STATUTORY INSTRUMENTS

2013 No. 363

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Primary Medical Services) (Miscellaneous Amendments and Transitional Provisions) Regulations 2013

Made	15th February 2013
Laid before Parliament	27th February 2013
Coming into force	1st April 2013

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 83, 85, 86(4), 88, 89, 90, 91, 93, 94, 97(6), 259 and 272(7) and (8) of the National Health Service Act 2006(1).

PART 1

GENERAL

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Primary Medical Services) (Miscellaneous Amendments and Transitional Provisions) Regulations 2013 and come into force on 1st April 2013.

(2) In these Regulations—

"GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2004(**2**); and

^{(1) 2006.} c.41. By virtue of section 271(1) of the Act, the powers conferred by these sections are exercisable by the Secretary of State only in relation to England. Section 83 is amended by section 55(1) of, and paragraph 30 of Schedule 4 to, the Health and Social Care Act 2012 (c.7) ("the 2012 Act"); section 86 is amended by section 55(1) of, and paragraph 32 of Schedule 4 to, the 2012 Act; section 89 is amended by sections 28(1), 55(1) and 202(2) of, and paragraph 34 of Schedule 4 to, the 2012 Act; section 91 is amended by section 55(1) of, and paragraph 35 of Schedule 4 to, the 2012 Act; section 93 is amended by section 55(1) and 202(2) of, and paragraph 34 of Schedule 4 to, the 2012 Act; section 91 is amended by section 55(1) of, and paragraph 35 of Schedule 4 to, the 2012 Act; section 93 is amended by sections 55(1) of, and paragraph 37 of Schedule 4 to, the 2012 Act; section 94 is amended by sections 28(2) and 55(1) of, and paragraph 38 of Schedule 4 to, the 2012 Act; section 97 is amended by section 55(1) of, and paragraph 41 of Schedule 4 to, the 2012 Act and section 259 is amended by section 55(1) of, and paragraph 132 of Schedule 4 to, the 2012 Act. See also section 275(1) for the definition of "prescribed" and "regulations".

 ⁽²⁾ S.I. 2004/291, amending instruments are S.I. 2004/2694, 2005/893, 3315, 3491 and 3315, 2006/1501, 2007/3491, 2008/528 and 1700, 2009/2205 and 2230, 2010/22, 231, 234, 478 and 578 and 2012/970, 1479, 1909 and 1916.

"PMS Agreements Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2004(**3**).

PART 2

AMENDMENT OF THE GMS CONTRACTS REGULATIONS

2. The GMS Contracts Regulations are amended in accordance with this Part.

Amendment of regulation 2

- 3. In regulation 2 (interpretation)—
 - (a) for the definition of "assessment panel", substitute—

""assessment panel" means the panel appointed by the Board under paragraph 35(3) of Schedule 6;";

(b) for the definition of "batch issue" substitute—

""batch issue" means a form, in the format required by the Board and approved by the Secretary of State which—

- (a) is issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a chemist or person who provides dispensing services to receive payment for the provision of repeat dispensing services;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is generated by a computer and not signed by a repeatable prescriber;
- (d) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs, medicines or appliances ordered on the non-electronic repeatable prescription may be provided; and
- (e) has included on it a number denoting its place in the sequence referred to in sub-paragraph (d);";
- (c) immediately after the definition of "batch issue", insert-

""the Board" means the National Health Service Commissioning Board;

"Care Quality Commission" means the body established by section 1 of the Health and Social Care Act 2008;

"CCG" means a clinical commissioning group;"(4);

- (d) in the definition of "chemist", for "a Primary Care Trust", substitute "the Board";
- (e) immediately after the definition of "childhood vaccines and immunisations", insert-

"chiropodist or podiatrist independent prescriber" means a person-

- (a) who is engaged or employed by the contractor or is a party to the contract; and
- (b) who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001 (establishment and maintenance of register), and against whose name in that register is recorded

⁽³⁾ S.I. 2004/627, amending instruments are S.I. 2004/2694, 2005/893, 3315 and 3491, 2006/1501, 2007/3491, 2008/528 and 1700, 2009/2205, 2230, 2010/22, 231, 234, 478 and 578 and 2012/970, 1479, 1909 and 1916.

^{(4) 2008} c.14. The National Health Service Commissioning Board is established by section 1H of the 2006 Act. Section 1H is inserted by section 9 of the 2012 Act. A clinical commissioning group is a body established under section 14D of the 2006 Act. Section 14D is inserted by section 25(1) of the 2012 Act. See also section 1I of the 2006 Act. Section 1I is inserted by section 10 of the 2012 Act.

an annotation signifying that the chiropodist or podiatrist is qualified to order drugs, medicines and appliances as a chiropodist or podiatrist independent prescriber;"(5);

- (f) in the definition of "contractor's list of patients", for "the Primary Care Trust", substitute "the Board";
- (g) in the definition of "dispensing services" for "regulation 48 of the Pharmaceutical Regulations", substitute "section 126 (arrangements for pharmaceutical services) and section 129 (regulations as to pharmaceutical services) of the 2006 Act";
- (h) for the definition of "Drug Tariff", substitute—

""Drug Tariff" means the publication known as the Drug Tariff which is published by the Secretary of State and which is referred to in section 127(4) (arrangements for additional pharmaceutical services) of the 2006 Act;";

(i) immediately after the definition of "electronic prescription form", insert-

""Electronic Prescription Service" means the service of that name which is operated by the Health and Social Care Information Centre;"(6);

(j) for the definition of "electronic repeatable prescription", substitute-

""electronic repeatable prescription" means a prescription which falls within paragraph (b) of the definition of "repeatable prescription";";

- (k) omit the definition of "ETP service";
- (l) in the definition of "home oxygen order form", for "the Primary Care Trust", substitute "the Board";
- (m) in the definition of "listed medicines voucher", for "a Primary Care Trust", substitute "the Board";
- (n) for the definition of "Local Medical Committee", substitute—

""Local Medical Committee" means a committee recognised by the Board under section 97 of the 2006 Act;"(7);

- (o) omit the definition of "local pharmaceutical services";
- (p) in the definition of "medical card" for "a Primary Care Trust", substitute "the Board";
- (q) for the definition of "medical performers list", substitute—

""medical performers list" means the list of medical practitioners maintained and published by the Board in accordance with section 91 (persons performing primary medical services) of the 2006 Act;"(8);

- (r) omit the definitions of "NHS Care Record" and "NHS Care Record Service";
- (s) for the definition of "nominated dispenser", substitute-

""nominated dispenser" means a chemist, medical practitioner or contractor who has been nominated in respect of a patient and the details of that nomination are held in respect of that patient in the Patient Demographics Service which is operated by the Information Centre for Health and Social Care;";

(t) for the definition of "non-electronic repeatable prescription", substitute-

""non-electronic repeatable prescription" means a form for the purpose of ordering a drug, medicine or appliance which—

⁽⁵⁾ S.I. 2002/254; article 5 is amended by S.I. 2009/1182. This Order is renamed by section 213(4) and (6) of the 2012 Act.

⁽⁶⁾ The Health and Social Care Information Centre is established under section 252 of the 2012 Act.

⁽⁷⁾ Section 97 is amended by section 55(1) of, and paragraph 41(1) and (2) of Schedule 4 to, the 2012 Act.

⁽⁸⁾ Section 91 is amended by section 55(1) of, and paragraph 35(1) and (2) of Schedule 4 to, the 2012 Act.

- (a) is provided by the Board, a local authority or the Secretary of State;
- (b) is issued by the prescriber;
- (c) indicates that the drug, medicine or appliance ordered may be provided more than once; and
- (d) specifies the number of occasions on which they may be provided;";
- (u) omit the definition of "NPSA";
- (v) immediately after the definition of "patient", insert-

""Patient Choice Extension Scheme" means the scheme of that name established by the Secretary of State under which primary medical services may be provided under arrangements made in accordance with directions given to the Board by the Secretary of State under section 98A (exercise of functions) of the 2006 Act;"(9);

- (w) omit the definition of "Pharmaceutical Regulations";
- (x) immediately after the definition of "pharmacist independent prescriber", insert-

"physiotherapist independent prescriber" means a person-

- (a) who is engaged or employed by the contractor or is a party to the contract; and
- (b) who is registered in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2001 (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the physiotherapist is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;";
- (y) for the definition of "prescriber", substitute—

"prescriber" means-

- (a) a chiropodist or podiatrist independent prescriber;
- (b) an independent nurse prescriber;
- (c) a medical practitioner;
- (d) an optometrist independent prescriber;
- (e) a pharmacist independent prescriber;
- (f) a physiotherapist independent prescriber; and
- (g) a supplementary prescriber,

who is either engaged or employed by the contractor or is a party to the contract;";

(z) for the definition of "prescription form", substitute—

""prescription form" means, except in the context of the expression "electronic prescription form" or "non-electronic prescription form"—

- (a) a form for the purpose of ordering a drug, medicine or appliance which is-
 - (i) provided by the Board, a local authority or the Secretary of State;
 - (ii) issued by the prescriber: and
 - (iii) does not indicate that the drug, medicine or appliance ordered may be provided more than once; or

⁽⁹⁾ Section 98A is inserted by section 49(1) of the 2012 Act. The Patient Choice Extension Scheme Directions signed on 11th February 2013 and published on the Department of Health website www.dh.gov.uk.

- (b) where paragraph 39A(1) (electronic prescriptions) of Schedule 6 applies, data created in an electronic form for the purpose of ordering a drug, medicine or appliance, which—
 - (i) is signed with a prescriber's advanced electronic signature;
 - (ii) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and
 - (iii) does not indicate that the drug, medicine or appliance ordered may be provided more than once;";
- (aa) for the definition of "Primary Care Trust", substitute-

""Primary Care Trust" means, unless the context otherwise requires, the Primary Care Trust which was a party to the contract immediately before the coming into force of section 34 (abolition of Primary Care Trusts) of the Health and Social Care Act 2012;";

- (bb) in the definition of "registered patient", in each place, for "the Primary Care Trust", substitute "the Board";
- (cc) in the definition of "relevant register"-
 - (i) in paragraph (a), omit "and"; and
 - (ii) at the end of paragraph (b), add—
 - "(c) in relation to an optometrist, the register maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989; and
 - (d) the part of the register maintained by the Health and Care Professions Council in pursuance of article 5 of the Health and Social Work Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) radiographers;"(10);
- (dd) omit the definition of "relevant Strategic Health Authority";
- (ee) for the definition of "repeatable prescription", substitute-

""repeatable prescription" means, except in the context of the expression "electronic repeatable prescription" or "non-electronic repeatable prescription", a prescription which—

- (a) is a form provided by the Board, a local authority or the Secretary of State for the purpose of ordering a drug, medicine or appliance which is in the format required by the NHS Business Services Authority and which—
 - (i) is issued by a repeatable prescriber to enable a chemist or person providing dispensing services to receive payment for the provision of repeat dispensing services;
 - (ii) indicates that the drug, medicine or appliance ordered may be provided more than once; and
 - (iii) specifies the number of occasions on which they may be provided; or
- (b) where paragraph 39A(1) of Schedule 6 applies, is data created in an electronic form for the purposes of ordering a drug, medicine or appliance, which—

⁽¹⁰⁾ Section 7 of the Opticians Act 1989 (c.44) is amended by articles 2 and 7 of S.I. 2005/848. Section 214 of the 2012 Act provides for the Health Professions Council to continue to exist and to change its name to the Health and Care Professions Council.

- (i) is signed with a prescriber's advanced electronic signature;
- (ii) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and
- (iii) indicates that the drug, medicine or appliance ordered may be provided more than once and specifies the number of occasions on which they may be provided;"(11);
- (ff) immediately after the definition of "section 28C provider", insert-

""service provider" has the same meaning as in regulation 2 of the Care Quality Commission (Registration) Regulations 2009 (interpretation);"(12); and

(gg) omit the definition of "walk-in centre".

Substitution of regulation 3

4. For regulation 3 (conditions: general), substitute—

"3. Subject to the provisions of any scheme made by the Secretary of State under section 300 (transfer schemes) and any order made under section 303 (power to make consequential provision) of the Health and Social Care Act 2012, the Board may only enter into a contract if the conditions set out in regulations 4 and 5 are met."

Amendment of regulation 4

- 5. In regulation 4 (conditions relating solely to medical practitioners)—
 - (a) in paragraph (2)(b)(ii), omit "a Primary Care Trust,"; and
 - (b) in paragraph (3)—
 - (i) in sub-paragraphs (a) and (b), immediately before "legally and beneficially", in each place, insert "both"; and
 - (ii) in sub-paragraph (b)(ii), omit "a Primary Care Trust,".

