appeal against the grant of an application, any person who was entitled to receive notification of the decision by virtue of paragraph 28(5) of Schedule 2;
- (c) in the case of an appeal in relation to a notifiable application, including against decisions as mentioned in paragraphs 32(4) and 36(1)(b) to (f) of Schedule 2—
 - (i) the applicant (unless they are the person bringing the appeal),
 - (ii) any person who was notified in relation to that application under paragraph 19 of Schedule 2 who made representations in writing about the application under paragraph 19(4) of that Schedule (unless they are also the person bringing the appeal), and
- (d) in the case of an appeal in relation to an application pursuant to regulation 26(1), 27 or 28 (including against decisions as mentioned in paragraph 36(1)(d) to (f) of Schedule 2), any person notified in relation to the decision on that application under paragraph 28(3)(c) or (4).

(2) Any person to whom a notice of appeal is sent under sub-paragraph (1) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they are sent the notice of appeal by the Secretary of State.

Notification of appeals relating to notices under regulation 45

- 4.—(1) A valid notice of appeal under regulation 45(1)(b) does not need to be notified to others.
- (2) The Secretary of State must send a valid notice of appeal—
- (a) against a determination under regulation 36(2) to the persons given notice of the proposed determination under regulation 38(1) or (2); or
 - (b) against a determination under regulation 41(2) or 42(1) to—

- (i) the person making the routine application to which the determination relates, and
- (ii) any person given notice of the determination who is mentioned in regulation 43(1)(b)(ii),

unless they are the person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

Notification of appeals relating to decisions under Part 8 of these Regulations

5.—(1) A valid notice of appeal under regulation 63(1)(a) does not need to be notified to others.

(2) The Secretary of State must send a valid notice of appeal against—

- (a) a decision mentioned in regulation 63(1)(b) to the persons, other than the appellant, given notice of the decision under regulation 50(6); or
- (b) a decision or determination mentioned in regulation 63(1)(c) to (f) to—
 - (i) the person who made the original application for outline consent or premises approval,
 - (ii) any person who was notified in relation to that application under regulation 52(1) to (3) who made representations in writing about the application under regulation 52(4), and
 - (iii) if the appeal is against a refusal to grant temporary premises approval, the applicant who made the relevant outstanding pharmacy application,

unless they are person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

Non notification of appeals relating to notices under regulation 77 or 98

6. A valid notice of appeal under regulation 77 or 98 does not need to be notified to others.

PART 3

Determination of appeals

Flexibility with regard to the manner of determining appeals

7.—(1) Except in so far as these Regulations provide to the contrary, the Secretary of State is to determine the appeal to which a valid notice of appeal under regulation 45, 63 or 77, or under paragraph 30, 32(5) or 36 of Schedule 2, relates in such manner (including with regard to procedures) as the Secretary of State sees fit.

(2) The Secretary of State may determine the appeal without hearing any oral representations, if the Secretary of State considers that oral representations are unnecessary.

(3) Where appropriate, the Secretary of State may, if the Secretary of State thinks fit, consider 2 or more appeals together and in relation to each other, but where the Secretary of State does so, the Secretary of State must give notice of the Secretary of State's intention to do so to—

- (a) the NHSCB;
- (b) the appellants; and
- (c) any other person notified in relation to the appeals under Part 2.

Oral hearings

8.—(1) If the Secretary of State does decide to hear oral representations, the Secretary of State must give not less than 14 days notice of the time and place at which the oral representations are to be heard to—

- (a) the NHSCB;
- (b) the person who made the original application to which the appeal relates;
- (c) if a person other than that applicant is bringing the appeal, the person bringing the appeal;
- (d) any Local Pharmaceutical Committee whose area includes all or part of the area, or in whose area is the location or are the premises, to which the decision relates;
- (e) any Local Medical Committee whose area includes all or part of the area, or in whose area is the location or are the premises, to which the decision relates; and
- (f) any additional presenters,

and they (or their duly authorised representatives) are to be the only persons entitled to make oral representations at the hearing.

(2) For these purposes, a person (P) is an “additional presenter” if—

- (a) P was notified of the appeal under Part 2 and has made written representations in accordance with paragraph 3(2), 4(3) or 5(3), which—
 - (i) indicated that, if there were to be an oral hearing in relation to the appeal, P would wish to make oral representations at that hearing, and
 - (ii) identified a matter about which the Secretary of State considers it would be desirable to hear further evidence from P at the oral hearing; and
- (b) the Secretary of State is satisfied that P made a reasonable attempt to express P’s views on the appeal adequately in P’s written representations.

Decisions of the Secretary of State

9.—(1) On determining an appeal relating to a valid notice under paragraph 30 or 36, the Secretary of State may—

- (a) if the appeal is an appeal to which paragraph 30 or 36(1)(a) of Schedule 2 applies (that is, against a decision to grant or refuse a routine or excepted application)—
 - (i) confirm the decision of the NHSCB,
 - (ii) quash the decision and redetermine the application, or
 - (iii) quash the decision and remit the matter to the NHSCB for it to redetermine the application, where the Secretary of State considers that there should be a (further) notification under paragraph 19 of Schedule 2, subject to such directions as the Secretary of State considers appropriate; or
- (b) if the appeal is an appeal to which paragraph 32(5) or 36(1)(b) to (f) applies—
 - (i) confirm the decision of the NHSCB, or
 - (ii) substitute for that decision any decision that the NHSCB could have taken when it took that decision.

(2) If the Secretary of State grants or confirms the grant of a routine application, the Secretary of State may direct the NHSCB—

- (a) to impose a condition under paragraph 33, in circumstances where the NHSCB could have imposed such a decision if it had granted the application; or
- (b) to take such action under regulation 50(4) or (5) as the Secretary of State thinks fit.

(3) On determining an appeal relating to a valid notice under regulation 45, the Secretary of State may—

- (a) confirm the decision or determination of the NHSCB;

- (b) substitute for that decision or determination any decision or determination that the NHSCB could have taken when it took that decision or made that determination; or
 - (c) quash the decision or determination of the NHSCB and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate.
- (4) On determining an appeal relating to a valid notice under regulation 63, the Secretary of State may—
- (a) in the case of decision or determination mentioned in regulation 63(1)(a), (b), (e) or (f)—
 - (i) confirm the decision or determination of the NHSCB,
 - (ii) substitute for that decision or determination any decision or determination that the NHSCB could have taken when it took that decision or made that determination, or
 - (iii) quash the decision or determination of the NHSCB and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate; or
 - (b) if the appeal is against a decision to grant or refuse an application for outline consent or premises approval—
 - (i) confirm the decision of the NHSCB,
 - (ii) quash the decision of the NHSCB and redetermine the application, or
 - (iii) quash the decision of the NHSCB and remit the matter to it for it to redetermine the application, subject to such directions as the Secretary of State considers appropriate.
- (5) On determining an appeal relating to a valid notice under regulation 77, the Secretary of State may—
- (a) confirm the decision of the NHSCB; or
 - (b) substitute for that decision any decision that the NHSCB could have taken when it took that decision.
- (6) If the Secretary of State grants or confirms the grant of an application for—
- (a) outline consent, the Secretary of State may direct the NHSCB to take such action under regulation 53(3) as the Secretary of State thinks fit; or
 - (b) premises approval, the Secretary of State may direct the NHSCB to take such action under regulation 57 as the Secretary of State thinks fit.

Notification of decisions and subsequent action by the NHSCB

10.—(1) Once the Secretary of State has determined the appeal, the Secretary of State must notify the following—

- (a) the NHSCB;
- (b) the person who made the original application to which the appeal relates;
- (c) if a person other than that person brought the appeal, the person who brought the appeal; and
- (d) any person who made written representations relating to the application pursuant to the notification under Part 2,

and must include with that notification a statement of the reasons for the Secretary of State's decision and the Secretary of State's findings of fact.

(2) If the Secretary of State has granted or confirmed the grant of a routine or excepted application—

- (a) the NHSCB must send to the applicant a template of the notice of commencement referred to in paragraph 29; and

- (b) the time periods in paragraphs 31, 32 and 34 thereafter apply as if the references to the applicant being sent notices of the NHSCB's decision were reference to the applicant being notified by the Secretary of State under paragraph (3).
- (3) If the Secretary of State has granted or confirmed the grant of—
 - (a) a routine application, the NHSCB must proceed as soon as is practicable to take such action under regulation 50(4) or (5) as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(2)(b);
 - (b) an application for outline consent, the NHSCB must proceed as soon as is practicable to make a determination under regulation 53(3), subject to any directions of the Secretary of State under paragraph 9(6)(a); or
 - (c) an application for premises approval, the NHSCB must proceed as soon as is practicable take such action under regulation 57 as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(6)(b).

Effect of decisions by the Secretary of State

11. For the purposes of these Regulations, the Secretary of State's decision becomes the NHSCB's decision on the matter (but no further appeal to the Secretary of State on that decision is possible), unless the Secretary of State's decision is overruled by a court.

SCHEDULE 4

Regulation 11(1)(a)(i)

Terms of service of NHS pharmacists

PART 1

General

Responsibilities of NHS pharmacists and pharmacy staff

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

- (a) if the NHS pharmacist is a registered pharmacist—
 - (i) that NHS pharmacist must comply with that requirement, or
 - (ii) if the NHS pharmacist employs or engages natural persons in connection with the provision of pharmaceutical services, the NHS pharmacist must either comply with that requirement or secure compliance with that requirement by—
 - (aa) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or
 - (bb) in other cases, by the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services; or
 - (b) if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—
 - (i) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or
 - (ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.
- (2) Where in this Schedule reference is made to an NHS pharmacist—

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

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

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

Breaches by directors and superintendents

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

PART 2

Essential services

Essential services

3. For the purposes of these Regulations, "essential services" means—

- (a) the services described in this Part; and
- (b) the activities described in this Part to be carried out in connection with those services.

Dispensing services

4. An NHS pharmacist must, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting prescriptions for drugs or appliances ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of drugs and appliances

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

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

- (a) any person presents to an NHS Pharmacist (P) a non-electronic prescription form which contains—
 - (i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations^(a) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference "SLS", or
 - (iii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; or
- (b) subject to sub-paragraph (4), P receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—

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

- (i) any person requests the provision of drugs or appliances in accordance with that prescription, or
- (ii) P has previously arranged with the patient that P will dispense that prescription on receipt,

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

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

- (a) any person presents to P a non-electronic repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(a), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference “SLS”,
 - (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber, or
 - (iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference “SLS”,

and also presents an associated batch issue; or

- (b) P receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or
 - (ii) P has previously arranged with the patient that P will dispense that repeatable prescription on receipt,

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

(4) P must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

(5) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) P has that prescription in P’s possession; and
- (b) that person presents, or P has in P’s possession, an associated batch issue.

Urgent supply without a prescription

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

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

- (a) in the case of a request for a drug, the drug is neither—

(a) 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.
 (b) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

- (i) a Scheduled drug, nor
 - (ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to—
- (i) give P a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or
 - (ii) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

Preliminary matters before providing ordered drugs or appliances

- 7.—(1) If a person specified in sub-paragraph (2) asks an NHS pharmacist (P) to do so—
- (a) P must give an estimate of the time when the drugs or appliances will be ready; and
 - (b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are ready).
- (2) A person specified in this sub-paragraph is a person—
- (a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or
 - (b) requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.
- (3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, P must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations^(a) (supply of drugs and appliances by chemists) by virtue of either—
- (a) entitlement to exemption under regulation 7(1) of the Charges Regulations^(b) (exemptions); or
 - (b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations^(c) (entitlement to full remission and payment),

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

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

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

- (a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—
 - (i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and

(a) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.

(b) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.

(c) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

- (ii) whether or not satisfactory evidence was produced to P as required by sub-paragraph (3);
- (b) in any case where a charge is due, confirmation that the relevant charge was paid; and
- (c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Providing ordered drugs or appliances

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

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 5(2) or (3); and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(a) and the following provisions of this Part.

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

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

- (a) who is disqualified from inclusion in a relevant list; or
- (b) who is suspended from the GPhC register.

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

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

(5) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with any relevant standard or formula specified therein.

(6) If the order—

- (a) is an order for a drug; but
- (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b) (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

and does not prescribe its quantity, strength or dosage, P (in this context, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care P considers to be appropriate and, subject to sub-paragraph (7), in such quantity as P considers to be appropriate for a course of treatment for a period not exceeding 5 days.

(7) Where an order to which sub-paragraph (6) applies is for—

- (a) an oral contraceptive substance;
- (b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs; or

(a) 1985 c.72.

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

- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, P may provide the minimum size available package.

(8) Where any drug to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by P in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile;
- (b) effervescent or hygroscopic;
- (c) a liquid preparation for addition to bath water;
- (d) a coal tar preparation;
- (e) a viscous preparation; or
- (f) packed at the time of its manufacture in a special container,

P must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

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

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

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

(11) In the case of oral liquid methadone, P (in practice, a registered pharmacist) must decide whether it would be most appropriate to provide—

- (a) each dose in a separate container;
- (b) an original pack (or original packs); or
- (c) the oral liquid methadone in some other way,

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

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

- (a) it is ordered as specified in sub-paragraph (13); or
- (b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations^(a) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

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

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

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

- (b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically); and
- (c) the Scheduled drug is not in a pack which consists of a drug in more than one strength, and providing it would involve the supply of part only of the pack.

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

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

Refusal to provide drugs or appliances ordered

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

- (a) P reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because P reasonably believes it has been stolen or forged);
- (b) it appears to P that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to P's (in practice, a registered pharmacist's) clinical judgement;
- (c) P or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person;
- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence; or
- (e) the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—
 - (i) the remuneration of persons providing pharmaceutical services, and
 - (ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

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

(2) P must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

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

- (a) P has no record of that prescription (other than on the first occasion on which the prescription is presented);
- (b) P does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to P;
- (c) it is not signed by a prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;

- (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or
- (h) P has been informed by the prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), P must only provide the drugs or appliances ordered if P is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of, or manner of utilisation of the appliance by, the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

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

- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—
 - (i) to enable them to utilise the drugs or appliances appropriately, and
 - (ii) to meet the patient's reasonable needs for general information about the drugs or appliances;
- (b) provide appropriate advice to patients to whom they provide drugs or appliances on—
 - (i) the safe keeping of the drugs or appliances, and
 - (ii) returning unwanted drugs or appliances to the pharmacy premises for safe destruction;
- (c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need;
- (d) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
 - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
 - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;
- (e) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;
- (f) keep and maintain records—
 - (i) of drugs and appliances provided, in order to facilitate the continued care of the patient;
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under sub-paragraph (e);

- (g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;
- (h) if P takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (i) if P provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;
- (j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
- (k) destroy any surplus batch issues relating to drugs or appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused the drugs or appliances pursuant to paragraph 9;
- (l) ensure that where a person is refused drugs or appliances pursuant to paragraphs 9(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice;
- (m) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;
- (n) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4);
- (o) when providing appliances, provide a patient with a written note of P's name, address and telephone number; and
- (p) when providing specified appliances, comply with the additional requirements set out in paragraph 12.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing services under paragraph 4, P is unable to provide an appliance, or stoma appliance customisation is required and P is unable to provide that, P shall—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to P.

Additional requirements in relation to electronic prescribing

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

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

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

- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; or
- (b) where the person does have a nominated dispensing contractor—
 - (i) a replacement dispensing contractor, or
 - (ii) a further dispensing contractor, chosen by that person.

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

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

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

- (a) explain to X that the ownership of the pharmacy premises has changed; and
- (b) ask X whether X wishes to maintain the nomination in respect of those pharmacy premises.

Additional requirements in relation to specified appliances

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

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

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

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

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

(4) If P is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), P must give the patient the contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to P.

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

- (a) advice is made available to patients through that telephone care line; or
- (b) the telephone number of NHS Direct National Health Service Trust^(a), or the website address of NHS Direct National Health Service Trust on line, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

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

(a) Established by S.I. 2007/478.

“out of hours periods”, in relation to pharmacy premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

Disposal service in respect of unwanted drugs

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

Basic procedure in respect of unwanted drugs

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

- (a) a private household; or
- (b) a children’s home; or
- (c) a residential care home, that is to say an establishment which exists wholly or mainly for the provision of residential accommodation, together with board and personal care, for persons in need of personal care because of—
 - (i) old age,
 - (ii) mental or physical disability,
 - (iii) past or present dependence on alcohol or drugs,
 - (iv) any past illnesses, or
 - (v) past or present mental disorder,

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

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

(3) On receipt of the drugs, P must—

- (a) where required to do so by the NHSCB or by a waste disposal contractor retained by the NHSCB, separate solid drugs or ampoules, liquids and aerosols from each other;
- (b) store the drugs in containers provided by the NHSCB, or by a waste disposal contractor retained by the NHSCB, for the purpose of storing drugs of that description; and
- (c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

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

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

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

- (a) ensure that P (including P’s staff) is aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks; and
- (b) ensure that P (including P’s staff) has readily available, and close to any place where waste drugs are stored, appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

Promotion of healthy lifestyles

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

Prescription linked intervention

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

- (a) presents a non-electronic prescription form or non-electronic repeatable prescription to an NHS pharmacist (P) or requests the provision of drugs or appliances in accordance with an electronic prescription; and
- (b) it appears to P that the person—
 - (i) has diabetes,
 - (ii) is at risk of coronary heart disease, especially those with high blood pressure, or
 - (iii) smokes or is overweight,

P must, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

- (a) by the provision of written material (for example leaflets); and
- (b) by referring the person to other sources of information or advice.

(3) P must, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record must be in a form that facilitates—

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

Public health campaigns

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

- (a) P (including P's staff) participates, in the manner reasonably requested by the NHSCB, in up to 6 campaigns in each calendar year to promote public health messages to users of P's pharmacy;
- (b) where requested to do so by the NHSCB, P records the number of people to whom P (including P's staff) has provided information as part of one of those campaigns.