Amendment of regulation 5

6. In regulation 5 (general condition relating to all contracts)—

- (a) in paragraph (1)(c)(ii) immediately before "legally and beneficially" insert "both";
- (b) in paragraph (3)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) in sub-paragraph (c)(i), immediately before "legally and beneficially" insert "both";
- (c) in paragraph (5)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) in sub-paragraph (c)(i), immediately before "legally and beneficially" insert "both"; and
- (d) add after paragraph (5)—

"(6) For the purposes of paragraph (2)(c), a health service body respectively includes a Strategic Health Authority or a Primary Care Trust which was established before the coming into force of section 33 or 34 of the Health and Social Care Act 2012."

⁽¹¹⁾ The NHS Business Services Authority is established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG (Establishment and Constitution) Order 2005 S.I. 2005/2414.

⁽¹²⁾ S.I. 2009/3112.

Amendment of regulation 6

- 7. In regulation 6 (reasons)—
 - (a) in paragraph (1), for "a Primary Care Trust", substitute "the Board"; and
 - (b) in paragraph (2)—
 - (i) for "The Primary Care Trust", substitute "The Board"; and
 - (ii) immediately before "legally and beneficially", insert "both".

Amendment of regulation 7

8. In regulation 7 (appeal), for "the Primary Care Trust", substitute "the Board".

Amendment of regulation 9

9. In regulation 9 (pre-contract disputes), in paragraph (3)(b), for "the Primary Care Trust", substitute "the Board".

Amendment of regulation 10

10. In regulation 10 (health service body status), in paragraphs (1), (4)(a), (5) and (7)(b), for "the Primary Care Trust", substitute "the Board".

Amendment of regulation 14

11. In regulation 14 (duration)—

- (a) in paragraph (2), for "the Primary Care Trust", substitute "the Board"; and
- (b) for paragraph (3), substitute—

"(3) Either party to a prospective contract to which paragraph (2) applies may, if it wishes to do so, invite the Local Medical Committee for the area in which it is intended that primary medical services are to be provided by the prospective contractor to participate in the negotiations intending to lead to such a contract.".

Amendment of regulation 15

- 12. In regulation 15 (essential services)—
 - (a) at the beginning of paragraph (1), insert "Subject to paragraph (1A),"; and
 - (b) after paragraph (1), insert—

"(1A) The services described in paragraphs (3), (5), (6) and (8) are not required to be provided by the contractor during any period in respect of which the Care Quality Commission has suspended the contractor as a service provider under section 18 of the Health and Social Care Act 2008 (suspension of registration)."; and

(c) in paragraph (9), omit "in the area of the Primary Care Trust".

Amendment of regulation 17

13. In regulation 17 (opt outs of additional and out of hours services)—

- (a) in paragraph (1), omit "except paragraphs 3(12) to (14)";
- (b) in paragraph (2), omit ", except paragraphs 4(9)" to the end of that paragraph;
- (c) in paragraph (3), omit ", except paragraph 4(8)" to the end of that paragraph; and

(d) omit paragraph (4).

Amendment of regulation 18

14. In regulation 18 (services generally), in paragraph (3), for "the Primary Care Trust", in each place, substitute "the Board".

Insertion of new regulation 20A

15. After regulation 20 (services generally), insert—

"Membership of a CCG

20A. A contract must contain a term which has the effect of requiring—

- (a) the contractor to be a member of a CCG; and
- (b) that contractor to appoint one individual who is a health care professional to act on its behalf in the dealings between it and the CCG to which it belongs.".

Amendment of regulation 22

16. In regulation 22 (finance), in paragraph (2), for "the Primary Care Trust", in each place, substitute "the Board".

Substitution of regulation 23

17. For regulation 23, substitute—

"23. The contract must contain a term to the effect that where, pursuant to directions under section 87 (GMS contracts: payments) or section 98A (exercise of functions) of the 2006 Act, the Board is required to make a payment to a contractor under a contract but subject to conditions, those conditions are to be a term of the contract.".

Amendment of regulation 24

18. In regulation 24 (fees and charges), in paragraph (4), for "the Primary Care Trust", in each place, substitute "the Board".

Amendment of regulation 26

19. In regulation 26 (other contractual terms), in paragraph (1) for "except paragraphs" to the end of that paragraph, substitute "except paragraphs 35(5) to (9), 36(5) to (17), 101(5) to (14) and 102.".

Omission of regulation 26A and insertion of new regulation 26B

20. Omit regulation 26A (variation of contractual terms in respect of entering into arrangements under the Patient Choice Scheme) and insert after regulation 26 (other contractual terms)—

"Variation of contractual terms in respect of entering into arrangements under the Patient Choice Extension Scheme

26B.—(1) This regulation applies where the contractor and the Board enter into arrangements under the Patient Choice Extension Scheme.

(2) The terms of the contract—

- (a) which have the same effect as the provisions specified in paragraph (3) must be varied in accordance with paragraph (4); and
- (b) must be varied to include terms which have the same effect as the provisions specified in paragraphs (5) to (6),

but only to the extent that such variations relate to the provision of primary medical services to patients who received such services under arrangements made in accordance with the Patient Choice Scheme and wish to continue to do so under the Patient Choice Extension Scheme with effect from the start of the day on which such arrangements commence and for the period ending at the end of the day which is the date of the termination of those arrangements, which must be no later than 31st March 2014.

(3) The terms of the contract specified in this paragraph are—

- (a) regulation 15 (essential services);
- (b) regulation 20 (which provides for arrangements to access services throughout core hours);
- (c) the provisions which provide for the contractor to provide out of hours services; and
- (d) in Schedule 6 (other contractual terms)—
 - (i) paragraph 2(1) (attendance at practice premises);
 - (ii) paragraph 3(2)(a) (attendance outside practice premises); and
 - (iii) paragraph 17(2) (refusal of applications for inclusion in the list of patients).

(4) The contract must include terms which have the effect of temporarily releasing the contractor and the Board from all obligations, payments, rights and liabilities relating to those terms (and only those terms) which have the same effect as the provisions specified in paragraph (3)—

- (a) including any right to enforce those terms only in respect of the provision of primary medical services to patients who wish to receive such services under arrangements made in accordance with the Patient Choice Extension Scheme; and
- (b) only where, in the opinion of the contractor, it is not clinically appropriate or practical to provide the services or access to such services in accordance with those terms or to comply with those terms, under arrangements made under the Patient Choice Extension Scheme.

(5) The contract must also include a term which has the effect of requiring the contractor to notify a person in writing that where the contractor is minded to continue to accept that person on its list of patients in accordance with the Patient Choice Extension Scheme the contractor is under no obligation to provide—

- (a) essential services, in a case where at the time treatment is required, it is not clinically appropriate or practical to provide primary medical services given the particular circumstances of the patient;
- (b) out of hours services, in a case where at the time treatment is required, it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient; or
- (c) additional services (within the meaning of regulation 2) to the patient if it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient.

(6) The contract must also include terms to have the effect of providing that immediately after the date of the termination of the arrangements under the Patient Choice Extension Scheme, the variations made as a consequence of paragraph (2) must terminate save to

the extent necessary in respect of enforcing any obligation, condition, payment, right and liability arising from those terms prior to the date of termination.".

Amendment of regulation 27

21. In regulation 27 (functions of Local Medical Committees)—

- (a) in paragraph (1)(b), for "the Primary Care Trust with whom the contract is held", substitute "the Board";
- (b) in paragraph (1)(c), for "the Primary Care Trust", substitute "the Board";
- (c) in paragraph (1)(d), for "the Primary Care Trust with whom the contractor holds a contract", substitute "the Board"; and
- (d) in paragraph (2)(c), immediately before "a legal and beneficial" insert "both".

Amendment of regulation 31

22. In regulation 31 (out of hours services) for paragraph (3)(b), substitute—

"(b) the Board has agreed in writing that the contractor need no longer provide some or all of those services to some or all of those patients.".

Omission of regulation 32 and Schedule 7

23. Omit regulation 32 and Schedule 7 (out of hours services).

Amendment of Schedule 2

24. In Schedule 2 (additional services), in paragraph 2(2)(a) (cervical screening) and 6(2)(b) (child health surveillance), for "the Primary Care Trust", substitute "the Board".

Amendment of Schedule 3

25.—(1) Schedule 3 (opt outs of additional and out of hours services) is amended as follows.

- (2) In paragraph 1 (opt outs of additional services: general)—
 - (a) in sub-paragraph (2), for "the relevant Primary Care Trust", substitute "the Board";
 - (b) in sub-paragraphs (3), (4) and (5), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (c) omit sub-paragraph (9).
- (3) In paragraph 2 (temporary opt outs and permanent opt outs following temporary opt outs)-
 - (a) in sub-paragraphs (1), (3), (4), (7), (10) and (15)(b), for "the Primary Care Trust", in each place, substitute "the Board";
 - (b) in sub-paragraphs (2), (6) and (8), for "a Primary Care Trust", substitute "the Board";
 - (c) in sub-paragraph (5)—
 - (i) for "the Primary Care Trust", in each place, substitute "the Board";
 - (ii) in paragraph (d)(i), after "28 days after the end date," insert "or"; and
 - (iii) omit at the end of paragraph (d)(ii) "or" and omit paragraph (d)(iii);
 - (d) in sub-paragraph (9), for "the relevant Primary Care Trust", substitute "the Board"; and
 - (e) omit sub-paragraphs (11), (12), (13) and (14);
- (4) In paragraph 3 (permanent opt outs)—

- (a) in sub-paragraphs (1) and (3), for "a Primary Care Trust", substitute "the Board";
- (b) in sub-paragraphs (2), (5), (6), (9) and (21)(b), for "the Primary Care Trust", in each place substitute "the Board";
- (c) in sub-paragraph (4)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "the Primary Care Trust's", substitute "the Board's";
- (d) in sub-paragraph (7)—
 - (i) except in paragraph (b), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (ii) in paragraph (b), omit "unless at least one month" to the end of that paragraph (b);
- (e) in sub-paragraph (8)—
 - (i) omit "unless at least one month" to the end of that sub-paragraph; and
 - (ii) for the remaining references to "the Primary Care Trust", substitute "the Board";
- (f) omit sub-paragraphs (10) to (19); and
- (g) in sub-paragraph (20)—
 - (i) for "sub-paragraphs (1) to (19)", substitute "sub-paragraphs (1) to (9)"; and
 - (ii) for "the Primary Care Trust", substitute "the Board".

(5) In paragraph 4 (out of hours opt outs where the opt out notice is served after 30th September 2004)—

- (a) in sub-paragraph (2), for "the relevant Primary Care Trust", substitute "the Board";
- (b) in sub-paragraphs (4), (5) and (8), for "the Primary Care Trust", substitute "the Board"; and
- (c) in sub-paragraph (7)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "the Primary Care Trust's", substitute "the Board's"; and
- (d) in sub-paragraph (9)—
 - (i) for "Sub-paragraphs (6) to (21)", substitute "Sub-paragraphs (6) to (9)"; and
 - (ii) omit "and the reference in paragraph 3(16)" to the end of that sub-paragraph.

(6) Omit paragraph 5 (out of hours opt outs where the opt out notice is served before 1st October 2004).

(7) In paragraph 6 (informing patients of opt outs), for "the Primary Care Trust", in each place substitute "the Board".

Amendment of Schedule 5

26. In Schedule 5 (fees and charges)—

- (a) in paragraph 1(c) and (g) for "the Primary Care Trust", substitute "the Board"; and
- (b) in paragraph (1)(k), for "by a Primary Care Trust" to the end of that sub-paragraph substitute—

"in accordance with arrangements made with the Board under section 126 (arrangements for pharmaceutical services) and in accordance with regulations made under section 129 (regulations as to pharmaceutical services) of the 2006 Act to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of dispensing services, any Scheduled drug;".

Amendment of Schedule 6

27.—(1) Schedule 6 (other contractual terms) is amended as follows.

(2) In paragraph 3 (attendance outside practice premises), in sub-paragraph (2)(b), for "the Primary Care Trust", substitute "the Board".

(3) In paragraph 4 (newly registered patients), in sub-paragraph (1)(b), for "the Primary Care Trust", substitute "the Board".

- (4) In paragraph 7 (clinical reports)—
 - (a) in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board"; and
 - (b) for sub-paragraph (2), substitute—

"(2) The Board must send any report received under sub-paragraph (1) to the person with whom the patient is registered for the provision of essential services or their equivalent.".

- (5) In paragraph 11A (supply of medicines etc. by contractors providing out of hours services)—
 - (a) in sub-paragraph (1)—

(i) omit the definition of "the Charges Regulations"; and

(ii) in the definition of "supply form" for "a Primary Care Trust", substitute "the Board";

- (b) in sub-paragraph (2), for "the Primary Care Trust", substitute "the Board"; and
- (c) for sub-paragraph (5)(a), substitute—
 - "(a) ask any person who makes a declaration that the patient does not have to pay any of the charges specified in regulations made under sections 172 (charges for drugs, medicines or appliances, or pharmaceutical services) and 174 (prepayment certificates) of the 2006 Act in respect of dispensing services to a patient by virtue of either—
 - (i) entitlement to exemption under regulations made under those sections; or
 - (ii) entitlement to full remission of charges under regulations made under sections 182 (remission and repayment of charges) or 183 (payment of travelling expenses) of that Act,

to produce satisfactory evidence of such entitlement, unless at the time of the declaration such evidence is available to the out of hours performer; and".

(6) In paragraph 12 (duty of co-operation in relation to additional, enhanced and out of hours services), in sub-paragraph (2)(b), for "the Primary Care Trust", substitute "the Board".

(7) In paragraph 13, for "the Primary Care Trust" to the end of that paragraph substitute "the Board or by any person with whom the Board intends to enter into a contract for the provision of such services.".

(8) In paragraph 14 (list of patients), for "The Primary Care Trust", substitute "The Board".

(9) In paragraph 15 (application for inclusion in a list of patients), in sub-paragraphs (5) and (6) for "the Primary Care Trust", substitute "the Board".

(10) In paragraph 16 (temporary residents), in sub-paragraph (4), for "the Primary Care Trust", substitute "the Board".

(11) In paragraph 17 (refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident), in sub-paragraph (4), for "the Primary Care Trust", substitute "the Board".

(12) In paragraph 19 (removal from the list at the request of the patient), in sub-paragraphs (1) to (4), for "the Primary Care Trust", in each place, substitute "the Board".

(13) In paragraph 20 (removal from the list at the request of the contractor)—

- (a) in sub-paragraphs (1)(a), (3), (7), (8) and (10), for "the Primary Care Trust", in each place, substitute "the Board";
- (b) in sub-paragraph (5)(c), immediately before "a legal and beneficial" insert "both"; and
- (c) in sub-paragraph (9)—
 - (i) for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (ii) in paragraph (a), for "the Trust", substitute "the Board".
- (14) In paragraph 21 (removals from the list of patients who are violent)—
 - (a) in sub-paragraphs (1), (4), (5), (6) and (7), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (b) in sub-paragraph (2)(c), immediately before "a legal and beneficial" insert "both".
- (15) In paragraph 22 (removals from the list of patients registered elsewhere)—
 - (a) for sub-paragraph (1), substitute—
 - "(1) The Board must remove a patient from the contractor's list of patients if-
 - (a) that patient has subsequently been registered with another provider of essential services (or their equivalent) within England; or
 - (b) it has received notice from a Local Health Board, a Health Board or a Health and Social Services Board that the patient has subsequently been registered with a provider of essential services (or their equivalent) outside England."; and
 - (b) in sub-paragraphs (2) and (3), for "the Primary Care Trust", in each place, substitute "the Board".

(16) In paragraph 23 and 24 (removals from the list of patients who have moved), for "the Primary Care Trust", in each place, substitute "the Board".

(17) In paragraph 25 (removals from the list of patients absent from the United Kingdom etc.), for "the Primary Care Trust", in each place, substitute "the Board".

(18) In paragraph 26 (removals from the list of patients accepted elsewhere as temporary residents)—

- (a) in sub-paragraphs (1) and (2), for "the Primary Care Trust", substitute "the Board"; and
- (b) in sub-paragraph (3), for paragraph (b) substitute "the name, postal and email address of the Board.".

(19) In paragraph 27 (removals from the list of pupils etc. of a school), for "the Primary Care Trust", in each place, substitute "the Board".

(20) In paragraph 28 (termination of responsibility for patients not registered with the contractor), in sub-paragraph (4), for "the Primary Care Trust", substitute "the Board".

- (21) In paragraph 29A (application for closure of list of patients)—
 - (a) in sub-paragraphs (1) to (5) and (7) to (12), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (b) in sub-paragraph (6)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "its area" substitute "the area in which the contractor provides services under the contract".
- (22) In paragraph 29B (approval of an application to close a list of patients)—
 - (a) in sub-paragraph (1)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and

- (ii) for "its area" substitute "the area in which the contractor provides services under the contract"; and
- (b) in sub-paragraph (2)(a)(ii), for "the Primary Care Trust", substitute "the Board".
- (23) In paragraph 29C (rejection of an application to close a list of patients)—
 - (a) in sub-paragraph (1)—
 - (i) for "a Primary Care Trust", substitute "the Board"; and
 - (ii) in paragraph (b), for "its area" substitute "the area in which the contractor provides services under the contract"; and
 - (b) in sub-paragraph (2), for "a Primary Care Trust" and "the Primary Care Trust" substitute "the Board".
- (24) In paragraph 29D (application for an extension of a closure period)—
 - (a) in sub-paragraphs (2) to (7), (9) and (11) for "the Primary Care Trust", in each place, substitute "the Board";
 - (b) in sub-paragraph (8)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) in paragraph (b), for "its area" substitute "the area in which the contractor provides services under the contract"; and
 - (c) in sub-paragraph (10)—
 - (i) for "a Primary Care Trust", substitute "the Board"; and
 - (ii) in paragraph (b) for "its area" substitute "the area in which the contractor provides services under the contract".

(25) In paragraph 29E (re-opening of list of patients), for "the Primary Care Trust", substitute "the Board".

(26) In paragraph 32 (assignment of patients to lists: open lists)-

- (a) in sub-paragraph (1), for "A Primary Care Trust", substitute "The Board";
- (b) for sub-paragraph (2), substitute—

"(2) In this paragraph and in paragraphs 33 and 35 to 37, a "new patient" means a person who—

- (a) has been refused inclusion in a list of patients or has not been accepted as a temporary resident by a contractor; and
- (b) wishes to be included in the list of patients of a contractor in whose area (as specified in accordance with regulation 18(1)(d)) that person resides.".
- (27) In paragraph 33 (assignment of patients to lists: closed lists)-
 - (a) in sub-paragraph (1), for "A Primary Care Trust", substitute "The Board"; and
 - (b) for sub-paragraph (2), substitute—

"(2) The Board may, subject to paragraph 34, assign a new patient to a contractor which has closed its list of patients, if—

- (a) the assessment panel has determined under paragraph 35(7) that patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Secretary of State under paragraph 36(13) or (where applicable) by a court; and
- (b) the Board has entered into discussions with the contractor in question regarding the assignment of a patient if such discussions are required under paragraph 37.".

(28) For paragraph 34 (factors relevant to assignments), substitute—

"**34.** In making an assignment to a contractor under paragraph 32 or 33, the Board must have regard to—

- (a) the wishes and circumstances of the patient to be assigned;
- (b) the distance between the patient's place of residence and the contractor's practice premises;
- (c) any request made by any contractor to remove the patient from its list of patients within the preceding period of 6 months starting on the date on which the application for assignment is received by the Board;
- (d) whether, during the preceding period of 6 months starting on the date on which the application for assignment is received by the Board, the patient has been removed from a list of patients on the grounds referred to in—
 - (i) paragraph 20 (removal from the list at the request of the contractor);
 - (ii) paragraph 21 (removal from the list of patients who are violent); or
 - (iii) the equivalent provisions to those paragraphs in relation to arrangements made under section 83(2) of the 2006 Act or under section 92 arrangements;
- (e) in a case to which sub-paragraph (d)(ii) applies (or the equivalent provisions as mentioned in sub-paragraph (d)(iii) apply), whether the contractor has appropriate facilities to deal with such patients; and
- (f) such other matters as the Board considers relevant.".

(29) For paragraph 35 (assignments to closed lists: determinations of the assessment panel), substitute—

"**35.**—(1) If the Board wishes to assign new patients to contractors which have closed their lists of patients, it must prepare a proposal to be considered by the assessment panel.

- (2) The Board must notify in writing—
 - (a) contractors, including those contractors who provide primary medical services under arrangements made under section 83(2) of the 2006 Act or under section 92 arrangements, which—
 - (i) have closed their lists of patients; and
 - (ii) may, in the opinion of the Board, be affected by the determination of the assessment panel; and
 - (b) the Local Medical Committee (if any) for the area in which the contractors referred to in paragraph (a) provide essential services (or their equivalent),

that it has referred the matter to the assessment panel.

(3) The Board must ensure the assessment panel is appointed to consider and determine the proposal made under sub-paragraph (1), and the composition of the assessment panel must be as described in sub-paragraph (4).

(4) The members of the assessment panel must be—

- (a) a member of the Board who is a director;
- (b) a patient representative who is a member of the Local Health and Wellbeing Board or Local Healthwatch organisation; and
- (c) a member of a Local Medical Committee but not a member of the Local Medical Committee formed for the area in which the contractors who may be assigned patients as a consequence of the panel's determination provide services.

(5) In reaching its determination, the assessment panel must have regard to relevant factors including—

- (a) whether the Board has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of assignment to a contractor with a closed list; and
- (b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.

(6) The assessment panel must reach a determination within a period of 28 days starting on the date on which the assessment panel was appointed.

- (7) The assessment panel—
 - (a) must determine whether the Board may assign patients to a contractor which has a closed list of patients; and
 - (b) if it so determines that the Board may make such an assignment, must determine, in the case where there is more than one contractor, those contractors to which patients may be assigned.

(8) The assessment panel may determine that the Board may assign new patients to contractors other than any of the contractors specified in its proposals under sub-paragraph (1), as long as the contractors were notified under sub-paragraph (2)(a).

(9) The assessment panel's determination must include its comments on the matters referred to in sub-paragraph (5), and must be notified in writing to those contractors referred to in sub-paragraph (2)(a)."(13).

(30) In paragraph 36 (assignments to closed lists: NHS dispute resolution procedure relating to determinations of the assessment panel), in sub-paragraphs (1), (13) and (16)(b), for "the Primary Care Trust", in each place, substitute "the Board".

(31) For the heading to paragraph 37 and for sub-paragraph (1) of paragraph 37 (assignments to closed lists: assignments of patients by a Primary Care Trust), substitute—

"Assignment to closed lists: assignments of patients by the Board

37.—(1) Before the Board may assign a new patient to a contractor, it must, subject to sub-paragraph (3), enter into discussions with the contractor regarding additional support that the Board can offer the contractor and the Board must use its best endeavours to provide appropriate support.".

- (32) In paragraph 39 (prescribing)—
 - (a) in sub-paragraph (1B), for paragraph (a), substitute—
 - "(a) the Secretary of State or the Board has made arrangements for the distribution of a listed medicine free of charge; and"; and
 - (b) in sub-paragraph (1C)—
 - (i) for paragraph (a), substitute—
 - "(a) the Secretary of State or the Board has made arrangements for the distribution of a listed medicine free of charge;"; and
 - (ii) in paragraph (c), for "the Primary Care Trust", substitute "the Board"; and
 - (c) in sub-paragraphs (6)(c)(ii) and (7)(c)(ii), for "ETP service", substitute "Electronic Prescription Service".

⁽¹³⁾ See section 222(2A) (arrangements under section 221(1)) of the Local Government and Public Involvement in Health Act 2007 (c.28) for the meaning of a Local Healthwatch organisation.

- (33) In paragraph 39A (electronic prescriptions)—
 - (a) in sub-paragraph (1)—
 - (i) for paragraph (a), substitute—
 - "(a) the Board authorises the contractor to use the Electronic Prescription Service;"; and
 - (ii) in paragraph (b)(i), omit "in his NHS Care Record"; and
 - (b) in sub-paragraph (3)(a), for "the Primary Care Trust", substitute "the Board".
- (34) In paragraph 39B (nomination of dispensers for the purpose of electronic prescriptions)—
 - (a) in sub-paragraph (1), for "operates the ETP service for its patients shall, if requested to do so by a patient, enter in that patient's NHS Care Record", substitute—

"is authorised to use the Electronic Prescription Service for its patients must enter into the particulars relating to that patient which is held in the Patient Demographic Service operated by the Information Centre for Health and Social Care,";

- (b) in sub-paragraph (2), for "ETP service", substitute "Electronic Prescription Service";
- (c) in sub-paragraph (4)(b), for "an ETP service" to the end, substitute "an Electronic Prescription Service as given to that contractor by the Board".

(35) In paragraph 40 (repeatable prescribing services)—

- (a) in sub-paragraphs (1)(b) and (3), for "the Primary Care Trust", substitute "the Board";
- (b) in sub-paragraph (2)(c), for "in an area of the Primary Care Trust", substitute "in a Local Authority area"; and
- (c) in sub-paragraph (7)(b), for "the Primary Care Trust under regulation 48 of the Pharmaceutical Regulations", substitute "the Board in accordance with arrangements made under section 126 (arrangements for pharmaceutical services) and section 129 (regulations as to pharmaceutical services) of the 2006 Act.".
- (36) In paragraph 41 (repeatable prescriptions)—
 - (a) in sub-paragraph (2)(b)(i)—
 - (i) for "the ETP service", substitute "the Electronic Prescription Service"; and
 - (ii) omit "in the person's NHS Care Record"; and
 - (b) in sub-paragraph (3)—
 - (i) for "the ETP service", substitute "the Electronic Prescription Service"; and
 - (ii) omit "in that person's NHS Care Record".