Signposting

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

Service outline in respect of signposting

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

- (a) requires advice, treatment or support that P cannot provide; but
- (b) another provider, of which P is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

P must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

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

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

- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to P.

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

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

- (a) auditing of the provision of pharmaceutical services by P; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Support for self-care

21. An NHS pharmacist must, to the extent paragraph 22 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

Service outline in respect of support for self-care

22.—(1) Where it appears to an NHS pharmacist (P), having regard to the need to minimise the inappropriate use of health and social care services, that a person (X) using P's pharmacy would benefit from advice from P to help X manage a medical condition (including, in the case of a carer, to help X in assisting in the management of another person's medical condition), P must provide advice to X as regards managing the medical condition, including, as appropriate, advice—

- (a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and
- (b) on changes to the patient's lifestyle.

(2) P must, in appropriate cases, keep and maintain a record of any advice given under subparagraph (1), and of any drugs supplied when the advice was given, and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by P; and
- (b) follow-up care for the person to whom or in respect of whom the advice has been given.

PART 3

Hours of opening

Pharmacy opening hours: general

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

- (a) for 40 hours each week;
- (b) for not less than 100 hours each week, in the case of premises in respect of which a 100 hours condition applies;
- (c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 40 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;
- (d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for

more than 40 hours per week, and at set times and on set days, at the times and on the days so set; or

- (e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 40 hours each week, but only on set times and on set days as regards the additional opening hours—
 - (i) for the total number of hours each week required by virtue of that direction, and
 - (ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction,

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

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

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

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

- (a) a notice specifying the days on which and times at which the premises are open for the provision of drugs and appliances (including times at which P is providing pharmaceutical services during supplementary opening hours); and
- (b) at times when the premises are not open, a notice based on information provided by the NHSCB, where practicable legible from outside the premises, specifying—
 - (i) the addresses of other NHS pharmacists and the days on which and times at which drugs and appliances may be obtained from those addresses, and
 - (ii) the addresses of LPS chemists in the area, the type of local pharmaceutical services which those LPS chemists provide, and the days on which and times at which their premises are open.

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

- (a) the days on which and times at which pharmaceutical services are provided at P’s pharmacy premises (including times at which P is providing pharmaceutical services during supplementary opening hours); and
- (b) the pharmaceutical services which P ordinarily provides at those premises.

(6) Where P changes—

- (a) the supplementary opening hours of P’s pharmacy premises; or
- (b) the pharmaceutical services which P ordinarily provides at those premises,

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

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

- (a) P must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the times set out in the notification (unless the notification has been superseded by a return, or a further return, under sub-paragraph (6)); and
- (b) P must not change—
 - (i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours which are neither additional opening hours

nor in total less than 40 (if those core opening hours are additional opening hours, or are in total less than 40, regulation 65(5) to (7) and paragraphs 25 and 26 apply),

- (ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 25 and 26 apply to changes to the total number of core opening hours),
 - (iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or
 - (iv) the pharmaceutical services which P is ordinarily to provide at those premises,
- for a period of at least 3 months after that notification was received by the NHSCB (or, before the appointed day, a Primary Care Trust), unless the NHSCB agrees otherwise.

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

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

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

- (a) P notifies the NHSCB of that suspension as soon as practical; and
- (b) P uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

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

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

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

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

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

- (2) In considering the matters mentioned in sub-paragraph (1), the NHSCB—
- (a) must treat any local pharmaceutical services being provided in its area as if they were pharmaceutical services being so provided; and
 - (b) may have regard to any pharmaceutical services that are being provided in its area during supplementary opening hours.

(3) The NHSCB may only direct that an NHS pharmacist (P) may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in its area is likely to be adequate to meet the need for such services at times when P is not providing pharmaceutical services.

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

Determination of pharmacy premises core opening hours instigated by the NHSCB

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

- (a) people in its area; or
- (b) other likely users of the pharmacy premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS pharmacist (P) whose premises they are to provide pharmaceutical services at the pharmacy premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the NHSCB must—

- (a) give notice to P of any proposed changes to the days on which or times at which the pharmacy premises are to be open; and
- (b) allow P 30 days within which to make written representations to the NHSCB about the proposed changes.

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

- (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
- (b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5); or
- (c) either—
 - (i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or
 - (ii) in a case where there is no existing direction, issue no direction,in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

(4) Where the NHSCB issues a direction under sub-paragraph (3) in respect of pharmacy premises that are to be required to be open—

- (a) for more than 40 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which P must provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional opening hours, the days on which and the times at which P is required to provide those services during those hours,but it must not set out in that direction the days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening hours; or

(b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at the pharmacy premises.

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

(6) The NHSCB must notify P of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which P is to provide pharmaceutical services at pharmacy premises, it must include with the notification a statement of—

- (a) the reasons for the change; and
- (b) P's right of appeal under paragraph (7).

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

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

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

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

- (a) if P has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (6); or
- (b) if P has appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (9).

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

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

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

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

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

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

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

- (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (5) and (6); or

(c) either—

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

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

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

(5) Where the NHSCB issues a direction under sub-paragraph (4) in respect of pharmacy premises that are to be required to be open—

(a) for more than 40 hours each week, it must set out in that direction—

(i) the total number of hours each week for which P must provide pharmaceutical services at the pharmacy premises, and

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

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

(b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at the pharmacy premises.

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

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

(8) The NHSCB must notify P of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send P a statement setting out—

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

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

(9) P may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under sub-paragraph (4).

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

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

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

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

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

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

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

- (a) P gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by P for the request are, in the opinion of the NHSCB, adequate reasons.

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

PART 4

Other terms of service

Clinical governance

28.—(1) An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is “acceptable” if it is considered acceptable by the NHSCB and comprises the following components—

- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that P produces in an approved manner, and makes available in an appropriate manner, a practice leaflet containing approved particulars in respect of P’s pharmacy premises,
 - (ii) a requirement that the pharmacist publicises the essential services and any advanced services that are available at or from the pharmacist’s pharmacy,
 - (iii) a requirement that where a pharmacist publicises the essential services or any directed services that are available at or from the pharmacist’s pharmacy (whether the pharmacist is producing their own publicity material or advertising services in material published by another person), the pharmacist does so in a manner which makes clear that the services are funded as part of the health service,
 - (iv) a requirement that P undertakes an approved patient satisfaction survey annually, in an approved manner,
 - (v) P’s monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
 - (vi) a requirement that P co-operates appropriately with any reasonable inspection or review that the NHSCB or any relevant statutory authority wishes to undertake, and
 - (vii) P’s monitoring arrangements in respect of P’s compliance with the Equality Act 2010(a);
- (b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one other audit agreed by the NHSCB in each financial year;

(a) 2010 c. 15.

- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock is procured and handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,
 - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State^(a) and the NHSCB,
 - (v) appropriate standard operating procedures, including standard operating procedures in respect of dispensing drugs and appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (vi) appropriate waste disposal arrangements (in addition to those required under Part 2) for clinical and confidential waste,
 - (vii) a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or who is the pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,
 - (viii) appropriate safeguarding procedures for service users,
 - (ix) P's monitoring arrangements in respect of P's compliance with the Health and Safety at Work etc. Act 1974^(b);
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by P—
- (i) in respect of the provision of drugs in accordance with a repeatable prescription,
 - (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
 - (iii) to people caring for themselves or their families,
- and arrangements for ensuring that P, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 10(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question;
- (e) a staffing and staff management programme, which includes—
- (i) arrangements for appropriate induction for staff (including locums),
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services, including continuing professional development for registered pharmacists and registered pharmacy technicians, and any necessary accreditation in respect of the provision of directed services,
 - (v) arrangements for addressing poor performance (in conjunction with the NHSCB as appropriate), and

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

(b) 1974 c. 37.

- (vi) arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist—
 - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996^(a) (meaning of protected disclosure) have the rights afforded in respect of such disclosures by that Act, and
 - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to the NHSCB which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;
- (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment; and
- (g) a premises standards programme, which includes—
 - (i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of health care acquired infection is minimised, and
 - (ii) arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive health care,

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

Professional Standards

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

Inducements etc.

30.—(1) An NHS pharmacist (P) (including P’s staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of P’s business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

- (a) presenting an order for drugs or appliances on a prescription form or repeatable prescription, non-electronic prescription form or non-electronic repeatable prescription;
- (b) nominating P as X’s dispensing contractor (or one of them) in X’s PDS patient details; or
- (c) receiving from P any directed services.

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

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

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

- (a) is supplied as part of the provision of any directed service to that patient;
- (b) is directly related to that directed service;
- (c) is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient's family of a healthy lifestyle; and
- (d) in the case of a gift which—
 - (i) is not a medicine, has a monetary value not exceeding £10, or
 - (ii) is a medicine, is supplied as part of the provision of a minor ailments service.

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

- (a) present to P an order for drugs or appliances on a prescription form or repeatable prescription;
- (b) nominate P as their dispensing contractor (or one of them) in their entry in their PDS patient details; or
- (c) ask P to provide them with any directed service.

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

- (a) any NHS body or provider of primary medical services; and
- (b) any person employed or engaged by any of the persons mentioned in paragraph (a).

(6) In the case of the provision of appliances, P (including P's staff) must not accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 12(4) or 20(2)(b); or
- (b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 10(2)(a) or 20(2)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness matters as they arise

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

- (a) are convicted of any criminal offence in the United Kingdom;
- (b) are bound over following a criminal conviction in the United Kingdom;
- (c) accept a police caution in the United Kingdom;
- (d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);
- (e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(a) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(b) (penalty as alternative to prosecution);

(a) 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; 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).

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

- (f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (h) are notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them;
- (i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;
- (j) become the subject of any investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;
- (k) become the subject of any investigation by the NHS BSA in relation to fraud;
- (l) become the subject of any investigation by another primary care organisation which might lead to their removal from a relevant list; or
- (m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

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

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

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) becomes the subject of any investigation by the NHS BSA in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;
- (g) becomes the subject of any investigation by another primary care organisation which might lead to its removal from any relevant list; or
- (h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) P or X must consent to a request being made by the NHSCB to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Other information to be supplied

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

- (a) any occurrence requiring a change in the information recorded about P in the pharmaceutical list which P has not otherwise notified to the NHSCB in accordance with these Regulations;
- (b) if P is an individual, any change to P's private address;
- (c) if P is a body corporate, any change to the name, registration number, registered office or telephone number relating to that office of the body corporate; and
- (d) any occurrence requiring P's addition to or removal from an EPS list or a change in the information recorded about P in that list.

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

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

- (a) the names of its directors; and
- (b) the name or address of its superintendent.

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

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

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

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

Co-operation with Health Education England

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

Complaints

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

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

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

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

Inspections and access to information

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

- (a) ascertaining whether or not P is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by P, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and
 - (ii) the management by P of the pharmaceutical services P provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the pharmacy premises are situated have been invited to be present at the inspection, where this is requested by P;
- (c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and
- (d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

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

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

SCHEDULE 5

Regulation 11(2)(a)(i)

Terms of service of NHS appliance contractors

Division of responsibilities between individuals and corporate bodies

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

- (a) if the NHS appliance contractor is a natural person—
 - (i) that person must comply with that requirement, or
 - (ii) if the NHS appliance contractor employs or engages other natural persons in connection with the provision of pharmaceutical services, the NHS appliance contractor must either comply with that requirement or secure compliance with that requirement by the other natural persons whom the NHS appliance contractor employs or engages; or
- (b) if the NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by the natural persons whom the NHS appliance contractor employs or engages in connection with the provision of pharmaceutical services.

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

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

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

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

Breaches by directors

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

Dispensing services

3. An NHS appliance contractor must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of appliances

4.—(1) In this Part, “signed” includes signature with a prescriber's advanced electronic signature.

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

- (a) any person presents to an NHS appliance contractor (C) a non-electronic prescription form which contains—
 - (i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
 - (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”; or
- (b) C receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) and (ii) and—
 - (i) any person requests the provision of an appliance in accordance with that prescription, or
 - (ii) C has previously arranged with the patient that C will dispense that prescription on receipt,

C must, with reasonable promptness, provide the appliance so ordered if C supplies it in the normal course of business.

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

- (a) any person presents to C a non-electronic repeatable prescription which contains—
 - (i) an order for appliances, not being restricted availability appliances, signed by a prescriber, or
 - (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”,and also presents an associated batch issue; or
- (b) C receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) or (ii) and—
 - (i) any person requests the provision of appliances in accordance with that prescription, or
 - (ii) C has previously arranged with the patient that the supplier will dispense that prescription on receipt,

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

(4) For the purposes of this paragraph, a non-electronic repeatable prescription for appliances shall be taken to be presented even if the person who wishes to obtain the appliances does not present that prescription, where—

- (a) C has that prescription in the supplier's possession; and
- (b) that person presents, or C has in C's possession, an associated batch issue.

Urgent supply without a prescription

5.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS appliance contractor (C) to provide an appliance.

(2) C may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to—

- (a) give C a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made; or
- (b) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

Preliminary matters before providing appliances

6.—(1) If a person specified in sub-paragraph (2) asks an NHS appliance contractor (C) to do so—

- (a) C must give an estimate of the time when the appliance will be ready; and
- (b) if it is not ready by then, P must give a revised estimate of the time when it will be ready (until it is ready).

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

- (a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or
- (b) requesting the provision of appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

(3) Before providing an appliance in accordance with a prescription form or repeatable prescription—

- (a) C must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations^(a) (supply of drugs and appliances by chemists) by virtue of either—
 - (i) entitlement to exemption under regulation 7(1) of the Charges Regulations^(b) (exemptions), or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations^(c) (entitlement to full remission and payment),

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

(a) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.

(b) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.

(c) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

- (b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by paragraph (a), is produced to C, C must endorse the form on which the declaration is made to that effect; and
- (c) in the case of an electronic prescription form or an electronic repeatable prescription, C must transmit to the Electronic Prescription Service—
 - (i) in a case where exemption from or remission of charges is claimed, a record of—
 - (aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case; and
 - (bb) whether or not satisfactory evidence was produced to C as required by subparagraph (a), and
 - (ii) in any case where a charge is due, confirmation that the relevant charge was paid.

Providing appliances

7.—(1) Where an NHS appliance contractor (C) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, C must only provide the appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4; and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985^(a) and the following provisions of this Schedule.

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

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

(3) If the order is for an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided must comply with the standard or formula specified therein.

Refusal to provide appliances ordered

8.—(1) An NHS appliance contractor (C) may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) C reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription (for example because C reasonably believes it has been stolen or forged);
- (b) it appears to C that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the appliance would be contrary to C's clinical judgement;
- (c) C or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with an electronic prescription form or repeatable prescription, or by any person accompanying that person;

(a) 1985 c. 72.

- (d) the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence; or
- (e) the prescription form or repeatable prescription is incomplete because it does not include information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—
 - (i) the remuneration of persons providing pharmaceutical services, and
 - (ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,
 unless C (or the person who employs or engages C) is to receive no pharmaceutical remuneration of any kind in respect of the appliances.

(2) C must refuse to provide appliances ordered on a repeatable prescription where—

- (a) C has no record of that prescription (other than on the first occasion on which the prescription is presented);
- (b) C does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to the supplier;
- (c) it is not signed by a prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time an appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;
- (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or
- (h) C has been informed by the prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), C must only provide the appliance ordered if C is satisfied that—

- (a) the patient to whom the prescription relates—
 - (i) is using and is likely to continue to use the appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient's treatment;
- (b) the manner of utilisation of the appliance by the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

9.—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor (C) must—

- (a) ensure that appropriate advice is given to patients about any appliances provided to them—
 - (i) to enable them to utilise the appliances appropriately, and
 - (ii) to meet the patient's reasonable needs for general information about the appliances;
- (b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances;

- (c) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
 - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
 - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;
- (d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available;
- (e) provide a patient with a written note of C's name, address and telephone number;
- (f) keep and maintain records—
 - (i) of appliances provided, in order to facilitate the continued care of the patient,
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescription), and
 - (iii) of notes provided under paragraph (d);
- (g) undertake appropriate training in respect of repeat dispensing having regard to any recommendations in respect of such training set out in the Drug Tariff;
- (h) if C takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (i) if C provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;
- (j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
- (k) destroy any surplus batch issues relating to appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused an appliance pursuant to paragraph 8;
- (l) ensure that where a person is refused appliances pursuant to paragraph 8(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;
- (m) where a patient is provided with appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;
- (n) notify the prescriber of any refusal to provide appliances pursuant to paragraph 8(4); and
- (o) when providing specified appliances, comply with the additional requirements set out in paragraph 11.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, C is unable to provide an appliance, or stoma appliance customisation is required and C is unable to provide that, C must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to C.

Additional requirements in relation to electronic prescribing

10.—(1) An NHS appliance contractor (C) must, if requested to do so by any person—

- (a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through C's appliance contractor premises; and
 - (b) where the Electronic Prescription Service is not available through C's appliance contractor premises, provide that person with the names of at least 2 NHS appliance contractors through whom the Electronic Prescription Service is available, if these details are known to C.
- (2) Where the Electronic Prescription Service is available through C's appliance contractor premises, C must, if requested to do so by any person, enter in that person's PDS patient details—
- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; or
 - (b) where the person does have a nominated dispensing contractor—
 - (i) a replacement dispensing contractor, or
 - (ii) a further dispensing contractor, chosen by that person.
- (3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors would thereby exceed the maximum number permitted by the Electronic Prescription Service.
- (4) Regulation 116(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.
- (5) If C is a nominated dispensing contractor for a person (X) but the nomination was made before C became the person listed in a pharmaceutical list in relation to the appliance contractor premises nominated in X's PDS patient details, C must within 6 months of C becoming the person so listed—
- (a) explain to X that the ownership of the appliance contractor premises has changed; and
 - (b) ask X whether X wishes to maintain the nomination in respect of those appliance contractor premises.

Additional requirements in relation to specified appliances

11.—(1) This paragraph sets out the additional requirements referred to in paragraph 9(1)(o) relating to the provision of specified appliances.

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

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

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

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

(4) If C is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), C must give the patient the contact details of at least 2 people who are NHS pharmacists

or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to C.

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

- (a) advice is made available to patients through that telephone care line; or
- (b) the telephone number of NHS Direct National Health Service Trust^(a), or website address of NHS Direct National Health Service Trust on line, are made available to patients through the telephone care line.

(6) For the purposes of this paragraph—

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

“out of hours periods”, in relation to the appliance contractor premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

Signposting

12.—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor (C) is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within C’s normal course of business, C must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to C.

(2) C must, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by C; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Opening hours: general

13.—(1) An NHS appliance contractor (C) must ensure that pharmaceutical services are provided at C’s appliance contractor premises—

- (a) for not less than 30 hours each week;
- (b) for not less than 100 hours per week, in the case of which a 100 hours condition (originally imposed under the 2005 Regulations) applies;
- (c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 30 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;
- (d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set; or
- (e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 30 hours

(a) Established by S.I. 2007/478.

each week, but only on set times and on set days as regards the additional opening hours—

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

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

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

(3) C must exhibit a notice specifying the days on which and times at which the appliance contractor premises are open for the provision of appliances.

(4) C must, on request, submit a return to the NHSCB setting out—

- (a) the days on which and times at which pharmaceutical services are provided at C’s appliance contractor premises (including times at which C is providing pharmaceutical services when C is not obliged to do so by virtue of sub-paragraph (1), which are referred to in these Regulations as “supplementary opening hours”); and
- (b) the pharmaceutical services which C ordinarily provides at those premises.

(5) Where C changes—

- (a) the supplementary opening hours of C’s appliance contractor premises; or
- (b) the pharmaceutical services which C is ordinarily to provide at those premises,

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

(6) Where C has notified to the NHSCB (or, before the appointed day, a Primary Care Trust) the days on which and the times at which pharmaceutical services are to be provided at C’s appliance contractor premises (for example, in a return under sub-paragraph (4) or (5) or in an application for inclusion in a pharmaceutical list)—

- (a) C must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the time set out in that notification (unless the notification has been superseded by a return, or further return, under sub-paragraph (5)); and

(b) C must not change—

- (i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours that are neither additional opening hours nor in total less than 30 (but if those core opening hours are additional opening hours, or are in total less than 30, regulation 65(5) to (7) and paragraphs 15 and 16 apply,
 - (ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 15 and 16 apply to changes to the total number of core opening hours),
 - (iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or
 - (iv) the pharmaceutical services which P is ordinarily to provide at those premises,
- for a period of at least 3 months after that notification was received by the NHSCB (or, before the appointed day, a Primary Care Trust), unless the NHSCB agrees otherwise.

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

(8) C may only make an arrangement with an LPS chemist under sub-paragraph (7) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which C ordinarily provides.

(9) Where there is a temporary suspension in the provision of pharmaceutical services by C for a reason beyond the control of C, C is not in breach of sub-paragraphs (1) and (6), provided that—

- (a) C notifies the NHSCB of that suspension as soon as practical; and
- (b) C uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(10) Planned refurbishment of appliance contractor premises is neither a “reasonable cause” for the purposes of sub-paragraph (7) nor a “reason beyond the control of C” for the purposes of sub-paragraph (9).

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

(12) In this Schedule, the “additional opening hours”, when they are required, are those hours during which C would not be providing pharmaceutical services, were C subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(e).

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

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

- (2) In considering the matters mentioned in sub-paragraph (1), the NHSCB—
- (a) must treat any local pharmaceutical services being provided in its area at the days and times in question as if they were pharmaceutical services being so provided; and
 - (b) may have regard to any pharmaceutical services that are being provided in its area in circumstances where the person providing the services is not obliged to provide those services.

(3) The NHSCB may only direct that an NHS appliance contractor (C) may provide pharmaceutical services at appliance contractor premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in its area are likely to be adequate to meet the need for such services at times when C is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65 or regulation 65 of the 2012 Regulations (core opening hours conditions), the NHSCB may only direct that C must provide pharmaceutical services at premises for more than 30 hours in any week if it is satisfied that C is to receive reasonable remuneration in respect of the additional opening hours for which C is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(6) in respect of those hours is “reasonable remuneration” for these purposes).

Determination of core opening hours instigated by the NHSCB

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

- (a) people in its area; or
- (b) other likely users of the appliance contractor premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor (C) to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the NHSCB must—

- (a) give notice to C of any proposed changes to the days on which or times at which the appliance contractor premises are to be open; and
- (b) allow C 30 days within which to make written representations to the NHSCB about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the NHSCB must—

- (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
- (b) confirm any existing direction in respect of the times at which C must provide pharmaceutical services at the appliance contractor premises, provided that the existing direction (whether issued under regulation 65, this Schedule, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5);
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which C must provide pharmaceutical services at the premises (whether issued under regulation 65, this Schedule, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(4) Where the NHSCB issues a direction under sub-paragraph (3) in respect of appliance contractor premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which C must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional opening hours for which C is to provide pharmaceutical services, the days on which and the times at which C is required to provide those services during those additional opening hours, but it must not set out in that direction the days on which or times at which C is to provide pharmaceutical services during hours which are not additional opening hours; or
- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The NHSCB must not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The NHSCB must notify C in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises, it must include with the notification a statement of—

- (a) the reasons for the change; and
- (b) C's right of appeal under paragraph (7).

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

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

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

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

- (a) if C has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which C receives notification under sub-paragraph (6); or
- (b) if C has appealed under sub-paragraph (7), not later than 8 weeks after the date on which C receives notification under sub-paragraph (9).

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

Determination of core opening hours instigated by the NHS appliance contractor

16.—(1) An NHS appliance contractor (C) may apply to the NHSCB for it to change the days on which or times at which C is obliged to provide pharmaceutical services at C's premises, in a way that—

- (a) reduces the total number of hours for which C is obliged to provide pharmaceutical services each week (but not any of those required under a 100 hours condition); or
- (b) keeps that total number of hours the same.

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

(3) The NHSCB must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of C in accordance with sub-paragraph (2)).

(4) In determining the application, the NHSCB must—

- (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (b) confirm any existing direction in respect of the times at which C must provide pharmaceutical services at the premises, provided that the existing direction (whether issued under regulation 65, this Schedule, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (5) and (6); or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which C must provide pharmaceutical services at the premises (whether issued under regulation 65, this Schedule, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), where this has the effect of granting the application under this paragraph or granting it only in part, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(5) Where the NHSCB issues a direction under sub-paragraph (4) in respect of appliance contractor premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—

- (i) the total number of hours each week for which C must provide pharmaceutical services at the premises, and
- (ii) as regards the additional opening hours for which C is to provide pharmaceutical services, the days on which and the times at which C is required to provide those services during those additional opening hours,

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

- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) The NHSCB must not issue a direction under sub-paragraph (4) that has the effect simply of requiring appliance contractor premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring appliance contractor premises to be open for either more or less than 30 hours each week).

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

(8) The NHSCB must notify C of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send C a statement setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
- (b) C's right of appeal under sub-paragraph (9).

(9) C may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under sub-paragraph (4).

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

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

- (a) if C has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which C receives notification under sub-paragraph (4); or
- (b) if C has appealed under sub-paragraph (9), not earlier than 30 days after the date on which C receives notification under sub-paragraph (11).

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

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

17.—(1) Notwithstanding the provisions of paragraphs 13 to 16, during an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from an NHS appliance contractor (C), permit C a temporary change to the days on which or times at which C is obliged to provide pharmaceutical services at appliance contractor premises, or permit temporary closure of those premises, if—

- (a) C gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by C for the request are, in the opinion of the NHSCB, adequate reasons.

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

the days on which or times at which C is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to C.

Clinical governance

18.—(1) An NHS appliance contractor (C) must, in connection with the pharmaceutical services provided by C, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is “acceptable” if it is considered acceptable by the NHSCB and comprises the following components—

- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that C produces in an approved manner a practice leaflet containing approved particulars in respect of each of the premises from which the supplier provides pharmaceutical services,
 - (ii) a requirement that C publicises the NHS services that are available at or from C’s appliance contractor premises,
 - (iii) a requirement that C undertakes an approved patient satisfaction survey annually, in an approved manner,
 - (iv) C’s monitoring arrangements in respect of appliances owed to patients but which are out of stock,
 - (v) an approved complaints system (which meets the requirements of paragraph 24),
 - (vi) a requirement that C co-operates appropriately with visits by an authorised representative of any relevant Local Healthwatch organisation and takes appropriate action following the outcome of such visits,
 - (vii) a requirement that C co-operates appropriately with any reasonable inspection or review that the NHSCB or any relevant statutory authority wishes to undertake, and
 - (viii) C’s monitoring arrangements in respect of C’s compliance with the Equality Act 2010(a);
- (b) a clinical audit programme (normally of 5 days) twice in each financial year;
- (c) a risk management programme, which includes—
 - (i) arrangements for ensuring that all stock is procured and handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,
 - (iv) appropriate standard operating procedures, including standard operating procedures in respect of dispensing appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (v) appropriate waste disposal arrangements for clinical and confidential waste,
 - (vi) identifying a clinical governance lead person in respect of each of C’s appliance contractor premises,
 - (vii) C’s monitoring arrangements of C’s compliance with the Health and Safety at Work etc. Act 1974(b);
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by C—

(a) 2010 c. 15.

(b) 1974 c. 37.

- (i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
 - (ii) to people caring for themselves or their families,
- and arrangements for ensuring that C, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 9(1)(f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;
- (e) a staffing and staff management programme, which includes—
 - (i) arrangements for appropriate induction for staff (including locums),
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services, including continuing professional development for registered pharmacists, registered nurses and registered pharmacy technicians and any necessary accreditation in respect of the provision of directed services, and
 - (v) arrangements for addressing poor performance (in conjunction with the NHSCB as appropriate); and
 - (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment.
- (3) For the purposes of sub-paragraph (2), “approved” means approved by the NHSCB.

Professional Standards

19. An NHS appliance contractor must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc.

20.—(1) An NHS appliance contractor (C) (including C’s staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

- (a) presenting an order for appliances on a prescription form or repeatable prescription; or
- (b) nominating C as X’s dispensing contractor (or one of them) in X’s PDS patient details.

(2) Promising, offering or providing a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

- (3) C (including C’s staff) must not accept or receive any gift or reward in respect of only—
 - (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 9(2)(b), 11(4) or 12(1)(b); or
 - (b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 9(2)(a) or 12(1)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness matters as they arise

21.—(1) An NHS appliance contractor (C) and, where C is a body corporate every director of C must, within 7 days of its occurrence, inform the NHSCB in writing if they—

- (a) are convicted of any criminal offence in the United Kingdom;
- (b) are bound over following a criminal conviction in the United Kingdom;
- (c) accept a police caution in the United Kingdom;
- (d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);
- (e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(a) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(b) (penalty as alternative to prosecution);
- (f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (h) are notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them;
- (i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;
- (j) become subject to an investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;
- (k) become the subject of any investigation by NHS BSA in relation to fraud;
- (l) become the subject of any investigation by another primary care organisation, which might lead to their removal from a relevant list; or
- (m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

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

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

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

(a) 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; 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).

(b) 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.

- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) becomes the subject of any investigation by the NHS BSA in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;
- (g) becomes the subject of any investigation by another primary care organisation which might lead to its removal from any relevant list; or
- (h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and X must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) C or X must consent to a request being made by the NHSCB to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Other information to be supplied

22.—(1) An NHS appliance contractor (C) must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about C in the pharmaceutical list which C has not otherwise notified to the NHSCB in accordance with these Regulations;
- (b) if C is an individual, any change of C's private address;
- (c) if C is a body corporate, any change to the name, registered number, registered office, telephone number relating to that office of the body corporate; and
- (d) any occurrence requiring C's addition to or removal from the EPS list or a change in the information recorded about C in that list.

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

(3) If C is a body corporate, it must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors.

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

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

- (a) in the case of a director of a body corporate, the name and registered office of the body corporate on the other relevant list; and
- (b) particulars of the other relevant list.

(6) C or a director C (if C is a body corporate) must inform the NHSCB if they, or a body corporate of which they are a director, apply to be included in a relevant list other than a pharmaceutical list held by the NHSCB, and of the outcome of any such application.

Co-operation with Health Education England

23. An NHS appliance contractor must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act^(a) (duty as to education and training).

Complaints

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

(2) In this paragraph, “complaint” means a complaint about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

Inspections and access to information

25.—(1) An NHS appliance contractor (C) must allow persons authorised in writing by the NHSCB to enter and inspect any premises C uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not C is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by C, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and
 - (ii) the management by C of the pharmaceutical services C provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by C;
- (c) the person authorised in writing (X) carries written evidence of X’s authorisation, which X produces on request; and
- (d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

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

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

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

^(b) S.I. 2009/309; amended by S.I. 2009/1768.

Terms of service of dispensing doctors

Persons duly authorised to dispense on behalf of dispensing doctors

1.—(1) Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which the dispensing doctor has duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement; and
- (b) the dispensing doctor must secure compliance with that requirement by that other person.

(2) Where reference is made in this Schedule to a dispensing doctor—

- (a) being the subject of an activity, and in fact a person duly authorised by the dispensing doctor is the subject of that activity; or
- (b) forming a view, and in fact a person duly authorised by the dispensing doctor is to form that view,

that reference is to be construed as referring, as appropriate, to that duly authorised person.

(3) References in this Schedule to a dispensing doctor are to be construed in accordance with sub-paragraphs (1) and (2).

Dispensing of drugs and appliances ordered by another prescriber

2.—(1) In this paragraph, “signed” includes signature with a prescriber’s advanced electronic signature.

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

- (a) any person presents to a dispensing doctor (D) a non-electronic prescription form which contains—
 - (i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than D,
 - (ii) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations^(a) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber other than D, and including the reference “SLS”, or
 - (iii) an order for restricted availability appliances, signed by a prescriber other than D and including the reference “SLS”; or
- (b) subject to sub-paragraph (4), D receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that prescription, or
 - (ii) D has previously arranged with the patient that D will dispense that prescription on receipt,

and D is authorised or required by virtue of Part 8 to provide the drugs or appliances so ordered, D must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as D supplies in the normal course of business.

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

- (a) any person presents to D a non-electronic repeatable prescription which contains—

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

- (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(a), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber other than D,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than D and including the reference “SLS”,
 - (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than D, or
 - (iv) an order for a restricted availability appliance, signed by a prescriber other than D, and including the reference “SLS”,
- and also presents an associated batch issue; or
- (b) D receives an electronic repeatable prescription from the Electronic Prescription Service which contains an order of a kind specified in paragraph (a)(i) to (iv) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or
 - (ii) D has previously arranged with the patient that D will dispense that repeatable prescription on receipt,

and D is authorised or required by virtue of Part 8 to provide the drugs or appliances so ordered, D must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as D supplies in the normal course of business.

(4) D must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

(5) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) D has that prescription in D’s possession; and
- (b) that person presents, or D has in D’s possession, an associated batch issue.

(6) Drugs and appliances provided under this paragraph must be provided in a suitable container.

Dispensing of drugs and appliances ordered by the dispensing doctor

3. In circumstances where paragraph 2 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor (D) is authorised or required by virtue of Part 8 to provide a drug or appliance to a person—

- (a) D must record any order for the provision of any drugs or appliances which are needed for the treatment of the patient, before the drugs or appliances are dispensed (unless it is personally administered)—
 - (i) on a prescription form completed in accordance with the term of the contract under which primary medical services are provided to the patient which gives effect to paragraph 39 of Schedule 6 to the GMS Regulations(c) (other contractual terms – prescribing) or an equivalent provision applying in relation to that contract,

(a) 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

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

(c) Paragraph 39 has been amended by S.I. 2005/893, 2007/3491 and 2009/2230.

- (ii) if paragraph 39A of Schedule 6 to the GMS Regulations^(a) (other contractual terms – electronic prescriptions) or an equivalent provision applies in relation to the contract under which primary medical services are provided to the patient, on an electronic prescription form, or
- (iii) in the case of a personally administered vaccine in respect of which the NHS BSA does not require an individual prescription form in order to process payment, on the form provided by the NHS BSA for the purposes of claiming payments for administering that vaccine (as well, potentially, as claiming other payments), and in the manner required by the NHS BSA (which may be as part of an aggregate total);
- (b) D must provide those drugs or appliances in a suitable container (unless it is personally administered);
- (c) D must provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations^(b) (drugs, medicines and other substances that may be ordered only in certain circumstances) only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations^(c) (other contractual terms – a restrictions on prescribing by medical practitioners) are satisfied; and
- (d) D must provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

Preliminary matters before providing ordered drugs or appliances

4. Before providing any drugs or appliances in accordance with paragraph 3, or in the circumstances set out in paragraph 5—

- (a) a dispensing doctor (D) must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations^(d) (supply of drugs and appliances by doctors) by virtue of either—
 - (i) entitlement to exemption under regulation 7(1) of the Charges Regulations^(e) (exemptions), or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations^(f) (entitlement to full remission and payment),
 to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 7 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5 of the Remission of Charges Regulations, and at the time of the declaration D has such evidence available to D;
- (b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (a), is produced to D, D must endorse the form on which the declaration is made to that effect; and
- (c) in the case of an electronic prescription, D must transmit to the Electronic Prescription Service—
 - (i) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—
 - (aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and
 - (bb) whether or not satisfactory evidence was produced to D as required by sub-paragraph (a),

^(a) Paragraph 39A was inserted by S.I. 2005/893 and has been amended by S.I. 2007/3491.

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

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

^(d) Regulation 4 has been amended by S.I. 2000/2393, 2001/2887, 2002/548 and 2352, 2005/578, 2008/571, 2009/411, 2010/1727 and 2011/518.

^(e) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.