(37) In paragraph 42 (restrictions on prescribing by medical practitioners), in sub-paragraph (2) (c)(ii), for "the Primary Care Trust", substitute "the Board".

(38) In paragraph 43 (restrictions on prescribing by supplementary prescribers), in subparagraph (2)(d)(iii), for "the Primary Care Trust", substitute "the Board".

(39) In paragraph 46 (excessive prescribing), for sub-paragraph (2) substitute—

"(2) In considering whether a contractor has breached its obligations under subparagraph (1) the Board must seek the views of the Local Medical Committee (if any) for the area in which the contractor provides services under the contract.".

- (40) In paragraph 53(qualifications of performers)-
 - (a) in sub-paragraph (1), for paragraph (a), substitute—
 - "(a) included in the medical performers list;";

- (b) in sub-paragraph (2)(c)—
 - (i) for "a Primary Care Trust", substitute "the Board";
 - (ii) in paragraph (i), for "the Primary Care Trust", substitute "the Board"; and
 - (iii) for paragraph (ii), substitute-
 - "(ii) the end of a period of 3 months, starting with the date on which that GP Registrar begins a postgraduate medical education and training scheme necessary for the award of a certificate of completion of training awarded under section 34L(1) (award and withdrawal of a Certificate of Completion of Training) of the Medical Act 1983; or"(14);
- (c) in sub-paragraph (2)(d)—
 - (i) for paragraph (iii), substitute—
 - "(iii) has notified the Board that he will be undertaking part or all of a postgraduate programme in England at least 24 hours before commencing any part of that programme; and"; and
 - (ii) in paragraph (iv), for "the Primary Care Trust", substitute "the Board"; and
- (d) omit sub-paragraph (3).
- (41) In paragraph 57 (conditions for employment and engagement)—
 - (a) for sub-paragraph (1)(a), substitute—
 - "(a) that practitioner has provided it with documentary evidence that the practitioner is on the medical performers list; and"; and
 - (b) for sub-paragraph (3)(a), substitute—
 - "(a) the GP Registrar has provided documentary evidence of the GP Registrar's application to the Board for inclusion on the medical performers list; and".
- (42) In paragraph 64 (arrangements for GP Registrars), for sub-paragraph (3), substitute—

"(3) A contractor which employs a GP Registrar must offer terms of employment in accordance with the rates and subject to the conditions contained in directions given by the Secretary of State under sections 7 and 8 of the 2006 Act to Health Education England."(15).

- (43) For-
 - (a) the heading to paragraph 65 and sub-paragraphs (1) and (2) of paragraph 65 (independent nurse prescribers, pharmacist independent prescribers and supplementary prescribers), substitute —

"Notification requirements in respect of specified prescribers

65.—(1) Where—

- (a) a contractor employs or engages a person who is specified in sub-paragraph (2A) whose functions will include prescribing;
- (b) a party to the contract is a person who is specified in sub-paragraph (2A) whose functions will include prescribing; or

^{(14) 1983 (}c.54). Section 34L is inserted by article 4 of, and paragraph 10 of Schedule 1 to, the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.I.2010/234).

⁽¹⁵⁾ Health Education England is established by the Health Education (Establishment and Constitution) Order 2012 (S.I. 2012/1273). Section 7 is amended by section 21 of the 2012 Act. Section 8 is amended by section 55 of, and paragraph 5 of Schedule 4 to, the 2012 Act.

(c) the functions of a person who is a person specified in sub-paragraph (2A) and is a person whom the contractor already employs or has already engaged are extended to include prescribing,

the contractor must notify the Board in writing within a period of 7 days starting on the date on which the contractor employed or engaged the person, the party became a party to the contract (unless immediately before becoming such a party, the person fell under paragraph (a)), or the person's functions were extended, as the case may be.

(2) Where—

- (a) the contractor ceases to employ or engage a person who is specified in subparagraph (2A) whose functions included prescribing in its practice;
- (b) the party to the contract who is a person who is specified in sub-paragraph (2A) ceases to be a party to the contract;
- (c) the functions of a person who is a person specified in sub-paragraph (2A) and whom the contractor employs or engages in its practice are changed so that the functions no longer include prescribing in its practice; or
- (d) the contractor becomes aware that a person who is specified in subparagraph (2A) whom it employs or engages has been removed or suspended from the relevant register,

the contractor must notify the Board by the end of the second working day after the day on which the event occurred.

(2A) The specified persons are—

- (a) a chiropodist or podiatrist independent prescriber;
- (b) an independent nurse prescriber;
- (c) a pharmacist independent prescriber;
- (d) a physiotherapist independent prescriber; and
- (e) a supplementary prescriber."; and
- (b) For "the Primary Care Trust" in sub-paragraphs (3) and (4) of paragraph 65, substitute "the Board".
- (44) In paragraph 68 (appraisal and assessment)----
 - (a) in sub-paragraph (1)—
 - (i) in paragraph (a) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for paragraph (b), substitute—
 - "(b) co-operates with the Board in relation to the Board's patient safety functions."(16).
 - (b) for sub-paragraph (2), substitute—

"(2) The Board must provide an appraisal system for the purposes of sub-paragraph (1) (a) after consultation with the Local Medical Committee (if any) which is formed for the area in which the contractor provides services under the contract and with such other persons as appear to it to be appropriate.".

- (45) In paragraph 69 (sub-contracting of clinical matters)—
 - (a) in sub-paragraphs (1)(b), (4) to (6), for "the Primary Care Trust", substitute "the Board"; and

⁽¹⁶⁾ See section 13R (information on safety of services provided by the health service) of the 2006 Act. Section 13R is inserted section 23(1) of the 2012 Act.

- (b) in sub-paragraph (8), for "a Primary Care Trust", substitute "the Board".
- (46) In paragraph 70 (sub-contracting of out of hours services)—
 - (a) in sub-paragraphs (1), (3), (5) and (7) for "the Primary Care Trust", substitute "the Board";
 - (b) in sub-paragraphs (2)(a), (4) and (8), for "a Primary Care Trust", substitute "the Board"; and
 - (c) in sub-paragraph (6)—
 - (i) for "The Primary Care Trust", substitute "The Board"; and
 - (ii) for "the Trust", substitute "the Board".
- (47) In paragraph 71 (withdrawal and variation of approval under paragraph 70)—
 - (a) in sub-paragraph (1), for "a Primary Care Trust", substitute "the Board"; and
 - (b) in sub-paragraphs (2) and (3), for "the Primary Care Trust", substitute "the Board".
- (48) In paragraph 72(1), for "a Primary Care Trust", substitute "the Board".
- (49) In paragraph 73 (patient records)—
 - (a) in sub-paragraphs (2)(a) and (b), (4), (6) to (8), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (b) for sub-paragraph (5), substitute—

"(5) Where a patient's records are computerised records, the contractor must, as soon as possible following a request from the Board, allow the Board to access the information recorded on the computer system on which those records are held by means of the audit function referred to in sub-paragraph (4)(b) to the extent necessary for the Board to confirm that the audit function is enabled and functioning correctly.".

- (50) In paragraph 77 (provision of information)—
 - (a) in sub-paragraphs (1) and (3)(a), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (b) for sub-paragraph (2), substitute—

"(2) The contractor is not required to comply with any request made in accordance with paragraph (1) unless it has been made by the Board in accordance with directions made by the Secretary of State under section 98A (exercise of functions) of the 2006 Act relating to the provision of information by contractors."

(51) In paragraph 79 (inquiries about prescriptions and referrals), for "the Primary Care Trust", in each place, substitute "the Board".

- (52) In paragraph 81 (annual return and review)—
 - (a) in sub-paragraphs (1), (1A), (1B), (2) and (4), for "the Primary Care Trust", substitute "the Board"; and
 - (b) for sub-paragraph (3), substitute—

"(3) Either the contractor or the Board may, if it wishes to do so, invite the Local Medical Committee for the area in which the contractor provides services under the contract to participate in the annual review."

(53) In the heading to paragraph 82 (notifications to the Primary Care Trust) and in paragraph 82 and paragraph 84, for "the Primary Care Trust", in each place, substitute "the Board".

(54) Omit paragraph 83.

(55) In paragraph 85 (notice provisions specific to a contract with a company limited by shares), in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board".

(56) In paragraph 86 (notice provisions specific to a contract with two or more individuals practising in partnership), in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board".

(57) In paragraph 87 (notification of deaths)—

- (a) in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board"; and
- (b) omit sub-paragraph (3).

(58) In paragraph 88 (notifications to patients following variation of the contract), for "the Primary Care Trust", substitute "the Board".

(59) Paragraph 89 (entry and inspection by the Primary Care Trust) and its heading are amended as follows—

- (a) in the heading to that paragraph and in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board"; and
- (b) for sub-paragraph (3), substitute—

"(3) The contractor, the Board or a person authorised in writing by the Board may, if it wishes to do so, invite the Local Medical Committee for the area in which the contractor provides services under the contract, to be present at an inspection of the practice premises which takes place under this paragraph.".

- (60) Omit paragraph 91A (entry and viewing by local involvement network representatives).
- (61) After paragraph 91 (entry and inspection by the Care Quality Commission) insert-

"Entry and viewing by Local Healthwatch organisations

91B. The contractor must comply with the requirement to allow an authorised representative to enter and view premises and observe the carrying-on of activities on those premises in accordance with regulations made under section 225 (duties of services-providers to allow entry by Local Healthwatch organisations or contractors) of the Local Government and Public Involvement Health Act 2007."(17).

- (62) In paragraph 92 (complaints procedure), omit sub-paragraph (3).
- (63) In paragraph 97 (co-operation with investigations)—
 - (a) in sub-paragraph (1)(a)(i), for "the Primary Care Trust", substitute "the Board";
 - (b) in sub-paragraph (2), in the definition of "NHS body"—
 - (i) for "a Primary Care Trust", substitute "the Board, a CCG,"; and
 - (ii) omit "a Strategic Health Authority,"; and
 - (c) in sub-paragraph (3), for "the Primary Care Trust", in each place, substitute "the Board".
- (64) In paragraph 99 (local resolution of contract disputes)—
- (i) in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board"; and
- (ii) for sub-paragraph (2), substitute—

"(2) Either the contractor or the Board may, if it wishes to do so, invite the Local Medical Committee for the area in which the contractor provides primary medical services to participate in discussions which take place pursuant to sub-paragraph (1)."

(65) In paragraph 100 (dispute resolution: non-NHS contracts) in sub-paragraph (1), for "the Primary Care Trust", in each place, substitute "the Board".

(66) In paragraph 104 (variation of a contract: general), for "the Primary Care Trust", in each place, substitute "the Board".

^{(17) 2007} c.28. Section 225 is amended by section 186(6) to (11) of, and paragraphs 148 and 151 of Schedule 5 and paragraphs 103 and 106 of Schedule 14 to, the 2012 Act.

(67) In paragraph 105 (variation provisions specific to a contract with an individual medical practitioner), in sub-paragraphs (1) and (4) to (6), for "the Primary Care Trust", in each place, substitute "the Board".

(68) In paragraph 106 (variation provisions specific to a contract with two or more individuals practising in partnership)—

(a) in sub-paragraphs (2), (4), (4E), (6) and (7), for "the Primary Care Trust", in each place, substitute "the Board";

(b) for sub-paragraphs (4B), (4C) and (4D), substitute—

- "(4B) If sub-paragraph (4A) does not apply, the Board—
 - (a) must enter into discussions with the remaining individual referred to in subparagraph (4) and use its reasonable endeavours to reach an agreement to enable the provision of clinical services to continue under the contract;
 - (b) if it considers it appropriate, may consult the Local Medical Committee for the area in which the partnership was providing clinical services under the contract or such other person as the Board considers necessary;
 - (c) may, if it considers it appropriate to enable clinical services under the contract to continue, offer the remaining individual reasonable support; and
 - (d) must notify the remaining individual if agreement has been reached in accordance with sub-paragraph (4C) or if agreement cannot be reached in accordance with sub-paragraph (4D).

(4C) If the Board reaches an agreement, the Board must serve notice in writing on the remaining individual confirming—

- (i) the terms upon which the Board agrees to the contract continuing with that individual including the period, as specified by the Board, during which the contract is to continue ("the interim period") and such a period must not exceed six months;
- (ii) that the remaining individual agrees to employing or engaging a general medical practitioner for the interim period to assist in the provision of clinical services under the contract; and
- (iii) the support, if any, which the Board is to provide to enable clinical services under the contract to continue during the interim period.
- (4D) If-
 - (a) the remaining individual referred to in paragraph (4) does not wish to employ or engage a medical practitioner;
 - (b) an agreement in accordance with paragraph (4B) cannot be reached; or
 - (c) the remaining individual wishes to withdraw from the agreed arrangements at any stage during the interim period,

the Board must serve notice in writing on the remaining individual terminating the contract forthwith.";

- (c) for sub-paragraph (5), substitute—
 - "(5) When the Board receives a notice pursuant to sub-paragraph (2) or (4)—
 - (a) it must acknowledge receipt of the notice in writing; and
 - (b) in relation to a notice served pursuant to sub-paragraph (2), the Board must acknowledge receipt of the notice before the date specified pursuant to sub-paragraph (3)(a)."; and

(d) add after sub-paragraph (8)-

"(9) Sub-paragraphs (4B) to (4D) do not affect any other right which the Board may have under the contract to vary or terminate the contract.".