^(f) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

- (ii) in any case where a charge is due, confirmation that the relevant charge was paid, and
- (iii) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Provision of Scheduled drugs

5.—(1) A dispensing doctor (D) must only provide for a patient any Scheduled drug if—

- (a) it is ordered as specified in sub-paragraph (2) or (4); or
- (b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations^(a) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

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

- (a) the prescribed drug is ordered by that non-proprietary name or by its formula; and
- (b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically).

(3) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (2) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(4) Nothing in this Schedule prevents D providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

6.—(1) A dispensing doctor (D) may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) D reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because D reasonably believes it has been stolen or forged);
- (b) it appears to D that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to D’s clinical judgement; or
- (c) where the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—
 - (i) the remuneration of persons providing pharmaceutical services, and
 - (ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

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

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

- (a) D has no record of that prescription;
- (b) D does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to D;

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

- (c) it is not signed by a prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;
- (f) if the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or
- (h) D has been informed by the prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), D must only provide the drugs or appliances ordered if D is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Dispensing doctors issuing prescription forms which may be presented to an NHS chemist

7. Notwithstanding the existence of arrangements under which a dispensing doctor (D) is to provide pharmaceutical services to a patient (P), if D determines that P requires a drug or appliance that is available on prescription from an NHS chemist—

- (a) D may with the agreement of P issue; or
- (b) if P so requests, D must not unreasonably refrain from issuing,

a prescription form that P may present to any NHS chemist instead of D supplying that drug or appliance to P.

Complaints procedures

8. Where a dispensing doctor is a provider of primary medical services, or is employed or engaged by such a provider, the complaints procedure established by—

- (a) the provider or practice; or
- (b) the provider or practice that employs or engages the dispensing doctor,

to deal with complaints in relation to the provision of primary medical services is also to apply in relation to a complaint about any matter reasonably connected with the provision of pharmaceutical services by that provider, practice or individual.

Inspections and access to information

9.—(1) A dispensing doctor (D) must allow persons authorised in writing by the NHSCB to enter and inspect any premises D uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not D is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by D, in the course of providing pharmaceutical services, for patient care and treatment, and

(ii) the management by D of the pharmaceutical services D provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Medical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by D;
- (c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and
- (d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

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

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

Voluntary closure of premises

10.—(1) Where a dispensing doctor (D) wishes—

- (a) to withdraw from a dispensing doctor list, or
- (b) except in the circumstances described in paragraph (2), for particular listed dispensing premises no longer to be listed in relation to D,

D must notify the NHSCB of D's wish at least 3 months in advance of the date on which pharmaceutical services are no longer to be provided, unless it is impracticable for D to do so, in which case D must notify the NHSCB as soon as it is practicable for D to do so.

(2) If particular listed dispensing premises no longer need to be listed in relation to D as a consequence of a relocation application under regulation 55, before the date on which D commences the provision of pharmaceutical services at the new premises, D must give notice to the NHSCB of when, before that date, D is to cease to provide pharmaceutical services at the existing premises.

SCHEDULE 7

Regulation 102(3)

Mandatory terms for LPS schemes

General provisions

1.—(1) The LPS contractor must comply with all relevant legislation, including—

- (a) the relevant provisions of Part 13 of these Regulations; and
- (b) relevant provisions that are—
 - (i) included in regulations under section 225 of the 2007 Act^(a) (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.

^(a) 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.

- (2) The LPS contractor must comply with the relevant provisions of the Drug Tariff.
- (3) The LPS contractor must have regard to all relevant guidance issued by—
 - (a) the NHSCB; or
 - (b) the Secretary of State.
- (4) To the extent that the provisions of the terms required by this Schedule impose a requirement on the LPS contractor (C) in respect of an activity which could only, or would normally, be undertaken by a natural person—
 - (a) if C is a registered pharmacist—
 - (i) C must comply with the requirement, or
 - (ii) if C employs or engages a registered pharmacist in connection with the provision of local pharmaceutical services under C's LPS scheme, C must either comply with that requirement or secure compliance with that requirement by the registered pharmacist C employs or engages; or
 - (b) if C is not a natural person, C must secure compliance with that requirement by the registered pharmacists C employs or engages, and references in this Schedule to an LPS contractor are to be construed accordingly.

Restrictions in an LPS scheme on supply

- 2.—(1) Where an LPS scheme is limited to the provision of specified drugs or appliances, the LPS contractor must not provide other drugs or appliances at or from the scheme premises.
- (2) An LPS scheme must contain the following terms, where applicable—
 - (a) where the local pharmaceutical services to be provided include the supply of appliances—
 - (i) the only appliances which may be supplied are appliances listed in Parts IXA, IXB, IXC or X of the Drug Tariff, and
 - (ii) those appliances must be supplied in accordance with the provisions of the Notes, and the List of Technical Specifications, which appear at the beginning of Part IX of the Drug Tariff, which apply at the time of supply; and
 - (b) where the local pharmaceutical services to be provided include the supply of chemical reagents, the only chemical reagents which may be supplied are those listed from time to time in Part IXR of the Drug Tariff.
- (3) Where an LPS scheme is limited to the provision of services—
 - (a) to a specified class of persons (for example persons who require the provision of local pharmaceutical services for the treatment of a specified disease or condition); or
 - (b) to persons residing in a particular place (for example persons in a specified residential home),

the LPS contractor must not provide local pharmaceutical services to persons other than those so specified.

Dispensing

- 3.—(1) Subject to any provisions of an LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule, where—
 - (a) any person presents to the LPS contractor (C) a non-electronic prescription form which contains—
 - (i) an order for a drug, not being a Scheduled drug, or for an appliance, not being a restricted availability appliance, signed by a prescriber,

- (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations^(a) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference “SLS”, or
- (iii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”; or
- (b) C receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii), and—
 - (i) any person requests the provision of a drug in accordance with that prescription, or
 - (ii) C has previously arranged with the patient that it will dispense that prescription on receipt,

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

(2) Where an LPS scheme includes the provision of repeat dispensing services, subject to any provisions of the LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule, where—

- (a) any person presents to C a non-electronic repeatable prescription which contains—
 - (i) an order for a drug, not being a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971^(b), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001^(c) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference “SLS”,
 - (iii) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
 - (iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference “SLS”,
 and also presents an associated batch issue; or
- (b) C receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in sub-paragraph (a)(i) to (iv) and—
 - (i) any person requests the provision of a drug or an appliance in accordance with that repeatable prescription, or
 - (ii) C has previously arranged with the patient that it will dispense that repeatable prescription on receipt,

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

(3) C must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

(4) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances must be taken to be presented even if the person who wishes to obtain the drug or appliance does not present that prescription, where—

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

- (a) C has that prescription in C's possession; and
- (b) that person presents, or C has in C's possession, an associated batch issue.

Urgent supply without a prescription

4. Where, in case of urgency, a prescriber personally known to the LPS contractor (C) requests C to provide a drug, C may provide that drug (where it would otherwise be able to provide that drug in accordance with the LPS scheme) before receiving a prescription form or repeatable prescription, provided that—

- (a) the drug is not a Scheduled drug;
- (b) the drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and
- (c) the prescriber undertakes to—
 - (i) give C a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug within 72 hours of the request being made, or
 - (ii) transmit to the Electronic Prescription Service within 72 hours of the request being made an electronic prescription.

Preliminary matters before providing ordered drugs or appliances

5.—(1) If a person specified in paragraph (2) asks the LPS contractor (C) to do so—

- (a) C must give an estimate of the time when the drugs or appliances will be ready; and
- (b) if they are not ready by then, C must give a revised estimate of the time when they will be ready (until they are ready).

(2) A person specified in paragraph (1) is a person—

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

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, C must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3 (1) or (1A) of the Charges Regulations^(a) (supply of drugs and appliances by chemists) by virtue of either—

- (a) entitlement to exemption under regulation 7(1) of the Charges Regulations^(b) (exemptions); or
- (b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations^(c) (entitlement to full remission and payment),

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

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

(a) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.

(b) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.

(c) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

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

- (a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—
 - (i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which is claimed applies to the case, and
 - (ii) whether or not satisfactory evidence was produced to C as required by sub-paragraph (3);
- (b) in any case where a charge is due, confirmation that the relevant charge was paid; and
- (c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Providing ordered drugs or appliances

6.—(1) Where the LPS contractor (C) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, C must only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 3(1) or (2); and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(a) and the following provisions of this Schedule.

(2) If the order is for an appliance of a type requiring measuring and fitting by C (for example a truss), C shall make all necessary arrangements for—

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

(3) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with the relevant standard or formula specified therein.

(4) If the order—

- (a) is an order for a drug; but
- (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971(b), other than a drug which is for the time being specified in Schedule 4 or 5 of the Misuse of Drugs Regulations 2001(c) (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

and does not prescribe its quality, strength or dosage, C (in practice, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of C's professional skill, knowledge and care C considers to be appropriate and, subject to sub-paragraph (5), in such quantity as C considers to be appropriate for a course of treatment for a period not exceeding 5 days.

(5) Where an order to which sub-paragraph (4) applies is for—

- (a) an oral contraceptive substance;

(a) 1985 c. 72.

(b) 1971 c.38; *see* section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.

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

- (b) a drug, which is available for supply as part of local pharmaceutical services only together with one or more other drugs; or
- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of local pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, C may provide the minimum size available package.

(6) Where any drug to which this sub-paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by C in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile;
- (b) effervescent or hygroscopic;
- (c) a liquid preparation for addition to bath water;
- (d) a coal tar preparation;
- (e) a viscous preparation; or
- (f) packed at the time of its manufacture in a special container,

C must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

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

(8) Subject to sub-paragraph (9), where a drug is ordered by a prescriber on a prescription form or repeatable prescription in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a holder of a marketing authorisation for the drug, C must provide the drug in an original pack (or in original packs) of that size which has been assembled by a manufacturer of the drug for such a holder of a marketing authorisation, unless—

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

(9) In the case of oral liquid methadone, C (in practice, a registered pharmacist) must decide whether it would be most appropriate to provide—

- (a) each dose in a separate container;
- (b) an original pack (or original packs); or
- (c) the oral liquid methadone in some other way,

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

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

- (a) it is ordered as specified in sub-paragraph (11); or
- (b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations^(a) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

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

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

- (a) the prescribed drug is ordered by that non-proprietary name or by its formula;
- (b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically); and
- (c) the Scheduled drug is not in a pack which consists of a drug in more than one strength, and providing it would involve the supply of part only of the pack.

(12) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (11) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(13) C must provide any drug which it is required to provide under paragraph 3 in a suitable container.

Refusal to provide drugs or appliances ordered

7.—(1) The LPS contractor (C) may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) C reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because C reasonably believes it has been stolen or forged);
- (b) it appears to C that—
 - (i) there is an error on the prescription form or on the repeatable prescription, or in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber), or
 - (ii) in the circumstances, providing the drugs or appliances would be contrary to the C's (in practice, a registered pharmacist's) clinical judgement;
- (c) C or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person;
- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any person accompanying that person, commits or threatens to commit a criminal offence; or
- (e) the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—
 - (i) the remuneration of persons providing local pharmaceutical services, and
 - (ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,
 unless C is to receive no pharmaceutical remuneration of any kind in respect of the drug or appliance.

(2) C must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

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

- (a) C has no record of that prescription;
- (b) C does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to C;
- (c) it is not signed by a prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;

- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;
- (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or
- (h) C has been informed by the prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that he makes such a request), C must only provide the drugs or appliances ordered if C is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

8. In connection with the services provided under paragraphs 3 to 7, the LPS contractor (C) must—

- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—
 - (i) to enable them to utilise the drugs or appliances appropriately, and
 - (ii) to meet the patient's reasonable needs for general information about the drugs or appliances;
- (b) provide appropriate advice to patients to whom they provide drugs or appliances on—
 - (i) the safe keeping of the drugs or appliances, and
 - (ii) returning unwanted drugs or appliances to the scheme premises for safe destruction;
- (c) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;
- (d) keep and maintain records—
 - (i) of drugs and appliances provided, in order to facilitate the continued care of the patient,
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under sub-paragraph (c);
- (e) if C provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed; and
- (f) ensure that where a person is refused drugs or appliances pursuant to paragraph 7(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice.

Additional requirements in relation to electronic prescribing

- 9.—(1) The LPS contractor (C) must, if requested to do so by any person—
- (a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through C's scheme premises; and
 - (b) where the Electronic Prescription Service is not available through C's scheme premises, provide that person with contact details of at least two pharmacies in the area through which the service is available, if these details are known to C.
- (2) Where the Electronic Prescription Service is available through C's scheme premises, C must, if requested to do so by any person, enter in that person's PDS patient details—
- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by the person; or
 - (b) where the person does have a nominated dispensing contractor—
 - (i) a replacement dispensing contractor, or
 - (ii) a further dispensing contractor, chosen by that person.
- (3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the Electronic Prescription Service.
- (4) If C is a nominated dispensing contractor for a person (X) but the nomination was made before C became the person specified in an LPS scheme in relation to the scheme premises nominated in X's PDS patient details, C must within 6 months of C becoming the person so specified—
- (a) explain to X that the ownership of the scheme premises has changed; and
 - (b) ask X whether X wishes to maintain the nomination in respect of those scheme premises.

Further activities in connection with repeat dispensing

10. In connection with the services provided under paragraphs 3 to 7, the LPS contractor (C) must—
- (a) provide appropriate advice to patients to whom C provides drugs or appliances in accordance with a repeatable prescription, in particular on the importance of only requesting those items which they actually need;
 - (b) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;
 - (c) if C takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
 - (d) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
 - (e) destroy any surplus batch issues relating to drugs or appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused the drugs or appliances pursuant to paragraph 7;
 - (f) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification; and
 - (g) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 7(4).

Information to be provided for the NHSCB's lists

11.—(1) The LPS contractor (C) must ensure that C provides to the NHSCB, on request, an up to date record of—

- (a) the services that C provides; and
- (b) the days on which and times at which those services are provided.

(2) Sub-paragraph (1) is without prejudice to the need for a variation of the LPS scheme if C wishes to change—

- (a) the services that C provides; and
- (b) the days on which and times at which those services are provided.

Clinical governance

12.—(1) The LPS contractor must participate, in the manner reasonably required by the NHSCB in an acceptable system of clinical governance.

(2) In this paragraph, “system of clinical governance” means a framework through which an LPS contractor endeavours to improve continuously the quality of the LPS contractor’s services and safeguards high standards of care by creating an environment in which clinical excellence can flourish.

Professional Standards

13. The LPS contractor must provide local pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc

14.—(1) The LPS contractor (C) (including C’s staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of C’s business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

- (a) presenting an order for drugs or appliances on a non-electronic prescription form or non-electronic repeatable prescription;
- (b) nominating C as X’s dispensing contractor (or one of them) in X’s PDS patient details; or
- (c) being provided with any LP service by C.

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

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

- (a) present to C an order for drugs or appliances on a prescription form or repeatable prescription;
- (b) nominate C as their dispensing contractor (or one of them) on their PDS patient details; or
- (c) are provided with any LP service by C.

(4) For the purpose of sub-paragraph (3), “relevant person” means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

- (a) any NHS body or provider of primary medical services; and
- (b) any person employed or engaged by any of the persons mentioned in paragraph (a).

Duty to provide information about fitness to practise matters as they arise

15.—(1) The LPS contractor (C) must within 7 days of its occurrence supply in writing information to the NHSCB as to whether a person (P) who is a relevant person in relation to C—

- (a) has been convicted of any criminal offence in the United Kingdom;
- (b) has been convicted elsewhere of an offence which would constitute a criminal offence if committed in England and Wales;
- (c) has been charged with an offence and is currently the subject of any proceedings which might lead to a conviction, which have not yet been notified to the NHSCB;
- (d) has accepted a police caution in the United Kingdom;
- (e) has become subject to an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995^(a) (admonition and absolute discharge) discharging R absolutely;
- (f) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995^(b) (fixed penalty: conditional offer by procurator fiscal);
- (g) has agreed to pay a penalty under section 115A of the Social Security Administration Act 1992^(c) (penalty as alternative to prosecution);
- (h) has, to P's knowledge, become subject to any investigation into P's professional conduct by any licensing body or is notified of the outcome of such an investigation where it is adverse;
- (i) has, to P's knowledge, become subject to an investigation into P's professional conduct in respect of any current or previous employment or is notified of the outcome of such an investigation where it is adverse;
- (j) has, to P's knowledge, become subject to any investigation by the NHS BSA in relation to fraud or is notified of the outcome of such an investigation where it is adverse;
- (k) has, to P's knowledge, become the subject of any investigation by another primary care organisation, which might lead to P's removal from any relevant list; or
- (l) either—
 - (i) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list of another primary care organisation,
 - (ii) has been suspended from such a list, on fitness to practise grounds, and if so, why and the name of that other primary care organisation, or
 - (iii) has become the subject of a national disqualification,

and if so, C must give details of any investigation or proceedings which are being or were undertaken or brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings commenced, and any outcome.

(2) P is a “relevant person” in relation to C for these purposes, in the case of a contractor that is—

- (a) an individual, if P is C;
- (b) a partnership, if P is a partner in C;
- (c) a body corporate, if P is a director, the chief executive, the company secretary or the superintendent pharmacist of C.

^(a) 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.

^(b) 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).

^(c) 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.

(3) C or any relevant person must consent to a request being made by the NHSCB to any employer or former employer or licensing body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Co-operation with Health Education England

16. The LPS contractor must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act^(a) (duty as to education and training).

Charges for drugs, appliances and containers, and ownership of containers

17.—(1) Subject to regulations made under Part 9 of the 2006 Act (charging), all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where the LPS contractor supplies a container in response to an order for drugs signed by a prescriber, other than equipment specified in the Drug Tariff as not returnable to the contractor, the container and equipment must remain the property of the LPS contractor.

Refunds of prescription charges

18.—(1) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents the LPS contractor with a valid claim for the repayment within three months of the date on which the charge was paid, the LPS contractor must make the repayment.