(69) In paragraph 107 (termination by agreement), for "The Primary Care Trust", substitute "The Board".

(70) In paragraph 107A (termination on the death of an individual medical practitioner)—

(a) for sub-paragraph (1), substitute—

"(1) Where the contract is with an individual medical practitioner and that practitioner dies, the contract must terminate at the end of the period of 7 days after the date of death of that practitioner unless, before the end of that period, sub-paragraph (2A) applies.

(2A) This paragraph applies where the contractor's personal representatives have confirmed in writing to the Board that they wish to employ or engage one or more general medical practitioners to assist in the continuation of the provision of clinical services under the contract and after discussions with the Board—

- (a) the Board agrees to provide reasonable support which would enable the provision of clinical services under the contract to continue;
- (b) the Board and the personal representatives agree the terms upon which clinical services under the contract can continue to be provided; and
- (c) the Board and the personal representatives agree the period during which clinical services must continue to be provided and such a period must not exceed 28 days starting on the day after the end of the period of 7 days referred to in sub-paragraph (1)."; and
- (b) in sub-paragraph (3), for "the Primary Care Trust", substitute "the Board".

(71) In paragraph 108 (termination by the contractor), in sub-paragraph (1), for "the Primary Care Trust", substitute "the Board".

(72) In paragraph 109 (late payment notices)—

- (a) in sub-paragraph (1) for "the Primary Care Trust" and "the Trust", in each place, substitute "the Board"; and
- (b) in sub-paragraphs (2) and (3), for "the Primary Care Trust", in each place, substitute "the Board".

(73) In the heading to paragraph 110 and in paragraph 110 (termination by the Primary Care Trust: general), for "the Primary Care Trust", in each place, substitute "the Board".

- (74) In—
 - (a) the heading to paragraph 111 and in paragraph 111(1), (1A), (3), (3A), (5) and (6) (termination by the Primary Care Trust for breach of conditions in regulation 4), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (b) paragraph 111, for sub-paragraph (4), substitute—

"(4) Before deciding which of the options in sub-paragraph (3) to pursue, the Board must, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for the area in which the contractor provides services under the contract."

(75) In the heading to paragraph 112 and in paragraph 112 (termination by the Primary Care Trust for the provision of untrue etc. information), for "the Primary Care Trust", in each place, substitute "the Board".

(76) The heading to paragraph 113 and paragraph 113 (other grounds for termination by the Primary Care Trust) are amended as follows—

- (a) in the heading and in sub-paragraphs (1) and (2)(d) and (o), for "the Primary Care Trust", in each place, substitute "the Board";
- (b) in sub-paragraph (1)(c)(ii), immediately before "legally and beneficially", insert "both";
- (c) in sub-paragraph (3)—
 - (i) for "A Primary Care Trust", substitute "the Board";
 - (ii) for "the Primary Care Trust", substitute "the Board";
 - (iii) in paragraph (c)(i), immediately before "legally and beneficially", insert "both";
- (d) in sub-paragraph (4)—
 - (i) for "A Primary Care Trust", substitute "the Board";
 - (ii) for "the Primary Care Trust", substitute "the Board; and
- (e) in sub-paragraph (5)—
 - (i) for "A Primary Care Trust", substitute "the Board";
 - (ii) for "the Primary Care Trust", substitute "the Board; and
 - (iii) in paragraph (c)(i), immediately before "legally and beneficially", insert "both".
- (77) In paragraph 114, for "the Primary Care Trust", in each place, substitute "the Board".

(78) In the heading to paragraph 114A and in paragraph 114A (termination by the Primary Care Trust for unlawful sub-contracting), for "the Primary Care Trust", in each place, substitute "the Board".

(79) The heading to paragraph 115 and paragraph 115 (termination by the Primary Care Trust: remedial notices and breach notices) are amended as follows—

- (a) in the heading to paragraph 115 and in paragraph 115, for "the Primary Care Trust", substitute "the Board"; and
- (b) in sub-paragraph (4), for "a Primary Care Trust", substitute "the Board".

(80) In the heading to paragraph 116 and in paragraph 116 (termination by the Primary Care Trust: additional provisions specific to contracts with two or more individuals practising in partnership and companies limited by shares), for "the Primary Care Trust", in each place, substitute "the Board".

(81) In paragraph 117 (contract sanctions), in sub-paragraphs (2) to (6), for "the Primary Care Trust", in each place, substitute "the Board".

(82) In paragraph 118 (contract sanctions and the NHS dispute resolution procedure), for "the Primary Care Trust", in each place, substitute "the Board".

(83) In paragraph 119 (termination and the NHS dispute resolution procedure), for "the Primary Care Trust", in each place, substitute "the Board".

(84) In paragraph 120 (consultation with the Local Medical Committee)-

- (a) in sub-paragraph (1)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "for its area", substitute "for the area in which the contractor provides services under the contract"; and
- (b) in sub-paragraph (2), for "the Primary Care Trust", substitute "the Board".
- (85) In paragraph 121A (clinical governance)-
 - (a) for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (b) for "the Controlled Drugs (Supervision of Management and Use) Regulations 2006", substitute "section 17 (accountable officers and their responsibilities as to controlled

drugs) and section 18 (co-operation between health bodies and other organisations) of the Health Act 2006".

(86) Immediately after paragraph 121A, insert-

"Duty as to education and training

121B. The contractor must co-operate with the Secretary of State in the discharge of the duty under section 1F of the 2006 Act (duty as to education and training), or co-operate with Health Education England where Health Education England is discharging that duty by virtue of a direction under section 7 of that Act.".

- (87) In paragraph 124 (gifts)-
 - (a) in sub-paragraph (2)(c)(i), immediately before "legally and beneficially", insert "both"; and
 - (b) in sub-paragraph (6), for "the Primary Care Trust", substitute "the Board".

(88) In paragraph 125 (compliance with legislation and guidance), for sub-paragraph (b) substitute—

"(b) have regard to all relevant guidance issued by the Board or the Secretary of State or Local Authorities in respect of the exercise of their functions under the 2006 Act.".

Amendment of Schedule 10

28.—(1) Schedule 10 (information to be included in practice leaflets) is amended as follows.

(2) In paragraph 18, for "the Primary Care Trust" to the end of that paragraph, substitute "the Board is responsible for the commissioning of those services.".

- (3) Omit paragraphs 19 and 20.
- (4) For paragraph 28, substitute—

"28. The full name, postal and email address and telephone number of the Board.".

Transitional provision

29. The transitional provisions set out in Schedule 1 have effect.

PART 3

AMENDMENTS OF THE PMS AGREEMENT REGULATIONS

30. The PMS Agreements Regulations are amended in accordance with this Part.

Amendment of regulation 2

- 31. Regulation 2 (interpretation) is amended as follows—
 - (a) for the definition of "assessment panel", substitute—

""assessment panel" means the panel appointed by the Board under paragraph 34(3) of Schedule 5;";

(b) for the definition of "batch issue", substitute—

""batch issue" means a form, in the format required by the Board and approved by the Secretary of State which—

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

""the Board" means the National Health Service Commissioning Board;

"CCG" means a clinical commissioning group;"(18);

- (d) in the definition of "chemist", for "a Primary Care Trust", substitute "the Board";
- (e) immediately after the definition of "child", insert-

""chiropodist or podiatrist independent prescriber" means a chiropodist or podiatrist who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001 (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiropodist or podiatrist is qualified to order drugs, medicines and appliances as a chiropodist or podiatrist independent prescriber;"(**19**);

(f) for the definition of "contractor", substitute-

""contractor" means a person or persons other than the Board who is a party, or are parties, to the agreement;";

- (g) in the definition of "contractor's list of patients", for "the Primary Care Trust", substitute "the Board";
- (h) in the definition of "dispensing services", for "regulation 48 of the Pharmaceutical Regulations", substitute "section 126 (arrangements for pharmaceutical services) and section 129 (regulations as to pharmaceutical services) of the 2006 Act";
- (i) for the definition of "Drug Tariff", substitute-

""Drug Tariff" means the publication known as the Drug Tariff which is published by the Secretary of State and which is referred to in section 127(4) (arrangements for additional pharmaceutical services) of the 2006 Act;";

(j) immediately after the definition of "electronic prescription form", insert-

""Electronic Prescription Service" means the service of that name which is operated by the Health and Social Care Information Centre;"(**20**);

(k) for the definition of "electronic repeatable prescription", substitute—

"electronic repeatable prescription" means a prescription which falls within paragraph (b) of the definition of "repeatable prescription";";

⁽¹⁸⁾ The National Health Service Commissioning Board is established by section 1H of the National Health Service Act 2006. Section 1H is inserted by section 9 of the 2012 Act. A clinical commissioning group is a body established under section 14D of the 2006 Act. Section 14D is inserted by section 25(1) of the 2012 Act. See also section 1I of the 2006 Act. Section 1I is inserted by section 10 of the 2012 Act.

⁽¹⁹⁾ S.I. 2002/254; article 5 is amended by S.I 2009/1182. This Order is renamed by section 213(1) and (6) of the 2012 Act.

⁽²⁰⁾ The Health and Social Care Information Centre is established under section 252 of the 2012 Act.

- (l) omit the definition of "ETP service";
- (m) in the definition of "home oxygen order form", for "a Primary Care Trust", substitute "the Board";
- (n) in the definition of "listed medicines voucher", for "a Primary Care Trust", substitute "the Board";
- (o) for the definition of "Local Medical Committee", substitute-

""Local Medical Committee" means a committee recognised by the Board under section 97 of the 2006 Act;"(21);

- (p) omit the definition of "local pharmaceutical services";
- (q) in the definition of "medical card", for "a Primary Care Trust", substitute "the Board";
- (r) for the definition of "medical performers list", substitute-

""medical performers list" means the list of medical practitioners maintained and published by the Board in accordance with section 91 (persons performing primary medical services) of the 2006 Act;"(22);

- (s) omit the definitions of "NHS Care Record" and "NHS Care Record Service";
- (t) for the definition of "nominated dispenser", substitute-

""nominated dispenser" means a chemist, medical practitioner or contractor who has been nominated in respect of a patient and the details of that nomination are held in respect of that patient in the Patient Demographics Service which is operated by the Information Centre for Health and Social Care;";

(u) for the definition of "non-electronic repeatable prescription", substitute—

""non-electronic repeatable prescription" means a form for the purpose of ordering a drug, medicine or appliance which is—

- (a) provided by the Board, a local authority or the Secretary of State;
- (b) issued by the prescriber;
- (c) indicates that the drug, medicine or appliance ordered may be provided more than once; and
- (d) specifies the number of occasions on which they may be provided;";
- (v) omit the definition of "NPSA";
- (w) immediately after the definition of "patient", insert-

""Patient Choice Extension Scheme" means the scheme of that name established by the Secretary of State under which primary medical services may be provided under arrangements made in accordance with directions given to the Board by the Secretary of State under section 98A (exercise of functions) of the 2006 Act;"(23);

- (x) omit the definition of "Pharmaceutical Regulations";
- (y) immediately after the definition of "pharmacist independent prescriber", insert-

""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 (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that

⁽²¹⁾ Section 97 is amended by section 55(1) of, and paragraph 41(1) and (2) of Schedule 4 to, the 2012 Act.

⁽²²⁾ Section 91 is amended by section 55(1) of, and paragraph 35(1) and (2) of Schedule 4 to, the 2012 Act.