(2) For the purposes of sub-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^(b) (repayment of charges); or
- (b) on the equivalent form issued in Scotland, Wales or Northern Ireland.

Remuneration, overpayments etc

19.—(1) The NHSCB must ensure that the LPS scheme requires it to remunerate the LPS contractor (C) promptly, in accordance with the remuneration arrangements provided for in the scheme, but subject to the arrangements for reductions of and deductions from payments provided for in the scheme.

(2) The NHSCB must ensure that the LPS scheme requires that payment of any item of remuneration which would, if it were payable to an NHS pharmacist in connection with providing pharmaceutical services, be pharmaceutical reimbursement, is to be paid in accordance with the Drug Tariff.

(3) For these purposes, “pharmaceutical reimbursement” means pharmaceutical remuneration of the type which may be payable to NHS chemists in accordance with determinations by (only) the Secretary of State under section 164 of the 2006 Act^(c) (remuneration for persons providing pharmaceutical services).

(4) Where an LPS scheme requires a fee, allowance or other item of remuneration to be made in accordance with the Drug Tariff and the Drug Tariff provides that the fee, allowance or other item of remuneration is to be determined by the NHSCB, that fee, allowance or other item of remuneration must be determined by the NHSCB.

(5) The NHSCB must ensure that the LPS scheme—

- (a) allows it to recover any payment made to C which should not have been made;

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

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

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

- (b) provides that any such recovery of an overpayment is without prejudice to any investigation of any alleged breach of the scheme; and
- (c) provides that the remuneration arrangements under the scheme, referred to in sub-paragraphs (1) to (4), are subject to any right the NHSCB may have to set off against any amount payable to C, any amount—
 - (i) owed by C to it, or
 - (ii) which it is entitled to withhold under the terms of the scheme (including terms of the Drug Tariff applied by the scheme).

Local resolution of disputes

20. In the case of any dispute arising out of, or in connection with, the LPS scheme, the LPS contractor and the NHSCB must make every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

Dispute resolution: non-NHS contracts

21.—(1) In the case of an LPS scheme which is not an NHS contract, any dispute arising out of or in connection with the scheme, except matters dealt with under the complaints procedure pursuant to paragraph 25, may be referred for consideration and determination to the Secretary of State, if—

- (a) the NHSCB so wishes and the contractor has agreed in writing; or
 - (b) the contractor so wishes (even if the NHSCB does not agree).
- (2) In the case of a dispute referred to the Secretary of State under sub-paragraph (1)—
- (a) the procedure to be followed is the NHS dispute resolution procedure; and
 - (b) the parties must agree to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

22.—(1) The procedure specified in this paragraph and paragraph 23 applies in the case of any dispute arising out of or in connection with an LPS scheme which is referred to the Secretary of State—

- (a) in accordance with section 9(6) of the 2006 Act (NHS contracts), where the scheme is an NHS contract; or
- (b) in accordance with paragraph 21(1), where the scheme is not an NHS contract.

(2) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send to the Secretary of State a written request for dispute resolution which must include or be accompanied by—

- (a) the names and addresses of the parties to the dispute;
- (b) a copy of the LPS scheme; and
- (c) a brief statement describing the nature and circumstances of the dispute.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (2) within a period of 3 years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(4) Where the dispute relates to an LPS scheme which is not an NHS contract, the Secretary of State may determine the matter himself or, if the Secretary of State considers it appropriate, appoint a person or persons to consider and determine it.

(5) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (4) or under section 9(8) of the 2006 Act, the Secretary of State must, within the period

of 7 days beginning with the date on which a matter was referred to the Secretary of State, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.

(6) The Secretary of State must give, with the notice given under sub-paragraph (5) to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.

(7) The Secretary of State must give a copy of any representations received from a party to the other party and must in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(8) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (5) or (7), the Secretary of State must, if the Secretary of State decides to appoint a person or persons to hear the dispute—

- (a) inform the parties in writing of the name of the person or persons whom the Secretary of State has appointed; and
- (b) pass to the person or persons so appointed any documents received from the parties pursuant to sub-paragraph (2), (5) or (7).

(9) For the purpose of assisting them in their consideration of the matter, the adjudicator may—

- (a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which the adjudicator wishes them to give special consideration; or
- (b) consult other persons whose expertise the adjudicator considers will assist the adjudicator's consideration of the matter.

(10) Where the adjudicator consults another person under sub-paragraph (9)(b), the adjudicator must notify the parties accordingly and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator must give to the parties such opportunity as the adjudicator considers reasonable in the circumstances to make observations on those results.

(11) In considering the matter, the adjudicator must consider—

- (a) any written representations made in response to a request under sub-paragraph (5), but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within a specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (9)(a);
- (d) the results of any consultation under sub-paragraph (9)(b); and
- (e) any observations made in accordance with an opportunity given under sub-paragraph (10).

(12) In this paragraph, "specified period" means such period as the Secretary of State must specify in the request, being not less than 2, nor more than 4 weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if the Secretary of State considers that there is good reason for doing so, extend any such period (even after it has expired) and, where the Secretary of State does so, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to the other provisions of this paragraph and paragraph 23, the adjudicator is to have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

Determination of dispute

23.—(1) The adjudicator must record the adjudicator’s determination, and the reasons for it, in writing and must give notice of the determination (including a record of the reasons) to the parties.

(2) In the case of a scheme referred for determination in accordance with paragraph 21(1), section 9(11) of the 2006 Act must apply as that subsection applies in the case of an LPS scheme referred for determination in accordance with section 9(6) of that Act.

Disputes: supplemental

24.—(1) In this Schedule, where reference is made to any dispute arising out of, or in connection with, an LPS scheme, that includes any dispute arising out of, or in connection with, the termination of the scheme.

(2) Any term of the LPS scheme that makes provision in respect of the requirements in paragraphs 20 to 23 must survive even where the scheme has terminated.

Complaints

25.—(1) The LPS contractor must have in place arrangements which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(a), for the handling and consideration of any complaints.

(2) In this paragraph, “complaint” means a complaint about a matter connected with the provision of local pharmaceutical services by the LPS contractor.

Variation of LPS schemes

26.—(1) Subject to sub-paragraphs (2) to (4), no amendment or variation to the LPS scheme is to have effect unless it is in writing and signed by or on behalf of the NHSCB and the (relevant) LPS contractor (C).

(2) The NHSCB may vary an LPS scheme without C’s consent where it—

- (a) is reasonably satisfied that it is necessary to vary the scheme so as to comply with the 2006 Act, any regulations made under that Act, or any direction given by the Secretary of State under that Act; and
- (b) notifies C in writing of the wording of the proposed variation and the date upon which that variation is to take effect,

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect must be not less than 14 days after the date on which the notice under paragraph (b) is served on C.

(3) During an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from C—

- (a) permit C a temporary change to the days on which or times at which C is obliged to provide local pharmaceutical services at the scheme premises, or permit temporary closure of those premises, if—
 - (i) C gives at least 24 hours notice of the change or closure, and
 - (ii) the reasons given by C for the request are, in the opinion of the NHSCB adequate reasons; or
- (b) permit C any other temporary variation to C’s LPS scheme that, in the opinion of the NHSCB, will facilitate continuity of the provision of services of a kind that may be provided under section 126, or by virtue of section 127, of the 2006 Act(b) (arrangements

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

(b) Section 126 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), sections 220(7) and 213(7)(k), and Schedule 4, paragraph 63. Section 127 has been amended by the 2012 Act, Schedule 4, paragraph 64.

for pharmaceutical services and additional pharmaceutical services) during the emergency.

(4) The NHSCB need not approve the request referred to in sub-paragraph (3)(a)(ii) in advance of the change or closure, but if it does not do so and decides subsequently that C's reasons are not, in its opinion, adequate reasons, then the days on which or times at which C is obliged to provide local pharmaceutical services at the scheme premises are to revert to the overridden days and times, from the day after the date on which that decision is given to C.

Termination by agreement

27. The NHSCB and the LPS contractor may agree in writing to terminate the LPS scheme (or end the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme), and if the parties so agree, they must agree the date upon which that termination should take effect and any further terms upon which the scheme should be terminated.

Termination by serving notice

28.—(1) Either the LPS contractor or the NHSCB may terminate the LPS scheme (or end the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme), at any time by serving notice of not less than 6 months in writing to the other party.

(2) Where a notice is served pursuant to sub-paragraph (1), the LPS scheme must terminate on the expiry of the notice period.

(3) This paragraph is without prejudice to any other rights to terminate the agreement which the LPS contractor and the NHSCB may have.

Termination of arrangements by the NHSCB on grounds of suitability etc

29.—(1) The NHSCB may serve notice in writing on the LPS contractor terminating the LPS scheme (or ending the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme) with immediate effect, or from such date as may be specified in the notice, if, in the case of an LPS scheme (or an agreement that is part of an LPS scheme) entered into—

- (a) with an individual as a party, that individual;
- (b) with more than one individual (whether or not practising in partnership), any of those individuals; or
- (c) with a body corporate—
 - (i) the body corporate, or
 - (ii) any director, chief executive, superintendent or company secretary of the body corporate,

falls within sub-paragraph (2) during the existence of the scheme (or the agreement).

(2) A person (X) falls within this sub-paragraph if—

- (a) X is the subject of a national disqualification;
- (b) subject to sub-paragraph (3), X is disqualified or suspended (other than by an interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;
- (c) X is removed from, or refused admission to, a relevant list by 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 X has subsequently been included in such a list;
- (d) X has been convicted in the United Kingdom of murder or a criminal offence other than murder—
 - (i) which was committed on or after 1st April 2006, and

- (ii) for which X has been sentenced to a term of imprisonment of over six months;
- (e) subject to sub-paragraph (4), X has been convicted outside the United Kingdom of an offence which, if committed in England and Wales—
 - (i) would constitute murder, or
 - (ii) would constitute an offence, and—
 - (aa) which was committed on or after 1st April 2006, and
 - (bb) for which X has been sentenced to a term of imprisonment of over six months;
- (f) X has been convicted of an offence referred to in—
 - (i) Schedule 1 to the Children and Young Persons Act 1933^(a) (offences against children and young persons with respect to which special provisions of this Act apply), or
 - (ii) Schedule 1 to the Criminal Procedure (Scotland) Act 1995^(b) (offences against children under the age of 17 years to which special provisions apply), which was committed on or after 1st April 2006;
- (g) X—
 - (i) has been adjudged bankrupt, or sequestration of X’s estate has been ordered, unless X has been discharged from the bankruptcy or the order has been annulled,
 - (ii) has become a person in relation to whom a moratorium period under a debt relief order (under Part 7A of the Insolvency Act 1986^(c) (debt relief orders)) applies,
 - (iii) has been made 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^(d) or Schedule 2A of the Insolvency (Northern Ireland) Order 1989^(e) (which relate to bankruptcy and debt relief restrictions orders and undertakings), which has not been annulled,
 - (iv) if X 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, X’s creditors and X has not been discharged in respect of it;
- (h) in respect of X there is—
 - (i) an administrator, administrative receiver or receiver appointed, or
 - (ii) an administration order made under Schedule B1 to the Insolvency Act 1986^(f) (administration);
- (i) X has 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—

(a) 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.

(b) 1995 c. 46.

(c) 1986 c. 45. Part 7A was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), Schedule 17.

(d) 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.

(e) S.I. 1989/2405 (N.I. 19); Schedule 2A was inserted by S.I. 2005/1455 (N.I. 10).

(f) Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), Schedule 16.

- (aa) section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990^(a) (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^(b) (powers of the Court of Session),

from being concerned with the management or control of any body;

- (j) X has been subject to—
 - (i) a disqualification order or disqualification undertaking under the Company Directors Disqualification Act 1986^(c) or the Company Directors Disqualification (Northern Ireland) Order 2002^(d), or
 - (ii) an order made under section 429(2) of the Insolvency Act 1986^(e) (disabilities on revocation of a county court administration order);
- (k) X (in the case of an individual) has refused to comply with a request by the NHSCB for X to be medically examined on the grounds that it is concerned that X is incapable of adequately providing services under the scheme; or
- (l) it comes to the attention of the NHSCB that information provided to it pursuant to—
 - (i) regulation 12 or 17 of the 2006 Regulations,
 - (ii) a term of the scheme required by paragraph 16 of Schedule 2 to the 2006 Regulations,
 - (iii) regulation 106, or
 - (iv) paragraph 15,
 was, when given, untrue or inaccurate in a material respect.

(3) The NHSCB is not to terminate the LPS scheme (or end an LPS contractor's participation in it) pursuant to sub-paragraph (2)(b) where it is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make X unsuitable to be—

- (a) an LPS contractor; or
- (b) in the case of an LPS scheme (or agreement) with a body corporate, a director, chief executive, superintendent or company secretary of a contractor.

(4) The NHSCB is not to terminate the scheme pursuant to sub-paragraph (2)(e) where it is satisfied that the conviction does not make X unsuitable to be—

- (a) an LPS contractor; or
- (b) in the case of an LPS scheme (or agreement) with a body corporate, a director, chief executive, superintendent or company secretary of an LPS contractor.

Termination by the NHSCB: patient safety and material financial loss

30. The NHSCB may serve notice in writing on the LPS contractor (C) terminating the LPS scheme (or ending the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme) with immediate effect or with effect from such date as may be specified in the notice if—

- (a) C has breached the scheme and as a result of that breach, the safety of C's patients is at serious risk if the scheme is not terminated (or C's participation in it is not ended, in the case of more than one LPS contractor being party to the scheme); or

(a) 1990 c.40; section 7 was repealed by the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), Schedule 4, paragraph 7(b).

(b) 2005 asp 10; section 34(5) has been amended by the section the Public Services Reform (Scotland) Act 2010 (asp 8), section 122.

(c) 1986 c.46.

(d) S.I. 2002/3150 (N.I. 4); relevant amendments were made by S.I. 2005/1454 (N.I. 9).

(e) Section 429(2) was amended by the Enterprise Act 2002 (c.40), Schedule 23, paragraph 15.

- (b) C's financial situation is such that the NHSCB considers that the NHSCB is at risk of material financial loss.

Termination and the NHS dispute resolution procedure

31.—(1) Where the NHSCB is entitled to serve written notice on the LPS contractor (C) terminating the LPS scheme (or ending C's participation in it) pursuant to paragraph 29 or 30, it must, in the notice served on C pursuant to those provisions, specify a date on which the scheme terminates (or C's participation in it is to end) that is not less than 28 days after the date on which the NHSCB has served that notice on C, unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the NHSCB is satisfied that a period less than 28 days, or termination with immediate effect, is necessary in order to—

- (a) protect the safety of the C's patients; or
- (b) protect itself from material financial loss.

(3) In a case falling within sub-paragraph (1), where—

- (a) the exceptions in sub-paragraph (2) do not apply;
- (b) C invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1); and
- (c) C notifies the NHSCB in writing that it has done so,

subject to paragraph (5), the LPS scheme (or C's participation in it) is not to terminate at the end of the notice period but instead is only to terminate in the circumstances specified in sub-paragraph (4).

(4) Subject to paragraph (5), the LPS scheme (or C's participation in it) is only to terminate if and when—

- (a) there has been a determination of the dispute pursuant to paragraph 23 and that determination permits the NHSCB to terminate the scheme; or
- (b) C ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the NHSCB is satisfied that it is necessary to terminate the scheme before the NHS dispute resolution procedure is concluded in order to—

- (a) protect the safety of the C's patients; or
- (b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the NHSCB is entitled to confirm, by written notice to be served on C, that the LPS scheme (or C's participation in it) will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 29(1) or 30.

Third party rights

32. The LPS scheme shall not create any right enforceable by any person not a party to it.

SCHEDULE 8

Regulation 91(1)(a)

Service remuneration determined by the NHSCB

1.—(1) Any fees and allowances payable to NHS pharmacists for professional services provided as part of the provision of pharmaceutical services.

(2) Without prejudice to the generality of sub-paragraph (1), those fees and allowances may include—

- (a) fees in connection with the dispensing of drugs and appliances, including any additional fees relating to the dispensing of particular types of drug or appliance;

- (b) payments made to NHS pharmacists in respect of their providing particular types of advice or assistance to patients or in respect of their participation in particular activities or schemes; and
- (c) payments made to NHS pharmacists that are a contribution to the overall cost of professional services provision (which may be calculated by reference to particular levels of activity).

(3) For the purposes of sub-paragraph (1), “professional services” does not include providing pre-registration training experience for pharmacy graduates or undergraduates.

2.—(1) Any fees and allowances payable to NHS appliance contractors for professional services provided as part of the provision of pharmaceutical services.

(2) Without prejudice to the generality of sub-paragraph (1), those fees and allowances may include—

- (a) fees in connection with the dispensing of appliances, including any additional fees relating to the dispensing of particular types of appliance;
- (b) payments made to NHS appliance contractors in respect of their providing particular types of advice or assistance to patients or in respect of their participation in particular activities or schemes; and
- (c) payments made to NHS appliance contractors that are a contribution to the overall cost of professional services provision (which may be calculated by reference to particular levels of activity).

SCHEDULE 9

Regulation 119

Transitional provisions

The continuity principles

1.—(1) Where by virtue of this Schedule—

- (a) a matter is to be dealt with in accordance with the 2006 Regulations or the 2012 Regulations; or
- (b) a matter (by virtue of having been dealt with in accordance with Schedule 7 to the 2012 Regulations (transitional provisions)), is to be dealt with in accordance with the 2005 Regulations or the SCAT Regulations,

if that matter under those Regulations would fall to be dealt with by a Primary Care Trust, unless the context requires otherwise, that matter is to be dealt with instead by the NHSCB.

(2) Any matter that is ongoing under the 2006 Regulations or the 2012 Regulations (including, by virtue of Schedule 7 of those Regulations, under the 2005 Regulations or the SCAT Regulations) immediately before the appointed day, unless the context requires otherwise—

- (a) is to be treated as ongoing under these Regulations on the appointed day (and where appropriate after that); and
- (b) where that matter becomes the responsibility of the NHSCB on the appointed day, anything done in relation to that matter by or with regard to a Primary Care Trust before the appointed day is to be treated as having been done (for the purposes of the ongoing treatment of the matter) by or with regard to the NHSCB.

(3) Where a period of time specified in a provision of the 2006 Regulations or the 2012 Regulations is current on the appointed day, and a period of time is also specified in a corresponding provision of these Regulations, unless the context requires otherwise, these Regulations have effect as if the corresponding provision of these Regulations had been in force when that period began to run.

(4) Where—

- (a) consideration of a matter under a provision of these Regulations in respect of a specified period of time requires consideration of a period of time before the appointed day; and
- (b) a corresponding provision of the 2006 Regulations or the 2012 Regulations also required consideration of that matter in respect of a specified period of time,

unless the context requires otherwise, the provision of these Regulations has effect as if it had been in force when the period of time specified in it began to run.

(5) Subject to sub-paragraphs (6) and (7), where on or after the appointed day—

- (a) a matter is to be dealt with in accordance with the SCAT Regulations, the 2005 Regulations, the 2006 Regulations or the 2012 Regulations; or
- (b) a matter that relates to circumstances that arose, or first arose, before the appointed day is to be dealt with in accordance with these Regulations or the Drug Tariff,

in dealing with that matter the NHSCB (or where appropriate, on appeal, the Secretary of State or the First-tier Tribunal) is to apply those Regulations, the Drug Tariff and related provisions of the 2006 Act subject to such modifications as it (or where appropriate, on appeal, the Secretary of State or the First-tier Tribunal) considers necessary or expedient.

(6) Modifications pursuant to paragraph (5) must—

- (a) be for a purpose related to—
 - (i) dealing with the matter justly, or
 - (ii) effecting an orderly transition from the scheme established by the Regulations mentioned in sub-paragraph (5)(a), read with the 2006 Act as in force before the appointed day, to the scheme established by these Regulations, read with the 2006 Act,

or for purposes related to both; and

- (b) take account, as appropriate, of the manner in which—
 - (i) provisions in the 2005 Regulations were carried forward into the 2012 Regulations,
 - (ii) provisions in the 2006 Regulations and the 2012 Regulations were carried forward into these Regulations, and
 - (iii) the 2006 Act was amended by the Health and Social Care Act 2012(a).

(7) Modifications pursuant to paragraph (5) may—

- (a) be for the purpose of seeking to ensure that a matter is dealt with expeditiously;
- (b) be for the purpose of seeking to ensure that a matter is dealt with proportionately, having regard to (as relevant)—
 - (i) the importance of protecting the safety of persons to whom pharmaceutical and local pharmaceutical services are provided,
 - (ii) the need for fairness,
 - (iii) the complexity of the issues,
 - (iv) the importance of protecting the NHSCB from material financial loss, and
 - (v) the importance of saving expense; or
- (c) (without prejudice to the generality of the power to make modifications) have the effect of—
 - (i) adding to, modifying or removing functions that would have been performed by a Primary Care Trust under the SCAT Regulations, the 2005 Regulations, the 2006 Regulations, the 2012 Regulations or the 2006 Act as in force before the appointed day, or
 - (ii) adding to, modifying or removing functions that are to be performed by the NHSCB or a HWB under these Regulations or the 2006 Act.

(a) 2012 c. 7.

(8) In this Schedule, “the continuity principles” means the provisions of sub-paragraphs (1) to (7).

Listing applications under the 2005 Regulations: NHS chemists

2.—(1) An application made to a Primary Care Trust under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations (which relate to applications for inclusion in a pharmaceutical list, preliminary consent applications and temporary provision during a period of suspension) which—

- (a) has not been determined before the appointed day; and
- (b) by virtue of Schedule 7 to the 2012 Regulations (transitional provisions), was to be determined in accordance with the 2005 Regulations and if relevant the 2006 Regulations,

is to be dealt with by the NHSCB in accordance with the 2005 Regulations.

(2) Where an application made under the 2005 Regulations for preliminary consent has been finally granted under those Regulations—

- (a) an application under regulation 5(1) of the 2005 Regulations that is in accordance with regulation 41(1) of those Regulations (effect of preliminary consent) may be made in relation to that consent (within the 6 months period referred to in regulation 40(4) of the 2005 Regulations); and
- (b) any such application is to be dealt with by the NHSCB in accordance with the 2005 Regulations.

(3) Where on or after the appointed day, by virtue of this paragraph, an application is to be determined by the NHSCB having regard to regulation 13(1)(a) of the 2005 Regulations (exemptions from the necessary or expedient test), for the purposes of that application an area is an approved retail area if on 31st August 2012 it was a retail area that was for the time being approved by the Secretary of State under regulation 15 of those Regulations (approved retail areas).

(4) Where an application under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations has been determined in accordance with the 2005 Regulations, whether before the appointed day or by virtue of this paragraph—

- (a) the arrangements for bringing an appeal in relation to that application; and
- (b) the determination of any appeal validly brought,

are to be in accordance with the 2005 Regulations.

Listing applications under the 2012 Regulations: NHS chemists

3.—(1) Where a routine application has been made to a Primary Care Trust before the appointed day under the 2012 Regulations, subject to paragraph (2)—

- (a) if that application has not been notified under Part 3 of Schedule 2 to the 2012 Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – notification of certain applications) before the appointed day, it is to be dealt with by the NHSCB in accordance with these Regulations; and
- (b) if that application has been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day, it is to be dealt by the NHSCB in accordance with the 2012 Regulations and the 2006 Act as in force immediately before the appointed day.

(2) Where—

- (a) a routine application has been made to a Primary Care Trust before the appointed day under the 2012 Regulations; and
- (b) determination of that application requires determination of whether granting it, or granting it in respect of some only of the services specified in it, would meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, which have been included in a pharmaceutical needs assessment,

it is to be dealt with by the NHSCB in accordance with the 2012 Regulations and the 2006 Act as in force immediately before the appointed day, whether or not it has been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day.

(3) Where an excepted application has been made to a Primary Care Trust before the appointed day under the 2012 Regulations—

- (a) if that application—
 - (i) is not a notifiable application, and
 - (ii) has not been determined by the Primary Care Trust before the appointed day, it is to be dealt with by the NHSCB in accordance with these Regulations;
- (b) if that application—
 - (i) is a notifiable application, and
 - (ii) has not been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day, it is to be dealt with in accordance with these Regulations; and
- (c) if that application—
 - (i) is a notifiable application, and
 - (ii) has been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day, it is to be dealt with in accordance with the 2012 Regulations and the 2006 Act as in force immediately before the appointed day.

(4) Where an application under the 2012 Regulations is determined in accordance with the 2012 Regulations, whether before the appointed day or by virtue of this paragraph—

- (a) the arrangements for bringing an appeal in relation to that application; and
- (b) the determination of any appeal validly brought,

are to be in accordance with the 2012 Regulations.

(5) In applying the continuity principles in relation to decisions which are to be made under the 2012 Regulations by virtue of this paragraph, the NHSCB must ensure that LPS chemists that would, by virtue of paragraph 32(5)(b)(ii) of Schedule 2 to these Regulations, have rights of appeal against particular types of decision under these Regulations, have the same rights of appeal against equivalent decisions under the 2012 Regulations, notwithstanding that those rights of appeal were not provided for in the 2012 Regulations.

Listing applications under the 2005 Regulations: dispensing doctors

4.—(1) An application made to a Primary Care Trust under Part 5 of the 2005 Regulations (provision of pharmaceutical services by doctors) for outline consent or premises approval (including temporary premises approval) which—

- (a) has not been determined before the appointed day; and
- (b) by virtue of Schedule 7 to the 2012 Regulations (transitional provisions) was to be determined in accordance with the 2005 Regulations,

is to be dealt with by the NHSCB in accordance with the 2005 Regulations.

(2) Where an application under Part 5 of the 2005 Regulations has been determined in accordance with those Regulations, whether before the appointed day or by virtue of subparagraph (1)—

- (a) the arrangements for bringing an appeal in relation to that application; and
- (b) the determination of any appeal validly brought,

are to be in accordance with the 2005 Regulations.

(3) If, before the appointed day—

- (a) a Primary Care Trust has required a doctor to provide pharmaceutical services under regulation 60(4)(a) of the 2005 Regulations^(a) (arrangements for provision of pharmaceutical services by doctors); and
- (b) the doctor has appealed against that decision,

the arrangements for bringing that appeal, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

Listing applications under the 2012 Regulations: dispensing doctors

5.—(1) Where an application has been made to a Primary Care Trust before the appointed day under Part 8 of the 2012 Regulations (dispensing doctors) for outline consent or premises approval, other than an application for temporary premises approval to which regulation 58 or 61 of those Regulations (which relate to temporary provision in cases where premises approval has not taken effect or during an emergency requiring the flexible provision of pharmaceutical services) applies—

- (a) if that application has not been notified under regulation 52 of the 2012 Regulations (notification of applications for outline consent and premises approval), it is to be dealt with by the NHSCB in accordance with these Regulations; and
- (b) if that application has been notified under regulation 52 of the 2012 Regulations, it is to be dealt with by the NHSCB in accordance with the 2012 Regulations.

(2) Where—

- (a) an application has been made to a Primary Care Trust before the appointed day under regulation 58 or 61 of the 2012 Regulations for temporary premises approval; and
- (b) that application has not been determined before the appointed day,

it is to be dealt with by the NHSCB in accordance with these Regulations.

(3) Where an application under that Part 8 of the 2012 Regulations has been determined in accordance with the 2012 Regulations, whether before the appointed day or by virtue of this paragraph—

- (a) the arrangements for bringing an appeal in relation to that application; and
- (b) the determination of any appeal validly brought,

are to be in accordance with the 2012 Regulations.

(4) If, before the appointed day, a Primary Care Trust has required a doctor to provide pharmaceutical services under regulation 48(5)(b) of the 2012 Regulations (arrangements for provision of pharmaceutical services by doctors: applications by patients), and—

- (a) the doctor has appealed against that decision before the appointed day; or
- (b) the time limit for bringing an appeal against the decision in regulation 63(1) of the 2012 Regulations (appeals against decisions under Part 8) has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

Outstanding cases relating to dispensing contractor lists

6.—(1) If, before the appointed day the Primary Care Trust was engaged in a process which could have led to the inclusion or removal of a contractor or premises from a dispensing contractor list, that process and the action to be taken following its outcome (including relating to any appeal) are to be dealt with by the NHSCB in accordance with paragraph 10 of Schedule 7 to the 2012 Regulations (transitional provisions – dispensing contractor lists).

(2) Where—

(a) Prior to its revocation, regulation 60(4) was amended by S.I. 2005/1015 and 2006/3373.

- (a) the NHSCB grants an application for premises approval by virtue of this paragraph; and
- (b) the NHSCB is as a consequence required to consider any postponement of the making of arrangements to provide dispensing services, arising out of that grant,

that consideration, the NHSCB's decision on any postponement, the arrangements for bringing an appeal against its decision, and the determination of any appeal validly brought, are to be in accordance with paragraph 10 of Schedule 7 to the 2012 Regulations.

(3) Conditions relating to postponement of the making of arrangements to provide dispensing services which are imposed by virtue of this paragraph, or which continued to have effect by virtue of paragraph 10 of Schedule 7 to the 2012 Regulations, continue to have effect as if imposed under these Regulations in relation to the provision of pharmaceutical services.

Controlled localities

7.—(1) The NHSCB must—

- (a) in respect of an area which on the appointed day continues to be, or to be part of, a controlled locality by virtue of regulation 36(1), delineate precisely the boundary of the controlled locality on a map (which may be part of a series of maps which relate to HWB areas);
- (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 controlled locality in its area.

(2) Where—

- (a) before the appointed day, a Primary Care Trust was considering whether or not an area is either a controlled locality or part of a controlled locality; or
- (b) the NHSCB is required, by virtue of paragraphs 2 to 5, to determine an application and in connection with determining that application, it also needs to determine whether or not an area is or is not a controlled locality, or part of a controlled locality,

paragraph (3) applies.

(3) Where—

- (a) consideration by a Primary Care Trust mentioned in sub-paragraph (2)(a) was, or (by virtue of paragraph 2 or 4) an application referred to in sub-paragraph (2)(b) is, to be dealt with under the 2005 Regulations—
 - (i) the consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with the 2005 Regulations, and
 - (ii) the arrangements for bringing an appeal in relation to the decision of the NHSCB, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations;
- (b) consideration by a Primary Care Trust mentioned in sub-paragraph (2)(a) was under the 2012 Regulations (unless it was in connection with an application which by virtue of paragraph 3 or 5 is to be determined in accordance with these Regulations)—
 - (i) the consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with the 2012 Regulations, and
 - (ii) the arrangements for bringing an appeal in relation to the decision of the NHSCB, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations,

but if that consideration was in connection with an application which by virtue of paragraph 3 or 5 is to be determined in accordance with these Regulations, the consideration of whether or not a locality is either a controlled locality or part of a

controlled locality is also to be dealt with by the NHSCB in accordance with these Regulations;

- (c) an application referred to in sub-paragraph (2)(b) is to be dealt with under the 2012 Regulations (by virtue of paragraphs 3 or 5)—
 - (i) the related consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with the 2012 Regulations, and
 - (ii) the arrangements for bringing an appeal in relation to the decision of the NHSCB, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations;
- (d) an application referred to in sub-paragraph (2)(b) is to be dealt with under these Regulations, the related consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with these Regulations.

(4) Where, by virtue of sub-paragraph (3), it is determined (whether by the NHSCB or on appeal by the Secretary of State) that an area is or is not, or is or is not part of, a controlled locality, the NHSCB must—

- (a) delineate precisely the boundary of any resulting controlled locality 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 any resulting controlled locality in its area,

and any area that becomes, or becomes part of, a controlled locality as a consequence of that determination is then a controlled locality, or part of a controlled locality, for the purposes of these Regulations (unless or until it is determined under these Regulations that it is no longer, or no longer part of, a controlled locality).

Reserved locations

8.—(1) Where—

- (a) an application has been received which is to be determined under the 2005 Regulations—
 - (i) in accordance with paragraph 2, and
 - (ii) having regard to regulation 12 or 13 of the 2005 Regulations (which relate to the necessary or expedient test and exemptions from it); and
- (b) the premises or relevant location at or from which the applicant wishes to provide pharmaceutical services is or may be a reserved location,

pending the final determination of that application, the classification of any area in relation to those premises or that relevant location as, or as not, a reserved location is to be determined in accordance with the 2005 Regulations (if a further reserved location determination is required after the application is finally determined, it is to be in accordance with these Regulations).

(2) Where a determination of whether or not an area is a reserved location is made under the 2005 Regulations by virtue of—

- (a) sub-paragraph (1); or
- (b) before the appointed day, paragraph 6 of Schedule 7 to the 2012 Regulations (transitional provisions – reserved locations),

the arrangements for bringing an appeal against the decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(3) Where—

- (a) a routine application was received by a Primary Care Trust which the NHSCB is required to determine under the 2012 Regulations in accordance with paragraph 3; and

- (b) the premises or relevant location at or from which the applicant wishes to provide pharmaceutical services is or may be a reserved location,

pending the final determination of that application, the classification of any area in relation to those premises or that relevant location as, or as not, a reserved location is to be determined in accordance with the 2012 Regulations (if a further reserved location determination is required after the application is finally determined, it is to be in accordance with these Regulations).

(4) Where before the appointed day—

- (a) a Primary Care Trust received a request for a determination under regulation 42 of the 2012 Regulations (second and subsequent determinations of reserved location status), but there is no related routine application which is (still) to be finally determined under the 2012 Regulations in accordance with paragraph 2; and

- (b) the request was notified under regulation 42(2)(a) of the 2012 Regulations,

the classification of any area as, or as not, a reserved location pursuant to that request is to be determined in accordance with the 2012 Regulations (if a further reserved location determination is required after that determination, it is to be in accordance with these Regulations).

(5) Where a determination of whether or not an area is a reserved location is made under the 2012 Regulations by virtue of sub-paragraph (3) or (4), the arrangements for bringing an appeal against the decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

(6) Where before the appointed day, a request is made to a Primary Care Trust for a reserved location determination, but the determination is not to be made under the 2005 Regulations or the 2012 Regulations by virtue of sub-paragraphs (1) to (5), it is to be made by the NHSCB (or on appeal the Secretary of State) under these Regulations.

(7) Where, by virtue of sub-paragraphs (1) to (5), it is determined (whether by the NHSCB or on appeal by the Secretary of State) that an area is a reserved location, if following the determination a reserved location thereafter takes effect (because the pharmacy premises to which it relates are included in a pharmaceutical list), 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.

Gradual discontinuation of the provision of pharmaceutical services by doctors

9.—(1) Where, when granting an application which by virtue of paragraph 2 is finally determined in accordance with the 2005 Regulations, the NHSCB is required to consider under regulation 20(2) of the 2005 Regulations (imposition of conditions)—

- (a) any termination of arrangements with any person on its dispensing doctor list; and
- (b) any postponement of any such termination,

arising out of that grant (but not for a reason set out in regulation 50(1)(a) to (c), (e) or (f) of these Regulations), that consideration and its decision are to be in accordance with the 2005 Regulations.

(2) Where before the appointed day a Primary Care Trust was considering under the 2005 Regulations, in any case in which it could postpone the termination of arrangements with a dispensing doctor—

- (a) the termination of arrangements with a dispensing doctor; or
- (b) the postponement of the termination of arrangements with a dispensing doctor,

that matter is to be dealt with by the NHSCB, in accordance with the 2005 Regulations.