⁽²³⁾ Section 98A is inserted by section 49(1) of the 2012 Act. The Patient Choice Extension Scheme Directions signed on 11th February 2013 and published on the Department of Health website www.dh.gov.uk.

the physiotherapist is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;";

(z) for the definition of "prescriber", substitute—

"prescriber" means-

- (a) a chiropodist or podiatrist independent prescriber;
- (b) an independent nurse prescriber;
- (c) a medical practitioner;
- (d) an optometrist independent prescriber;
- (e) a pharmacist independent prescriber;
- (f) a physiotherapist independent prescriber; and
- (g) a supplementary prescriber,

who is either engaged or employed by the contractor or is a party to the agreement;";

(aa) for the definition of "prescription form", substitute-

""prescription form" means, except in the context of the expression "electronic prescription form" or "non-electronic prescription form"—

- (a) a form for the purpose of ordering a drug, medicine or appliance which is—
 - (i) provided by the Board, a local authority or the Secretary of State;
 - (ii) issued by the prescriber; and
 - (iii) does not indicate that the drug, medicine or appliance ordered may be ordered more than once; or
- (b) where paragraph 38A(1) (electronic prescriptions) of Schedule 5 applies, data created in an electronic form for the purpose of ordering a drug, medicine or appliance, which—
 - (i) is signed with a prescriber's advanced electronic signature;
 - (ii) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and
 - (iii) does not indicate that the drug, medicine or appliance ordered may be provided more than once;";
- (bb) for the definition of "Primary Care Trust", substitute-

""Primary Care Trust" means, unless the context otherwise requires, the Primary Care Trust which was a party to the agreement immediately before the coming into force of section 34 (abolition of Primary Care Trusts) of the Health and Social Care Act 2012;";

(cc) for the definition of "registered patient" substitute-

"registered patient" means-

- (a) a person who is recorded by the Board pursuant to paragraph 13 of Schedule 5 as being on the contractor's list of patients; or
- (b) a person whom the contractor has accepted for inclusion on its list of patients, whether or not notification of that acceptance has been received by the Board and who has not been notified by the Board as having ceased to be on that list;";
- (dd) for the definition of "relevant body", substitute-

""relevant body" means-

- (a) in a case where a contractor is a party to an agreement with a Primary Care Trust immediately before the coming into force of section 34 (abolition of Primary Care Trusts) of the Health and Social Care Act 2012, that Primary Care Trust; and
- (b) in the case where a contractor is a party to an agreement with a Strategic Health Authority immediately before the coming into force of section 33 (abolition of Strategic Health Authorities) of the Health and Social Care Act 2012, that Strategic Health Authority;";
- (ee) in the definition of "relevant register"-
 - (i) in paragraph (a), omit "and"; and
 - (ii) at the end of paragraph (b), insert—
 - "(c) in relation to an optometrist, the register maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989; and
 - (d) the part of the register maintained by the Health and Care Professions Council in pursuance of article 5 of the Health and Social Work Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) radiographers;"(24);
- (ff) for the definition of "relevant Strategic Health Authority"-

""relevant Strategic Health Authority" means, unless the context otherwise requires, the Strategic Health Authority established for an area which includes the area for which the Primary Care Trust was established and subsisted immediately before the coming into force of section 33 and section 34 of the Health and Social Care Act 2012;";

(gg) for the definition of "repeatable prescription", substitute-

""repeatable prescription" means, except in the context of the expression "electronic repeatable prescription" and "non-electronic repeatable prescription", a prescription which—

- (a) is a form provided by the Board, a local authority or the Secretary of State for the purpose of ordering a drug, medicine or appliance which is in the format required by the NHS Business Services Authority and which—
 - (i) is issued by a repeatable prescriber to enable a chemist or person providing dispensing services to receive payment for the provision of repeat dispensing services;
 - (ii) indicates that the drug, medicine or appliance ordered may be provided more than once; and
 - (iii) specifies the number of occasions on which they may be provided; or
- (b) where paragraph 38A(1) of Schedule 5 applies, is data created in an electronic form for the purposes of ordering a drug, medicine or appliance, which—
 - (i) is signed with a prescriber's advanced electronic signature;
 - (ii) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and

⁽²⁴⁾ Section 7 of the Opticians Act 1989 (c.44) is amended by articles 2 and 7 of S.I. 2005/848. Section 214 of the 2012 Act provides for the Health Professions Council to continue to exist and to change its name to the Health and Care Professions Council.

(iii) indicates that the drug, medicine or appliance ordered may be provided more than once and specifies the number of occasions on which they may be provided;"(25); and

(hh) omit the definition of "walk-in centre".

Substitution of regulation 3

32. For regulation 3 (conditions: introductory), substitute—

"3. Subject to the provisions of any scheme made by the Secretary of State under section 300 (transfer schemes) and any order made under section 303 (power to make consequential provision) of the Health and Social Care Act 2012, the Board may make an agreement only if the conditions set out in regulation 5 are met.".

Amendment of regulation 5

33. In regulation 5 (general condition relating to all agreements)—

- (a) in paragraph (1), for "A relevant body", substitute "The Board";
- (b) in paragraph (2)—

(i) for "A relevant body", substitute "The Board"; and

- (ii) in sub-paragraph (b), immediately before "legally and beneficially" insert "both";
- (c) in paragraph (4)—
 - (i) for "the relevant body", substitute "the Board"; and
 - (ii) in sub-paragraph (b)(i), immediately before "legally and beneficially" insert "both";
- (d) in paragraph (6)(b)(i), immediately before "legally and beneficially" insert "both"; and
- (e) add after paragraph (6)—

"(7) For the purposes of paragraph (3)(c), a health service body respectively includes a Strategic Health Authority or a Primary Care Trust which was established before the coming into force of section 33 or 34 of the Health and Social Care Act 2012.".

Amendment of regulation 6

- 34. In regulation 6 (reasons)—
 - (a) in paragraph (1), for "a relevant body", substitute "the Board"; and
 - (b) in paragraph (2)—
 - (i) for "The relevant body", substitute "The Board"; and
 - (ii) immediately before "legally and beneficially", insert "both".

Amendment of regulation 7

35. In regulation 7 (appeal), for "the relevant body", substitute "the Board".

Amendment of regulation 8

36. In regulation 8 (pre-agreement disputes), in paragraph (3)(b), for "the relevant body", substitute "the Board".

⁽²⁵⁾ The NHS Business Services Authority is established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG (Establishment and Constitution) Order S.I. 2005/2414.

Amendment of regulation 9

37. In regulation 9 (health service body status), in paragraphs (1), (4)(a), (5), (6) and (8)(b) for "the relevant body", in each place, substitute "the Board".

Amendment of regulation 11

38. In regulation 11 (agreements: general), omit paragraph (4).

Insertion of new regulation 11A

39. After regulation 11 (agreements: general), insert-

"Membership of a CCG

11A. An agreement must contain a term which has the effect of requiring—

- (a) the contractor, if that contractor provides essential services to patients on its list of patients, to be a member of a CCG; and
- (b) that contractor to appoint one individual who is a health care professional to act on its behalf in the dealings between it and the CCG to which it belongs.".

Amendment of regulation 13

- 40. In regulation 13 (finance)—
 - (a) in paragraph (1), for "under section 17" to the end of that paragraph substitute—
 - "under section 94(4) (regulations about section 92 arrangements) and section 98A (exercise of functions) of the 2006 Act.".
 - (b) in paragraph (2)—
 - (i) for "the relevant body", in each place, substitute "the Board"; and
 - (ii) for "section 17 or 28E(3A)", substitute "section 94(4) and section 98A of the 2006 Act".

Substitution of regulation 14

41. For regulation 14 (finance), substitute—

"14. The agreement must contain a term to the effect that where, as a consequence of regulation 94(4) or pursuant to directions made under section 98A of the 2006 Act, the Board is required to make a payment to a contractor under an agreement but subject to conditions, those conditions are to be a term of the agreement."

Amendment of regulation 15

42. In regulation 15 (fees and charges), in paragraph (4) for "the relevant body", in each place, substitute "the Board".

Amendment of regulation 16

43. In regulation 16 (opt outs of out of hours services)-

- (a) in paragraph (1), omit "except paragraph 1(15)" to the end of that paragraph;
- (b) in paragraph (2)—
 - (i) omit "(other than a Primary Care Trust)"; and

(ii) omit "except paragraph 1(15)" to the end of that paragraph; and

(c) omit paragraph (3).

Substitution of regulation 18

44. For regulation 18 (other contractual terms), substitute—

"18.—(1) An agreement must, unless it is of a type or nature to which the particular term does not apply, contain other terms which have, or make provision having, the same effect as those specified in Schedule 5 except paragraphs 34(5) to (9), 35(5) to (17) (in so far as it relates to a determination by the Secretary of State of an appeal) and paragraphs 95(5) to (14) and 96 (in so far as it relates to an appeal to the Secretary of State).

(2) Paragraphs 34(5) to (9), 35(5) to (17) (in so far as it relates to a determination by the Secretary of State) and paragraphs 95(5) to (14) and 96 (in so far as it relates to an appeal to the Secretary of State) have effect in relation to the matters set out in those paragraphs."

Omission of regulation 18A and insertion of new regulation 18B

45. Omit regulation 18A (variation of contractual terms in respect of entering into arrangements under the Patient Choice Scheme) and after regulation 18 (other contractual terms), insert—

"Variation of contractual terms in respect of entering into arrangements under the Patient Choice Extension Scheme

18B.—(1) This regulation applies where the contractor and the Board enter into arrangements under the Patient Choice Extension Scheme.

(2) The terms of the agreement—

- (a) which have the same effect as the provisions specified in paragraph (3) must be varied in accordance with paragraph (4); and
- (b) must be varied to include terms which have the same effect as the provisions specified in paragraphs (5) and (6),

but only to the extent that such variations relate to the provision of primary medical services to patients who received such services under the Patient Choice Scheme and wish to continue to do so under arrangements made in accordance with the Patient Choice Extension Scheme with effect from the start of the day on which such arrangements commence and for the period ending at the end of the day which is the date of the termination of those arrangements, which must be no later than 31st March 2014.

(3) The terms of the agreement specified in this paragraph are—

- (a) the terms which require the contractor to provide essential services and any other service;
- (b) the terms which require the contractor to provide out of hours services to patients to whom it provides essential services;
- (c) the following terms in Schedule 5 (other contractual terms)—
 - (i) paragraph 1 (services to registered patients);
 - (ii) paragraph 3(1) (attendance at practice premises);
 - (iii) paragraph 4(2)(a) (attendance outside practice premises); and
 - (iv) paragraph 16(2) (refusal of applications for inclusion in the list of patients).

(4) The agreement must include terms which have the effect of temporarily releasing the contractor and the Board from all obligations, payments, rights and liabilities relating to those terms (and only those terms) which have the same effect as the provisions specified in paragraph (3)—

- (a) including any right to enforce those terms only in respect of the provision of primary medical services to patients who wish to receive such services under arrangements made in accordance with the Patient Choice Extension Scheme; and
- (b) only where, in the opinion of the contractor, it is not clinically appropriate or practical to provide the services or access to such services in accordance with those terms, or comply with those terms, under arrangements made under the Patient Choice Extension Scheme.

(5) The agreement must also include a term which has the effect of requiring the contractor to notify a person in writing that where the contractor is minded to continue to accept that person on its list of patients in accordance with the Patient Choice Extension Scheme the contractor is under no obligation to provide—

- (a) essential services and any other service in core hours, in a case where at the time the treatment is required, it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient; or
- (b) out of hours services, in a case where at the time treatment is required, it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient.

(6) The agreement must also include terms to have the effect of providing that immediately after the date of the termination of the arrangements under the Patient Choice Extension Scheme, the variations made as a consequence of paragraph (2) must terminate save to the extent necessary in respect of enforcing any obligation, condition, payment, right and liability arising from those terms prior to the date of termination."

Amendment of regulation 19

46. In regulation 19 (right to a general medical services contract)—

- (a) in paragraphs (1), (2)(b), (4), (5), (8), (9) and (11), for "the relevant body", in each place substitute "the Board"; and
- (b) in paragraph (6)(b), for "the Primary Care Trust", substitute "the Board".

Omission of regulation 21 and Schedule 6

47. Omit regulation 21 (out of hours services) and Schedule 6 (out of hours transitional provisions).

Amendment to Schedule 3

48. Schedule 3 (fees and charges) is amended as follows—

- (a) in paragraphs (c) and (g), for "the relevant body", substitute "the Board"; and
- (b) for paragraph (k), substitute—
 - "(k) where it is a contractor authorised or required in accordance with arrangements made with the Board under section 126 (arrangements for pharmaceutical services) and in accordance with regulations made under section 129 (regulations as to pharmaceutical services) of the 2006 Act to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of dispensing services, any Scheduled drug; and".

Amendment of Schedule 4

49.—(1) Schedule 4 (opt outs of out of hours services) is amended as follows.

(2) In paragraph 1 (opt outs of out of hours services where the opt out notice is served after 30th September 2004)—

- (a) in the heading and in sub-paragraph (1), for "after 30th September 2004", substitute "on or after 1st April 2013";
- (b) in sub-paragraph (1), omit "(other than a Primary Care Trust)";
- (c) in sub-paragraph (2), in the definition of "OOH day", for "a Primary Care Trust", substitute "the Board";
- (d) in sub-paragraphs (3), (5), (8), (9), (12) and (24)(b), for "the Primary Care Trust", in each place, substitute "the Board";
- (e) in sub-paragraph (7)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "the Primary Care Trust's", substitute "the Board's".
- (f) in sub-paragraph (10)—
 - (i) except in paragraph (b), for "the Primary Care Trust", in each place, substitute "the Board"; and
 - (ii) in paragraph (b), omit "unless at least one month" to the end of that paragraph (b);
- (g) in sub-paragraph (11)—
 - (i) omit "unless at least one month" to the end of that sub-paragraph; and
 - (ii) for the remaining references to "the Primary Care Trust", substitute "the Board";
- (h) omit sub-paragraphs (13) to (23).

(3) Omit paragraph 2 (opt outs of out of hours services where the opt out notice is served before 1st October 2004).

(4) In paragraph 3 (informing patients of opt outs), for "the Primary Care Trust", in each place, substitute "the Board".

Amendment of Schedule 5

50.—(1) Schedule 5 (other contractual terms) is amended as follows.

(2) In paragraph 4 (attendance outside practice premises), in sub-paragraph (2)(b), for "the relevant body", substitute "the Board".

(3) In paragraph 5 (clinical reports)—

(a) in sub-paragraph (2)—

(i) omit "(other than a Primary Care Trust)"; and

(ii) for "the relevant body", substitute "the Board"; and

- (b) in sub-paragraph (3)—
 - (i) for "The relevant body", substitute "The Board"; and
 - (ii) for paragraph (b), substitute—
 - "(b) if the person referred to in paragraph (a) is not known to the Board, to the Local Health Board, Health Board or Health and Social Services Board, in whose area the patient is resident.".
- (4) In paragraph 9A (supply of medicines etc. by contractors providing out of hours services)—

(a) in sub-paragraph (1)—

(i) omit the definition of "the Charges Regulations"; and

- (ii) in the definition of "supply form", for "a Primary Care Trust", substitute "the Board";
- (b) in sub-paragraph (2), for "the relevant body", substitute "the Board"; and
- (c) for sub-paragraph (5)(a), substitute—
 - "(a) ask any person who makes a declaration that the patient does not have to pay any of the charges specified in regulations made under sections 172 (charges for drugs, medicines or appliances, or pharmaceutical services) and 174 (prepayment certificates) of the 2006 Act in respect of dispensing services to a patient by virtue of either—
 - (i) entitlement to exemption under regulations made under those sections; or
 - (ii) entitlement to full remission of charges under regulations made under sections 182 (remission and repayment of charges) or 183 (payment of travelling expenses) of that Act,

to produce satisfactory evidence of such entitlement, unless at the time of the declaration such evidence is available to the out of hours performer; and".

(5) In paragraph 10 (duty of co-operation), in sub-paragraph (2)(b), for "the relevant body" substitute "the Board".

(6) In paragraph 11, for "the relevant body or by any person" to the end of that paragraph substitute "the Board or by any person with whom the Board intends to enter into an agreement for the provision of such services.".

(7) In paragraph 12 (general provision), omit sub-paragraph (2).

(8) In paragraph 13 (list of patients), for "the Primary Care Trust", substitute "the Board".

(9) In paragraph 14 (application for inclusion in a list of patients), in sub-paragraphs (5) and (6), for "the Primary Care Trust", substitute "the Board".

(10) In paragraph 15 (temporary residents), in sub-paragraph (4) for "the Primary Care Trust", substitute "the Board".

(11) In paragraph 16 (refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident), in sub-paragraph (4) for "the Primary Care Trust", substitute "the Board".

(12) In paragraph 18 (removal from the list at the request of the patient), in sub-paragraphs (1) to (4), for "the Primary Care Trust", in each place, substitute "the Board".

(13) In paragraph 19 (removal from the list at the request of the contractor), in sub-paragraphs (1)(a), (3), and (6) to (9) for "the Primary Care Trust", in each place, substitute "the Board".

(14) In paragraph 20 (removals from the list of patients who are violent), in sub-paragraphs (1) and (4) to (7), for "the Primary Care Trust", in each place, substitute "the Board".

(15) In paragraph 21 (removals from the list of patients registered elsewhere)-

(a) for sub-paragraph (1), substitute—

- "(1) The Board must remove a patient from the contractor's list of patients if—
 - (a) that patient has subsequently been registered with another provider of essential services (or their equivalent) within England; or
 - (b) it has received notice from a Local Health Board, a Health Board or a Health and Social Services Board that the patient has subsequently been registered with a provider of essential services (or their equivalent) outside England."; and
- (b) in sub-paragraphs (2) and (3), for "the Primary Care Trust", in each place, substitute "the Board".

(16) In paragraphs 22 and 23 (removals from the list of patients who have moved), for "the Primary Care Trust", in each place, substitute "the Board".

(17) In paragraph 24 (removal from the list of patients absent from the United Kingdom etc), for "the Primary Care Trust", in each place, substitute "the Board".

(18) In paragraph 25 (removals from the list of patients accepted elsewhere as temporary residents)—

- (a) in sub-paragraphs (1) and (2), for "the Primary Care Trust", substitute "the Board"; and
- (b) in sub-paragraph (3), for paragraph (b) substitute "the name, postal and email address of the Board".

(19) In paragraph 26 (removals from a list of pupils etc. of a school), for "the Primary Care Trust", substitute "the Board".

(20) In paragraph 27 (termination of responsibility for patients not registered with the contractor), in sub-paragraph (4), for "the Primary Care Trust", substitute "the Board".

(21) In paragraph 28A (application for closure of list of patients)-

- (a) in sub-paragraphs (1) to (5) and (7) to (12), for "the Primary Care Trust", in each place, substitute "the Board"; and
- (b) in paragraph (6)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "its area" substitute "the area in which the contractor provides services under the agreement".
- (22) In paragraph 28B (approval of an application to close a list of patients)—
 - (a) in sub-paragraph (1)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) for "its area" substitute "the area in which the contractor provides services under the agreement"; and
 - (b) in sub-paragraph (2)(a)(ii), for "the Primary Care Trust", substitute "the Board".
- (23) In paragraph 28C (rejection of an application to close a list of patients)—
 - (a) in sub-paragraph (1)—
 - (i) for "a Primary Care Trust", substitute "the Board"; and
 - (ii) in paragraph (b), for "its area", substitute "the area in which the contractor provides services under the agreement"; and
 - (b) in sub-paragraph (2), for "a Primary Care Trust" and "the Primary Care Trust", substitute "the Board".
- (24) In paragraph 28D (application for an extension of a closure period)—
 - (a) in sub-paragraphs (2) to (7), (9) and (11), for "the Primary Care Trust", in each place, substitute "the Board";
 - (b) in sub-paragraph (8)—
 - (i) for "the Primary Care Trust", substitute "the Board"; and
 - (ii) in paragraph (b), for "its area" substitute "the area in which the contractor provides services under the agreement"; and
 - (c) in sub-paragraph (10)—
 - (i) for "a Primary Care Trust", substitute "the Board"; and

(ii) in paragraph (b), for "its area" substitute "the area in which the contractor provides services under the agreement".

(25) In paragraph 28E (re-opening of list of patients), for "a Primary Care Trust", substitute "the Board".

- (26) In paragraph 31 (assignment of patients to lists: open lists)-
 - (a) in sub-paragraph (1), for "A Primary Care Trust", substitute "The Board";
 - (b) for sub-paragraph (2), substitute—

"(2) In this paragraph and paragraphs 32, and 34 to 36, a "new patient" means a person who— $\!\!\!\!$

- (a) has been refused inclusion in a list of patients or has not been accepted as a temporary resident by a contractor; and
- (b) wishes to be included in the list of patients of a contractor in whose area (as specified in accordance with regulation 11(1A)) that person resides."

(27) In paragraph 32 (assignment of patients to lists: closed lists)-

- (a) in sub-paragraph (1), for "A Primary Care Trust", substitute "The Board"; and
- (b) for sub-paragraph (2), substitute—

"(2) The Board may, subject to paragraph 33, assign a new patient to a contractor which has closed its list of patients, if—

- (a) the assessment panel has determined under paragraph 34(7) that patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Secretary of State under paragraph 35(13) or (where applicable) by a court; and
- (b) the Board has entered into discussions with the contractor in question regarding the assignment of a patient if such discussions are required under paragraph 36.".
- (28) For paragraph 33 (factors relevant to assignments), substitute-

"33. In making an assignment to a contractor under paragraph 31 or 32, the Board must have regard to—

- (a) the wishes and circumstances of the patient to be assigned;
- (b) the distance between the patient's place of residence and the contractor's practice premises;
- (c) any request made by any contractor to remove the patient from its list of patients within the preceding period of 6 months starting on the date on which the application for assignment is received by the Board;
- (d) whether, during the preceding period of 6 months starting on the date on which the application for assignment is received by the Board, the patient has been removed from a list of patients on the grounds referred to in—
 - (i) paragraph 19 (removals from the list at the request of the contractor);
 - (ii) paragraph 20 (removals from the list of patients who are violent); or
 - (iii) the equivalent provisions to those paragraphs in relation to arrangements made under section 83(2) of the 2006 Act or under a contract made in accordance with the General Medical Services Contracts Regulations;
- (e) in a case to which sub-paragraph (d)(ii) applies (or the equivalent provisions as mentioned in sub-paragraph (d)(iii) apply), whether the contractor has appropriate facilities to deal with such patients; and

(f) such other matters as the Board considers relevant.".

(29) For paragraph 34 (assignments to closed lists: determinations of the assessment panel), substitute—

"**34.**—(1) If the Board wishes to assign new patients to contractors which have closed their lists of patients, it must prepare a proposal to be considered by the assessment panel.

- (2) The Board must notify in writing—
 - (a) contractors, including those contractors who provide primary medical services under arrangements made under section 83(2) of the 2006 Act or under a contract made in accordance with the General Medical Services Contracts Regulations, which—
 - (i) have closed their lists of patients; and
 - (ii) may, in the opinion of the Board, be affected by the determination of the assessment panel; and
 - (b) the Local Medical Committee (if any) for the area in which the contractors referred to in paragraph (a) provide essential services (or their equivalent),

that it has referred the matter to the assessment panel.

(3) The Board must ensure the assessment panel is appointed to consider and determine the proposal made under sub-paragraph (1), and the composition of the assessment panel must be as described in sub-paragraph (4).

(4) The members of the assessment panel must be-

- (a) a member of the Board who is a director;
- (b) a patient representative who is a member of the Local Health and Wellbeing Board or Local Healthwatch organisation; and
- (c) a member of a Local Medical Committee but not a member the Local Medical Committee formed for the area in which the contractors, who may be assigned patients as a consequence of the panel's determination, provide essential services.

(5) In reaching its determination, the assessment panel must have regard to relevant factors including—

- (a) whether the Board has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of its proposed assignment to a contractor with a closed list; and
- (b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.

(6) The assessment panel must reach a determination within a period of 28 days starting on the date on which the assessment panel was appointed.

(7) The assessment panel—

- (a) must determine whether the Board may assign patients to a contractor which has a closed list of patients; and
- (b) if it so determines that the Board may make such an assignment, must determine in the case where there is more than one contractor, those contractors to which patients may be assigned.

(8) The assessment panel may determine that the Board may assign new patients to contractors other than any of the contractors specified in its proposals under sub-paragraph (1), as long as the contractors were notified under sub-paragraph (2)(a).

(9) The assessment panel's determination must include its comments on the matters referred to in sub-paragraph (5), and must be notified in writing to those contractors referred to in sub-paragraph (2)(a)."(26).

(30) In paragraph 35 (assignment to closed lists: NHS dispute resolution procedure relating to determinations of the assessment panel), in sub-paragraphs (1), (13) and (16)(b), for "the Primary Care Trust", in each place, substitute "the Board".

(31) In paragraph 36 (assignments to closed lists: assignments of patients), for sub-paragraph (1), substitute—

"36.—(1) Before the Board may assign a new patient to a contractor, it must, subject to paragraph (3), enter into discussions with the contractor regarding additional support that the Board can offer the contractor and the Board must use its best endeavours to provide appropriate support."