(3) Where, under the 2005 Regulations—

- (a) a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor is made by virtue of sub-paragraph (1) or (2); or
- (b) before the appointed day, a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor was made by a Primary Care Trust under the 2005 Regulations, and—
 - (i) that decision has been appealed before the appointed day, or
 - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(4) Where, when granting an application which by virtue of paragraph 3 is finally determined in accordance with the 2012 Regulations, the NHSCB is required to consider under regulation 50(1) or (3) of the 2012 Regulations (discontinuation of arrangements for the provision of pharmaceutical services by doctors)—

- (a) any termination of arrangements with any person on its dispensing doctor list; and
- (b) any postponement of any such termination,

arising out of that grant, that consideration and its decision are to be in accordance with the 2012 Regulations.

(5) Where before the appointed day a Primary Care Trust was considering under regulation 50(1) to (6) of the 2012 Regulations, in any case in which it could postpone the termination of arrangements with a dispensing doctor—

- (a) the termination of arrangements with a dispensing doctor; or
- (b) the postponement of the termination of arrangements with a dispensing doctor,

that matter is to be dealt with by the NHSCB, in accordance with the 2012 Regulations.

(6) Where, under the 2012 Regulations—

- (a) a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor is made by virtue of sub-paragraph (4) or (5); or
- (b) before the appointed day, a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor was made by a Primary Care Trust pursuant to the 2012 Regulations, and—
 - (i) that decision has been appealed before the appointed day, or
 - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

(7) Regulation 50(1)(f) applies to a determination under the 2005 Regulations or the 2012 Regulations (either before the appointed day or by virtue of paragraph 8) that a location ceases to be or be part of a reserved location as it does to a determination referred to in regulation 42 as D2.

(8) Conditions imposed by virtue of—

- (a) regulation 20(2) or 35(6)(b) (pharmaceutical services in reserved locations) of the 2005 Regulations; or
- (b) regulation 50(2), (5) or (6) of the 2012 Regulations,

relating to the postponement of termination of arrangements with a dispensing doctor, whether or not imposed by virtue of this paragraph, continue to have effect as if imposed under these Regulations.

Gradual introduction of the provision of pharmaceutical services by doctors

10.—(1) Where, when granting an application which by virtue of paragraph 4 is finally determined in accordance with the 2005 Regulations, the NHSCB is required to consider under regulation 20(2) of the 2005 Regulations (imposition of conditions) any postponement of the making of arrangements with a dispensing doctor arising out of that grant, that consideration and its decision are to be in accordance with the 2005 Regulations.

(2) Where before the appointed day a Primary Care Trust is considering under regulation 20(2) of the 2005 Regulations the postponement of the making of arrangements with a dispensing doctor, that matter is to be dealt with by the NHSCB, in accordance with the 2005 Regulations.

(3) Where, under the 2005 Regulations—

- (a) a decision relating to postponement of the making of arrangements with a dispensing doctor is made by virtue of sub-paragraph (1) or (2); or
- (b) before the appointed day, a decision relating to postponement of the making of arrangements with a dispensing doctor was made by a Primary Care Trust under the 2005 Regulations, and—
 - (i) that decision has been appealed before the appointed day, or
 - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(4) Where, when granting an application which by virtue of paragraph 5 is finally determined in accordance with the 2012 Regulations, the NHSCB is required to consider under regulation 57(1) of the 2012 Regulations (gradual introduction of premises approval)—

- (a) any postponement of the making of arrangements with a dispensing doctor arising out of that grant; or
- (b) any limitation on the patients to whom a dispensing doctor is able to provide pharmaceutical services,

that consideration and its decision are to be in accordance with the 2012 Regulations.

(5) Where before the appointed day a Primary Care Trust is considering under regulation 57(1) of the 2012 Regulations—

- (a) the postponement of the making of arrangements with a dispensing doctor; or
- (b) any limitation on the patients to whom a dispensing doctor is able to provide pharmaceutical services,

that matter is to be dealt with by the NHSCB, in accordance with the 2012 Regulations.

(6) Where, under the 2012 Regulations—

- (a) a decision relating to—
 - (i) postponement of the making of arrangements with a dispensing doctor, or
 - (ii) limiting the patients to whom a dispensing doctor is able to provide pharmaceutical services,is made by virtue of sub-paragraph (1) or (2); or
- (b) before the appointed day, a decision relating to postponement of the making of arrangements with a dispensing doctor, or to limiting the patients the patients to whom a dispensing doctor is able to provide pharmaceutical services, was made by a Primary Care Trust pursuant to the 2012 Regulations, and—
 - (i) that decision has been appealed before the appointed day, or
 - (ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

(7) Conditions imposed by virtue of—

- (a) regulation 20(2) of the 2005 Regulations relating to postponement of the making of arrangements with a dispensing doctor; or
- (b) regulation 57(1) of the 2012 Regulations relating to—
 - (i) the postponement of the making of arrangements with a dispensing doctor, or
 - (ii) limiting the patients to whom a dispensing doctor is able to provide pharmaceutical services,

whether or not imposed by virtue of this paragraph, continue to have effect as if imposed under these Regulations.

Giving effect to listing decisions: pharmaceutical lists and dispensing doctor lists

11.—(1) Where, before the appointed day or as a consequence of paragraphs 2 or 4, a person is entitled on the basis of a decision (whether by a Primary Care Trust or the NHSCB, or on appeal)—

- (a) to be included in pharmaceutical list but has not been included in that list;
- (b) to have listed in relation to their entry in a pharmaceutical list premises that have not been listed in relation to them;
- (c) to be included in a dispensing doctor list but has not been included in that list;
- (d) to have listed in relation to their entry in a dispensing doctor list premises that have not been listed in relation to them; or
- (e) to have listed in relation to their entry in a dispensing doctor list an area that has not been listed in relation to them,

the arrangements for the listing of that person, those premises or that area, and the circumstances in which that decision lapses, are as set out in the 2005 Regulations.

(2) Where, before the appointed day or as a consequence of paragraphs 3 or 5, a person is entitled on the basis of a decision (whether by a Primary Care Trust or the NHSCB, or on appeal)—

- (a) to be included in pharmaceutical list but has not been included in that list;
- (b) to have listed in relation to their entry in a pharmaceutical list premises that have not been listed in relation to them;
- (c) to be included in a dispensing doctor list but has not been included in that list;
- (d) to have listed in relation to their entry in a dispensing doctor list premises that have not been listed in relation to them; or
- (e) to have listed in relation to their entry in a dispensing doctor list an area that has not been listed in relation to them,

the arrangements for the listing of that person, those premises or that area, and the circumstances in which that decision lapses, are as set out in the 2012 Regulations.

Pharmaceutical lists, EPS lists and dispensing doctor lists: continuity of entries and decisions

12.—(1) Subject to sub-paragraph (2), the entries in pharmaceutical lists, EPS lists or dispensing doctor lists of Primary Care Trusts that are current immediately before the appointed day are to be current entries in the pharmaceutical lists, EPS lists and dispensing doctor lists maintained by the NHSCB on the appointed day under regulations 10 and 46 (albeit that the lists may be maintained by reference to different geographical areas).

(2) Where immediately before the appointed day a Primary Care Trust was required or entitled to give effect to a decision reached before the appointed day to change, remove or include an entry in a pharmaceutical list, EPS list or dispensing doctor list but had not done so, the NHSCB is required or entitled (unless the context requires otherwise) to give effect to that decision on or after the appointed day.

- (3) If, as regards a decision to which paragraph (2) applies, before the appointed day—
- (a) removal of an entry in a pharmaceutical list, EPS list or dispensing doctor list—
 - (i) would have resulted in removal of a person from a pharmaceutical list, EPS list or dispensing doctor list but no longer does so, or
 - (ii) would not have resulted in removal of a person from a pharmaceutical list, EPS list or dispensing doctor list but on or after the appointed day does so; or
 - (b) inclusion of an entry in a pharmaceutical list, EPS list or dispensing doctor list—
 - (i) would have required the new inclusion of a person in a pharmaceutical list, EPS list or dispensing doctor list but no longer does so, or
 - (ii) would not have required the new inclusion of a person in a pharmaceutical list, EPS list or dispensing doctor list but on or after the appointed day does so,

the NHSCB is nevertheless required or entitled (unless the context requires otherwise) to give effect to that decision, and in a manner that reflects the new arrangements for maintaining pharmaceutical lists, EPS lists and dispensing doctor lists, regardless of whether or not a different procedure would have been followed before the appointed day, had the nature of the listing change been as it is on or after the appointed day.

Service provision issues: NHS chemists

13.—(1) Subject to sub-paragraph (3), where by virtue of a transfer scheme or paragraph 12, NHSCB becomes engaged in any matter—

- (a) arising under the 2005 Regulations before the appointed day; and
- (b) relating to compliance with the terms of service of a chemist (whether compliance by the chemist or a Primary Care Trust),

that matter is to be resolved in accordance with the 2005 Regulations, and where applicable the SCAT Regulations and the Drug Tariff, and the continuity principles are to be applied accordingly.

(2) Subject to sub-paragraph (3), as regards the resolution of any matter—

- (a) arising under the 2005 Regulations before the appointed day; and
- (b) relating to changing or removing any entry in a pharmaceutical list by virtue the 2005 Regulations other than pursuant to an application under regulation 5(1), 40(1) or 54(2) of those Regulations (which relate to applications for inclusion in a pharmaceutical list, preliminary consent applications and temporary provision during a period of suspension) (paragraph 2 applies in those cases),

that matter is to be resolved in accordance with the 2005 Regulations, and where applicable the SCAT Regulations and the Drug Tariff, and the continuity principles are to be applied accordingly.

(3) Sub-paragraphs (1) and (2) are without prejudice to the ability of the NHSCB to commence proceedings under Chapter 6 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – disqualification) on or after the appointed day that relate to matters arising before 1st September 2012 (potentially together with matters arising between 1st September 2012 and the appointed day, or on or after the appointed day), but any decisions in such proceedings are to be reached in accordance with the relevant provisions of these Regulations (and that Chapter 6).

(4) Subject to sub-paragraph (6), where by virtue of a transfer scheme or paragraph 12, NHSCB becomes engaged in any matter—

- (a) arising under the 2012 Regulations before the appointed day; and
- (b) relating to compliance with the terms of service of an NHS chemist (whether compliance by the NHS chemist or a Primary Care Trust),

that matter is to be resolved in accordance with the 2012 Regulations and where applicable the Drug Tariff, and the continuity principles are to be applied accordingly.

(5) Subject to sub-paragraph (6), as regards the resolution of any matter—

- (a) arising under the 2012 Regulations before the appointed day; and
- (b) relating to changing or removing any entry in a pharmaceutical list by virtue the 2012 Regulations other than pursuant to a routine or excepted application (paragraph 3 applies in those cases),

that matter is to be resolved in accordance with the 2012 Regulations and where applicable the Drug Tariff, and the continuity principles are to be applied accordingly.

(6) Sub-paragraphs (4) and (5) are without prejudice to the ability of the NHSCB—

- (a) to commence proceedings under Chapter 6 of Part 7 of the 2006 Act on or after the appointed day that relate to matters arising before the appointed day (potentially together with matters arising on or after the appointed day), but any decisions in such proceedings are to be reached in accordance with the relevant provisions of these Regulations (and that Chapter 6);
- (b) to issue breach or remedial notices under Part 10 on or after the appointed day that relate to matters arising before the appointed day (potentially together with matters arising on or after the appointed day); or
- (c) to take action under regulation 73 based on breach or remedial notices issued by a Primary Care Trust under Part 10 of the 2012 Regulations (performance related sanctions and market exit).

(7) Decisions and reviews of decisions in any proceedings commenced under Chapter 6 of Part 7 of the 2006 Act before the appointed day—

- (a) which by virtue of paragraph 10 of Schedule 7 to the 2012 Regulations (transitional provisions – other continuing matters: NHS chemists) were being determined in accordance with the 2005 Regulations and that Chapter 6 are to continue to be so determined; or
- (b) were being determined in accordance with Part 11 of the 2012 Regulations (enforcement, reviews and appeals relating to fitness matters) and that Chapter 6 are to continue to be so determined,

except in the case of a review of a decision where the request by the practitioner for a review is made on or after the appointed day (such a review is to be in accordance with the relevant provisions of these Regulations and that Chapter 6).

(8) Where a person was suspended from a pharmaceutical list by virtue of Chapter 6 of Part 7 of the 2006 Act before the appointed day—

- (a) decisions on payments in respect of any part of the period of suspension that preceded 1st September 2012, and any appeals relating to those decisions, are to be in accordance with the 2005 Regulations and with the determinations under regulation 58 of the 2005 Regulations (a) (payments to suspended chemists) that were in force immediately before 1st September 2012; and
- (b) decisions on payments in respect of any part of the period of suspension between 1st September 2012 and 31st March 2013 inclusive, and any appeals relating to those decisions, are to be in accordance with the 2012 Regulations and with the determinations under regulation 98 of the 2012 Regulations (payments to suspended chemists) that were in force immediately before the appointed day.

(9) Any direction or approval under, or that continues in effect under, a provision of Schedule 4 or 5 of the 2012 Regulations (terms of service of NHS pharmacists and terms of service of NHS appliance contractors) is to continue in effect as a direction or approval under the corresponding

(a) Prior to its revocation, regulation 58 was amended by S.I. 2006/3373.

provision of Schedule 4 or 5 to these Regulations, unless or until it is amended or revoked by virtue of that corresponding provision or as a consequence of a decision under this paragraph.

Service provision issues: dispensing doctors

14.—(1) Where, by virtue of a transfer scheme or paragraph 12, the NHSCB becomes engaged in any matter—

- (a) arising under the 2005 Regulations before the appointed day; and
- (b) relating to compliance with the terms of service of a dispensing doctor (whether compliance by the dispensing doctor or a Primary Care Trust),

that matter is to be resolved in accordance with the 2005 Regulations, and where applicable the SCAT Regulations and directions under section 87 of the 2006 Act (GMS contracts: payments), and the continuity principles are to be applied accordingly.

(2) Where, by virtue of a transfer scheme or paragraph 12, the NHSCB becomes engaged in any matter arising under the 2012 Regulations before the appointed day and relating to compliance with the terms of service mentioned in regulation 47(2) of the 2012 Regulations (terms of service of dispensing doctors: general), the arrangements mentioned in regulation 47(2)(a) of those Regulations must provide for the matter to be resolved—

- (a) justly;
- (b) in a manner that effects an orderly transition from the scheme established by the 2012 Regulations to the scheme established by these Regulations; and
- (c) if necessary or expedient in a manner that is inconsistent with these Regulations, or with regulations or directions under the 2006 Act that were in force immediately before the appointed day,

and the continuity principles are to be applied, and that matter is to be acted upon, accordingly.

(3) As regards the resolution of any matter—

- (a) arising under the 2012 Regulations before the appointed day; and
- (b) relating to changing or removing any entry in a dispensing doctor list by virtue the 2012 Regulations other than pursuant to an application under Part 8 of those Regulations (dispensing doctors) for premises approval or outline consent (paragraph 5 applies in those cases),

the matter is to be resolved in accordance with the 2012 Regulations, and the continuity principles are to be applied accordingly.

LPS schemes: replacement of Primary Care Trusts with the NHSCB and service provision issues

15.—(1) For the purposes of this paragraph, “the relevant transitional provisions” means—

- (a) in the case of an LPS pilot scheme, paragraph 92(8) of Schedule 4 to the Health and Social Care Act 2012(a) (amendments of the National Health Service Act 2006); or
- (b) in the case of LPS schemes that are not LPS pilot schemes, paragraph 93(6) of Schedule 4 to the Health and Social Care Act 2012.

(2) The changes to LPS schemes by virtue of the relevant transitional provisions take effect on the appointed day without the need for notices—

- (a) in the case of LPS pilot schemes, under any terms of those schemes; or
- (b) in the case of LPS schemes that are not LPS pilot schemes, under the terms of the schemes that give effect to paragraph 26 of Schedule 7.

(a) 2012 c. 7.

(3) Where, by virtue of a transfer scheme or the relevant transitional provisions, the NHSCB becomes engaged in any matter arising under an LPS scheme before the appointed day and relating to compliance with the terms of the LPS scheme (whether compliance by the LPS chemist or a Primary Care Trust)—

- (a) that matter is to be resolved in accordance with the relevant provisions of the LPS scheme, and any applicable provisions of 2006 Regulations and the Drug Tariff; and
- (b) the NHSCB may vary those terms, if necessary or expedient in a manner that is inconsistent with—
 - (i) the 2006 Regulations,
 - (ii) these Regulations, or
 - (iii) any directions under Chapter 2 of Part 7 of, and Schedule 11 to, the 2006 Act (which relate to local pharmaceutical services pilot schemes) that were in force immediately before the appointed day,

in order to provide for the matter to be resolved justly and in a manner that effects an orderly transition from the regulatory schemes for local pharmaceutical services established by the 2006 Regulations and directions under the 2006 Act to the regulatory schemes for local pharmaceutical services established by these Regulations and directions under the 2006 Act,

and the continuity principles are to be applied, and the matter is to be acted upon, accordingly.

Notification of LPS designations and completion of reviews

16.—(1) The making, varying or cancellation of a designation by a Primary Care Trust under Part 2 of the 2006 Regulations (designation) before the appointed day that was not, before the appointed day, notified in accordance with that Part is to be notified by the NHSCB as if it were made, varied or notified under Part 13 of these Regulations.

(2) Any review of a designation which was being undertaken by a Primary Care Trust before the appointed day but which was not completed before the appointed day is to be completed by the NHSCB.

The application of Group 12 of Schedule 8 to the Value Added Tax Act 1994

17. Pending amendment of Group 12 of Schedule 8 to the Value Added Tax Act 1994(a) (zero rating: drugs, medicines, aids for the handicapped, etc.) to take account of the coming into force of these Regulations, the definition of “relevant provision” in Note (2D) shall apply in relation to supplies on or after the appointed day as if for paragraph (j) there were substituted—

“(j) Part 8 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.”.

SCHEDULE 10

Regulation 120

Amendments and revocations

Amendment of the National Health Service (Charges for Drugs and Appliances) Regulations 2000

1. In regulation 2(1) of the Charges Regulations(b) (interpretation), for the definition of “Drug Tariff” substitute the following definition—

(a) 1994 c.23; relevant amendments have been made to Group 12 by S.I. 2009/2972.

(b) S.I. 2000/620; relevant amendments were made to regulation 2 by S.I. 2003/699, 2004/865, 2006/913, 2007/674 and 2012/1909.

““Drug Tariff” has the same meaning as in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;”.

Revocation of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002

2. The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(a) are revoked.

Revocation of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002

3. The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(b) are revoked.

Revocation of the National Health Service (Pharmaceutical Services) Amendment Regulations 2005

4. The National Health Service (Pharmaceutical Services) Amendment Regulations 2005(c) are revoked.

Revocation of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 and amendments to those Regulations

5.—(1) The National Health Service (Local Pharmaceutical Services etc.) Regulations(d) are revoked.

(2) The following provisions are revoked—

- (a) regulation 4 of the National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations 2006(e);
- (b) regulation 8 of the National Health Service (Pharmaceutical Services) (Remuneration for Persons Providing Pharmaceutical Services) (Amendment) Regulations 2007(f);
- (c) Part 2 of the National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009(g);
- (d) paragraphs 134 to 136 of Schedule 3 to the Transfer of Tribunal Functions Order 2010(h); and
- (e) paragraph 53 of Schedule 4 to the Pharmacy Order 2010(i).

Revocation of the National Health Service (Pharmaceutical Services) (Amendment) Regulations 2006

6. The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2006(j) are revoked.

-
- (a) S.I. 2002/888.
 - (b) S.I. 2002/2016.
 - (c) S.I. 2005/1015.
 - (d) S.I. 2006/552.
 - (e) S.I. 2006/913.
 - (f) S.I. 2007/674.
 - (g) S.I. 2009/2205.
 - (h) S.I. 2010/22.
 - (i) S.I. 2010/231.
 - (j) S.I. 2006/3373.

Amendments to the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009

7. In the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(a)—

- (a) in the definition of “relevant complaints procedure” in regulation 2 (interpretation), for paragraphs (i) to (iii) of sub-paragraph (a) substitute the following paragraphs—
 - “(i) paragraph 34 of Schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;
 - (ia) paragraph 24 of Schedule 5 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;
 - (ii) paragraph 8 of Schedule 6 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013; or
 - (iii) paragraph 25 of Schedule 7 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013; or”; and
- (b) paragraph 2 of the Schedule is revoked.

Revocation of the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Amendment Regulations 2009

8. The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Amendment Regulations 2009(b) are revoked.

Revocation of the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment) Regulations 2010

9. The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment) Regulations 2010(c) are revoked.

Revocation of the National Health Service (Local Pharmaceutical Services) Amendment Regulations 2012

10. The National Health Service (Local Pharmaceutical Services) Amendment Regulations 2012(d) are revoked.

Revocation of the National Health Service (Pharmaceutical Services) Regulations 2012 and of amendments to those Regulations

- 11.—(1) The following Regulations are revoked—
- (a) the National Health Service (Pharmaceutical Services) Regulations 2012(e); and
 - (b) National Health Service (Pharmaceutical Services) Regulations 2012 (Amendment) Regulations 2012(f).

Amendment of the Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch Arrangements etc.) Regulations 2012

12. In regulation 12(3)(d) of the Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch Arrangements etc.) Regulations 2012(g) (National Health

-
- (a) S.I. 2009/309.
 - (b) S.I. 2009/599.
 - (c) S.I. 2010/914.
 - (d) S.I. 2012/1467.
 - (e) S.I. 2012/1909.
 - (f) S.I. 2012/2371.
 - (g) S.I. 2012/3094.

Service payments by local authorities to specified NHS bodies in respect of prescribed functions) for “National Health Service (Pharmaceutical Services) Regulations 2012” substitute “National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations replace the National Health Service (Pharmaceutical Services) Regulations 2012 (“the 2012 Regulations”) and the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (“the 2006” Regulations”) as the Regulations which govern the arrangements, in England, for the provision of pharmaceutical and local pharmaceutical services under Part 7 of the National Health Service Act 2006 (“the 2006 Act”).

Part 1 contains introductory provisions. Part 2 sets out the requirements relating to the production of pharmaceutical needs assessments (“PNAs”) A PNA is a statement of the assessment that each Health and Wellbeing Board (“HWB”) must make, at least every 3 years, of the needs in its area for pharmaceutical services provided as part of the National Health Service. This Part includes the consultation requirements that have to be fulfilled before a PNA is completed and published (regulation 8) and the matters to which a HWB must have regard when producing a PNA (regulation 9) – and Schedule 1 thereafter sets out the information that must be included in PNAs. Pending full revision of a PNA, a HWB may address in a supplementary statement changes to the availability of pharmaceutical services since the PNA was published (regulation 6). Provision is also made for the temporary extension of PNAs of Primary Care Trusts, who were responsible for PNAs prior to their abolition (regulation 7).

Pharmaceutical services provision by virtue of these Regulations is essentially of three types: service provision by virtue of being included in pharmaceutical lists maintained by the National Health Service Commissioning Board (“the NHSCB”); service provision by virtue of being included in a dispensing doctor list maintained by the NHSCB; and service provision by virtue of an agreement to provide local pharmaceutical services with the NHSCB.

The pharmaceutical list system is a system under which retail pharmacy businesses and appliance contractors (together referred to as “chemists”) are given permission to provide NHS pharmaceutical services from particular premises, provided both they and the relevant premises are included in a pharmaceutical list maintained by the NHSCB. These lists are kept by reference to the areas of HWBs (regulation 10).

Part 3 includes general matters relating to pharmaceutical lists and applications from chemists join them – and also relating to applications from chemists on the lists to relocate to different premises or open new premises. The presumption is that “routine” applications (defined in regulation 12) will be assessed against the relevant PNA. The detail of the new arrangements, including the matters to which, in addition to the relevant PNA, the NHSCB must have regard when determining applications, is set out in this Part. There is also provision (regulation 18) for granting routine applications that offer improvements or better access to pharmaceutical services that were not foreseen when the relevant PNA was published, in certain circumstances. Subject to this exception, routine applications must be refused unless they offer to meet needs, or secure improvements or better access, that are mentioned in the relevant PNA (regulation 22).

Part 4 sets out a number of types of applications in respect of pharmaceutical lists, known as “excepted” applications, that do not have to be assessed as provided for in Part 3. These include, for example, relocation applications that do not result in significant change to pharmaceutical services provision (regulation 24) and change of ownership applications (regulation 26). Under Chapter 6 of Part 7 of the 2006 Act, there are powers to suspend chemists on pharmaceutical lists during fitness investigations or pending fitness appeals – and an exception is also made in respect of a temporary chemist joining a pharmaceutical list to provide services in place of a suspended chemist (regulation 27). A further exception is made (in regulation 28) to allow chemists who provide local pharmaceutical services a right of return to a pharmaceutical list in appropriate circumstances. A new exception (with effect from 1st April 2013) has been created to allow for the temporary relocation of chemists to nearby premises where there is a temporary suspension in

the provision of pharmaceutical services for a reason beyond the control of the chemist (regulation 29).

Part 5 contains some grounds for refusing different types of applications in respect of pharmaceutical lists, for example because the premises to which the application relates are in an area that has been set aside for tendering arrangements for a contract to provide local pharmaceutical services (regulation 32).

Part 6 provides for refusal and deferral of applications, and for conditional inclusion in pharmaceutical lists, for fitness reasons. There are some mandatory grounds (for example, murder convictions) as a consequence of which a person, partnership or body corporate must be refused entry onto a pharmaceutical list, and some discretionary grounds (regulation 33). If, instead of refusing an application, the NHSCB decides to grant it subject to permissible fitness conditions, and these conditions are not appealed or are upheld on appeal, the applicant has to decide within a set timetable whether or not they wish to withdraw the granted application (regulation 35).

Part 7 covers determinations as to whether or not an area is a controlled locality or a reserved location. Controlled locations are areas that are rural in character where doctors may apply to provide dispensing services (a restricted range of pharmaceutical services), if certain conditions are met. Determinations that an area is a controlled locality may only take place once every 5 years unless there is a substantial change of circumstances in the intervening period (regulation 36). Routine applications from retail pharmacy businesses to locate pharmacy premises in a controlled locality face two additional hurdles to those already set out in Part 3: firstly, applications in defined parts of a controlled locality cannot be made within 5 years of either the refusal of a similar pharmacy application or the grant of a relevant permission to doctors to dispense, unless there is a substantial change of circumstances affecting the locality (regulation 40); and secondly, the applications are subject to the “prejudice test” (regulation 44), under which the NHSCB is required to refuse the application if it would prejudice the proper provision of relevant NHS services. Where an application for a new pharmacy in a controlled locality is granted, the NHSCB may determine that the pharmacy is at the centre of a reserved location – that is, essentially, an area of below a specified population threshold in which patients are to have the option of receiving dispensing services from either a dispensing doctor or a retail pharmacy business.

The procedures, generally, for dealing with pharmaceutical list applications and related appeals are dealt with in Schedules 2 and 3. These procedures provide for the content of applications (Part 1 of Schedule 2), the process for notifying most types of applications to interested parties that might want to make representations in relation to them (Part 3 of Schedule 2), and the decision making processes – including provision for oral hearings (Part 4 of Schedule 2). There is also provision for the notification of decisions – and arrangements for when, and subject to what notification requirements, chemists may open new premises that are the subject of successful applications (Part 5 of Schedule 2). The procedures with regard to appeals, either by applicants against refusals or by third parties with appeal rights, are for the most part covered in Schedule 3 – and again there is provision for notification of interested parties both of appeals (to allow for third party representations in most cases) and of decisions on appeals.

Part 8 sets out the arrangements under which an NHS general practitioner who has, or whose practice has, a registered patient list may provide dispensing services. Generally to do so, individual general practitioners or their medical practice face three hurdles: firstly, the patients to whom they could provide dispensing services must have applied to them for such services (regulation 48); secondly, they must have been granted premises approval for the medical practice premises from which they wish to dispense; and thirdly, they must have been granted outline consent in relation to the area to whose residents they wish to dispense (or have relevant historic rights to dispense). The taking effect of decisions to grant outline consent and premises approval may be delayed to allow for the processing of outstanding pharmacy applications (regulations 52 and 56) and to mitigate the effects on other providers of pharmaceutical services locally (regulation 57).

Once included on a dispensing doctor list maintained by the NHSCB (under regulation 46) and so permitted to provide dispensing services, dispensing doctors have to comply with the terms of service for dispensing doctors set out in Schedule 6 and which for the most part deal with specific issues relating to dispensing. Dispensing doctors may however be required to discontinue that provision if the conditions that led to the grant of their entitlement to dispense no longer apply (generally, unless the practice premises are in a reserved location, discontinuation will result from the opening of a pharmacy nearby) – subject to arrangements for possible postponement of the discontinuation (regulation 50). There are also circumstances in which outline consent and premises approval may lapse, for example where it has been more than 6 months since any drug or appliance was dispensed under the arrangements with the dispensing doctor (regulation 60) – and there are also procedures for dealing with medical practices either relocating or amalgamating (regulations 54, 55 and 59).

Part 9 sets out some conditions that are to be imposed on chemists as part of their terms of service with the NHSCB, which include requirements relating to co-operation with the NHSCB over local resolution of disputes (regulation 68). These Part 9 conditions are in addition to the principal terms of service for chemists, which are in Schedule 4 for retail pharmacy businesses and Schedule 5 for appliance contractors.

The terms of service in Schedule 4 include obligations to provide what are described as the essential services that must be provided at each pharmacy. These essential services include not only dispensing services but other services, for example disposal services in respect of unwanted drugs and promotion of healthy lifestyles. As well as providing essential services, retail pharmacy businesses are subject to other compulsory requirements by virtue of Schedule 4, for example with regard to having acceptable systems of clinical governance and providing information about fitness matters. The range of necessary services required of appliance contractors in Schedule 5 is more limited, but also includes requirements with regard to dispensing and additional compulsory requirements with regard to clinical governance and providing information about fitness matters. Both of these types of provider of pharmaceutical services are also subject to detailed requirements with regard to their opening hours and changes to them.

Part 10 sets out the arrangements for dealing with breaches of terms of service by chemists (breaches by dispensing doctors are dealt with under their parallel arrangements for providing primary medical services to registered patients, which they must have in order to be providers of pharmaceutical services). Where a dispute between a chemist and the NHSCB cannot be resolved under the local dispute resolution procedures (or where that procedure may be by-passed), the chemist faces the possibility of a breach or remedial notice, as a part of which there may be a payment withholding (regulations 70 to 72). In some cases, repeated failures to comply with terms of service, or failures with particularly serious consequences, may thereafter lead to the removal of a chemist's business premises from the relevant pharmaceutical list. Removal of such premises is also a possibility in other cases, for example (subject to exceptions) where a chemist has not provided NHS pharmaceutical services for more than 6 months, and there are also arrangements for voluntary removal, which may be prevented if the contractor is subject to ongoing fitness proceedings (regulations 73 to 76).

Part 11 contains procedures for dealing with fitness issues with regard to chemists on pharmaceutical lists. These include procedures for reviewing fitness conditions imposed under regulation 35 on chemists as a condition of their inclusion in a pharmaceutical list – but for the most part, the procedures complement the arrangements for imposing fitness sanctions that are set out in Chapter 6 of Part 7 to the 2006 Act. There are also substantive requirements that complement those Chapter 6 arrangements, for example a prescribed list of grounds for which the NHSCB must remove a chemist from a pharmaceutical list in an unsuitability case under section 151(4) of the 2006 Act, a list which includes murder convictions (regulation 81). Where fitness sanctions are imposed, there are notification requirements that provide for dissemination of relevant information to other bodies that may need to consider taking action, for example the devolved administrations and the General Pharmaceutical Council, and to other persons who are entitled to request the information (regulation 88).

Part 12 contains provisions relating to financial matters. Regulation 89 provides for the publication of the Drug Tariff, the main statement of the financial entitlements of chemists that provide pharmaceutical services. The Secretary of State is the determining authority for reimbursement referable to the cost of drugs and appliances, but the NHSCB acts as the determining authority for other remuneration, in particular for some additional services and for the items listed in Schedule 8 (regulation 91). Dispensing doctor remuneration is linked to what their entitlement is or would be under a general medical services contract (regulation 92). There are also provisions for dealing with supplemental matters, for example overpayments and refunds of prescription charges. The Secretary of State is also given powers to make a separate determination of remuneration which will apply to chemists who are suspended from a pharmaceutical list, either during an investigation or pending an appeal, for fitness reasons (regulation 98).

Part 13 and Schedule 7 deal with local pharmaceutical services, which are a set of contractual arrangements, known as LPS schemes, with the NHSCB under which chemists provide pharmaceutical services whilst not on a pharmaceutical list. LPS schemes come in two types: LPS pilot schemes, a set of schemes whose main terms, and any arrangements for entering into them, are set out in a separate set of directions, and the standard form of LPS schemes, the mandatory terms for which are set out in Schedule 7 and cover matters such as dispensing arrangements (all LPS schemes must include provision for the dispensing of drugs – regulation 102), clinical governance, professional standards, inducements, remuneration and charges, complaints, dispute resolution and termination.

Before commissioning services under the standard form of LPS scheme, the NHSCB may decide to designate an area of a HWB, premises or descriptions of premises (regulation 99), the effect of which will be to allow for the deferral of routine applications (regulation 32) for the duration of the designation, facilitating the commissioning of local pharmaceutical services at the location in question. There are also arrangements for the review and cancellation of designations (regulations 100 and 101). Where the NHSCB does enter into the standard form of LPS scheme, there are arrangements for that scheme being (unless the contractor objects) an NHS contract, which affects the arrangements for dispute resolution (regulation 103). Only contractors demonstrating certain fitness requirements may become parties to such schemes (regulation 105), and persons proposing to enter into such schemes must first send the NHSCB information about their fitness to be parties to them (regulation 106). Proposals for the standard form of LPS scheme that may proceed for development also have to be notified to interested parties by the NHSCB (regulation 107). If a contractor, on entering into the standard form of LPS scheme, gives up a right to be on a pharmaceutical list, they may be given a right of return (regulation 108). There are also provisions about whether or not LPS pilot schemes are to be NHS contracts (regulation 109), and about what happens on termination of pilot schemes. In effect, unless the pilot scheme terminates for a reason relating to the fitness of the provider to be a provider of pharmaceutical services, the scheme premises and the contractor are included in a pharmaceutical list (regulation 110). There are also other administrative provisions relating to LPS schemes, including arrangements for dealing with emergencies requiring the flexible provision of pharmaceutical services (regulation 111).

Part 14 deals with some miscellaneous matters, for example a provision that allows for applications for services to be made on behalf of some patients by duly authorised persons (regulation 116) and the delegation of certain functions of the Secretary of State to the National Health Service Litigation Authority (regulation 117).

Regulation 119 introduces Schedule 9, which sets out a number of transitional provisions. These include arrangements to deal with the abolition of Primary Care Trusts. Outstanding listing applications under the 2012 Regulations, and the LPS schemes and listing entries that are already in existence, are preserved. Ongoing matters essentially carry on.

Regulation 120 introduces Schedule 10, which contains a number of consequential amendments and revocations.

These Regulations will be the subject of a published review by 31st August 2017 (regulation 121).



Published by TSO (The Stationery Office) and available from:

Online

www.tsoshop.co.uk

Mail, Telephone, Fax & E-mail

TSO

PO Box 29, Norwich, NR3 1GN

Telephone orders/General enquiries: 0870 600 5522

Fax orders: 0870 600 5533

E-mail: customer.services@tso.co.uk

Textphone: 0870 240 3701

TSO@Blackwell and other Accredited Agents

ISBN 978-0-11-153489-2



9 780111 534892

S.I. 2013 No. 349

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