- (32) In paragraph 38 (prescribing)-
 - (a) in sub-paragraph (1B), for paragraph (a), substitute—
 - "(a) the Secretary of State or the Board has made arrangements for the distribution of a listed medicine free of charge; and";
 - (b) in sub-paragraph (1C)—
 - (i) for paragraph (a), substitute—
 - "(a) the Secretary of State or the Board has made arrangements for the distribution of a listed medicine free of charge;" and
 - (ii) in paragraph (c), for "Primary Care Trust", substitute "the Board"; and
 - (c) in sub-paragraphs (6)(c)(ii) and (7)(c)(ii), for "ETP service" substitute "Electronic Prescription Service".
- (33) In paragraph 38A (electronic prescriptions)—
 - (a) in sub-paragraph (1)—
 - (i) for paragraph (a), substitute—
 - "(a) the Board authorises the contractor to use the Electronic Prescription Service;"; and
 - (ii) in paragraph (b), omit "in his NHS Care Record"; and
 - (b) in sub-paragraph (3)(a), for "the Primary Care Trust", substitute "the Board".
- (34) In paragraph 38B (nomination of dispensers for the purpose of electronic prescriptions)—
 - (a) in sub-paragraph (1), for "operates the ETP service for its patients shall, if requested to do so by the patient, enter in that Patient's NHS Care Record", substitute—

"is authorised to use the Electronic Prescription Service for its patients must enter into the particulars relating to that patient which is held in the Patient Demographic Service which is operated by the Information Centre for Health and Social Care,";

- (b) in sub-paragraph (2), for "ETP service", substitute "Electronic Prescription Service"; and
- (c) in sub-paragraph (4)(b), for "an ETP service" to the end, substitute "an Electronic Prescription Service as given to the contractor by the Board".
- (35) In paragraph 39 (repeatable prescribing services)—

⁽²⁶⁾ See section 222(2A) (arrangements under section 221(1)) of the Local Government and Public Involvement in Health Act 2007 (c.28) for the meaning of a Local Healthwatch organisation.

- (a) in sub-paragraph (1)(b), substitute—
 - "(b) has notified the Board of its intention to provide repeatable prescribing services in accordance with sub-paragraphs (3) and (4).";
- (b) in sub-paragraph (2)(d) for "in an area of the Primary Care Trust", substitute "in the Local Authority area";
- (c) in sub-paragraph (7), for "the Primary Care Trust under regulation 48 of the Pharmaceutical Regulations" substitute "the Board in accordance with arrangements made under section 126 (arrangements for pharmaceutical services) and section 129 (regulations as to pharmaceutical services) of the 2006 Act."; and
- (d) in sub-paragraph (8)(b), insert immediately before "a legal and beneficial", "both".
- (36) In paragraph 40 (repeatable prescriptions)—
 - (a) in sub-paragraph (2)(b)(i)—
 - (i) for "the ETP service", substitute "the Electronic Prescription Service"; and
 - (ii) omit "in the person's NHS Care Record"; and
 - (b) in sub-paragraph (3)—
 - (i) for "the ETP service", substitute "the Electronic Prescription Service"; and

(ii) omit "in that person's NHS Care Record".

(37) In paragraph 41 (restrictions on prescribing by medical practitioners), in sub-paragraph (2) (c)(ii), for "the Primary Care Trust", substitute "the Board".

(38) In paragraph 42 (restrictions on prescribing by supplementary prescribers), in subparagraph (2)(d)(iii), for "the Primary Care Trust", substitute "the Board".

(39) In paragraph 44 (excessive prescribing), for sub-paragraph (2), substitute—

"(2) In considering whether a contractor has breached its obligations under subparagraph (1), the Board may, if the contractor consents, seek the views of the Local Medical Committee (if any) for the area in which the contractor provides services under the agreement.".

- (40) In paragraph 53 (qualifications of performers)-
 - (a) in sub-paragraph (1), for paragraph (a), substitute—
 - "(a) included in the medical performers list;";
 - (b) in sub-paragraph (2)(c)—
 - (i) for "a Primary Care Trust", substitute "the Board";
 - (ii) in paragraph (i), for "the Primary Care Trust" substitute "the Board"; and
 - (iii) for paragraph (ii), substitute-
 - "(ii) the end of a period of 3 months, starting with the date on which that GP Registrar begins a postgraduate medical education and training scheme necessary for the award of a Certificate of Completion of Training awarded under section 34L(1) (award and withdrawal of a Certificate of Completion of Training) of the Medical Act 1983;"(27);
 - (c) in sub-paragraph (2)(d)—
 - (i) for paragraph (iii), substitute—

^{(27) 1983 (}c.54). Section 34L is inserted by article 4 of, and paragraph 10 of Schedule 1 to, the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.1.2010/234).

- "(iii) has notified the Board that he will be undertaking part or all of a postgraduate programme in England at least 24 hours before commencing any part of that programme; and"; and
- (ii) in paragraph (iv), for "the Primary Care Trust", substitute "the Board"; and
- (d) omit sub-paragraph (3).
- (41) In paragraph 57 (conditions for employment and engagement)—
 - (a) for sub-paragraph (1)(a), substitute—
 - "(a) that practitioner has provided it with documentary evidence that the practitioner is on the medical performers list; and"; and
 - (b) for sub-paragraph (3)(a), substitute—
 - "(a) the GP Registrar has provided documentary evidence of the GP Registrar's application to the Board for inclusion on the medical performers list; and".
- (42) In paragraph 63 (arrangements for GP Registrars), for sub-paragraph (3), substitute—

"(3) A contractor which employs a GP Registrar must offer terms of employment in accordance with the rates and subject to the conditions contained in directions given by the Secretary of State under sections 7 and 8 of the 2006 Act to Health Education England."(28).

- (43) For-
 - (a) the heading to paragraph 65 and for sub-paragraphs (1) to (3) of paragraph 65 (independent nurse prescribers, pharmacist independent prescribers and supplementary prescribers), substitute—

"Notification requirements in respect of specified prescribers

65.--(1) Where---

- (a) a contractor employs or engages a person who is specified in sub-paragraph (3) whose functions will include prescribing;
- (b) a party to the agreement is a person who is specified in sub-paragraph (3); or
- (c) the functions of a person who is a person specified in sub-paragraph (3) and is a person whom the contractor already employs or has already engaged are extended to include prescribing,

the contractor must notify the Board in writing within a period of 7 days starting on the date on which the contractor employed or engaged the person, the party to the agreement (unless immediately before becoming such a party, the person fell under paragraph (a)), or the person's functions were extended.

- (2) Where—
 - (a) a contractor ceases to employ or engage a person who is specified in subparagraph (3) whose functions will include prescribing in its practice;
 - (b) a party to the agreement who is a person who is specified in sub-paragraph (3) ceases to be a party to the agreement;
 - (c) the functions of a person who is a person specified in sub-paragraph (3) and whom the contractor employs or engages in its practice are changed so that the functions no longer include prescribing in its practice, or

⁽²⁸⁾ Health Education England is established by the Health Education (Establishment and Constitution) Order 2012 (S.I 2012/1273). Section 7 is amended by section 21 of the 2012 Act. Section 8 is amended by section 55 of, and paragraph 5 of Schedule 4 to, the 2012 Act.

(d) the contractor becomes aware that a person who is specified in sub-paragraph (3) whom it employs or engages has been removed or suspended from the relevant register,

the contractor must notify the Board by the end of the second working day after the day on which the event occurred.

- (3) The specified persons are—
 - (a) a chiropodist or podiatrist independent prescriber;
 - (b) an independent nurse prescriber;
 - (c) a pharmacist independent prescriber;
 - (d) a physiotherapist independent prescriber; and
 - (e) a supplementary prescriber."; and
- (b) for "the relevant body" in paragraph 65(4) and (5), substitute "the Board".
- (44) In paragraph 68 (appraisal and assessment)—
 - (a) in sub-paragraph (1)—
 - (i) for paragraph (a), substitute—
 - "(a) participates in the appraisal system provided by the Board, unless that contractor participates in an appropriate appraisal system provided by another health service body or is an armed forces GP; and"; and
 - (ii) for paragraph (b), substitute—
 - "(b) co-operates with the Board in relation to the Board's patient safety functions."(29).
 - (b) for sub-paragraph (2), substitute—

"(2) The Board must provide an appraisal system for the purposes of sub-paragraph (1) (a) after consultation with the Local Medical Committee (if any) which is formed for the area in which the contractor provides services under the agreement and with such other persons as appear to it to be appropriate.".

(45) In paragraph 69 (sub-contracting of clinical matters) in sub-paragraph (2), for "the relevant body", in each place, substitute "the Board".

- (46) In paragraph 70 (patient records)—
 - (a) in sub-paragraphs (3) and (7)—
 - (i) omit "(other than a Primary Care Trust)"; and
 - (ii) for "the relevant body", in each place, substitute "the Board";
 - (b) in sub-paragraph (6)—
 - (i) omit "(other than the Primary care Trust)"; and
 - (ii) for "the relevant body", in each place, substitute "the Board";
 - (c) in sub-paragraphs (5), (8) and (9) for "the relevant body", in each place, substitute "the Board".
- (47) In paragraph 73 (provision of information)—
 - (a) for sub-paragraphs (1) and (2), substitute—

⁽²⁹⁾ See section 13R (information on safety of services provided by the health service) of the 2006 Act. Section 13R is inserted section 23(1) of the 2012 Act.

"(1) Subject to sub-paragraph (2), the contractor must, at the request of the Board, produce to it or to a person authorised in writing by the Board, or allow it, or a person authorised by it to access—

- (a) any information which is reasonably required by the Board for the purposes of or in connection with the agreement; and
- (b) any other information which is reasonably required by it in connection with the Board's functions.

(2) The contractor is not required to comply with any request made in accordance with sub-paragraph (1) unless it has been made by the Board in accordance with directions made by the Secretary of State under section 98A (exercise of functions) of the 2006 Act relating to the provision of information by contractors."; and

- (b) in sub-paragraph (3)(a), for "the relevant body", substitute "the Board".
- (48) In paragraph 75 (inquiries about prescriptions and referrals)—
 - (a) in sub-paragraph (1)—
 - (i) omit "(other than a Primary Care Trust)"; and
 - (ii) for "the relevant body", substitute "the Board"; and
 - (b) in sub-paragraphs (2) and (3), for "the relevant body", in each place, substitute "the Board".
- (49) In paragraph 77 (annual return and review)-
 - (a) in sub-paragraph (1)—
 - (i) for "the relevant body", substitute "the Board"; and
 - (ii) for "that body", substitute "it"; and
 - (b) in sub-paragraphs (1A), (1B), (2) and (3), for "the relevant body", in each place, substitute "the Board".
- (50) For-
 - (a) the heading to paragraph 78 and in paragraph 78 (notifications to the relevant body), for "the relevant body", in each place, substitute "the Board";
 - (b) "the relevant body's" in paragraph 78(b), substitute "the Board's"; and
 - (c) "a Primary Care Trust" in paragraph 78(c) and (d), substitute "the Board".
- (51) Omit paragraph 79.

(52) In paragraph 80 (notice provisions specific to an agreement with a qualifying body), in subparagraph (1) for "the relevant body", substitute "the Board".

(53) In paragraph 81 (notification of deaths)—

- (a) in sub-paragraph (1), for "the relevant body", substitute "the Board"; and
- (b) omit sub-paragraphs (3) and (4).

(54) In paragraph 82 (notifications to patients following variation of the agreement), for "the relevant body, or where the relevant body is a Strategic Health Authority, the contractor" substitute "the Board".

(55) In the heading to paragraph 83 and in paragraph 83(1) (entry and inspection by the relevant body), for "the relevant body", substitute "the Board".

(56) In paragraph 85 (entry and inspection by the Care Quality Commission), omit "(other than a Primary Care Trust)".

(57) Omit paragraph 85A and after paragraph 85 (entry and inspection by the Care Quality Commission) insert—

"Entry and viewing by Local Healthwatch organisations

85B. The contractor must comply with the requirement to allow an authorised representative to enter and view premises and observe the carrying-on of activities on those premises in accordance with regulations made under section 225 (duties of services-providers to allow entry by Local Healthwatch organisations or contractors) of the Local Government and Public Involvement Health Act 2007."(**30**).

- (58) In paragraph 86 (complaints procedure), omit paragraph (3).
- (59) In paragraph 91 (co-operation with investigations)—
 - (a) in sub-paragraph (1)—
 - (i) omit "(other than a Primary Care Trust"); and
 - (ii) for paragraph (a), substitute "(a) the Board; and";
 - (b) in sub-paragraph (3), in the definition of "NHS body"—
 - (i) for "a Primary Care Trust", substitute "the Board, a CCG"; and
 - (ii) omit "a Strategic Health Authority,"; and
 - (c) in sub-paragraph (4), for "the relevant body", in each place, substitute "the Board".

(60) In paragraph 93 (local resolution of agreement disputes), in sub-paragraph (1), for "the relevant body", substitute "the Board".

(61) In paragraph 94 (dispute resolution: non-NHS contracts) in sub-paragraph (1), for "the relevant body", in each place, substitute "the Board".

(62) In paragraph 98 (variation of an agreement: general), for "the relevant body", in each place, substitute "the Board".

(63) In paragraph 99 (termination by agreement), for "The relevant body", substitute "The Board".

(64) In paragraph 99A (termination on death) for "the Primary Care Trust", in each place, substitute "the Board".

(65) In paragraph 100 (termination by serving notice), in sub-paragraphs (1) and (4), for "the relevant body", substitute "the Board".

(66) In paragraph 101 (late payment notices), in sub-paragraphs (1) to (3), in each place, for "the relevant body", in each place, substitute "the Board".

(67) In the heading to paragraph 104 and in paragraph 104 (termination by the relevant body for the provision of untrue etc. information), for "the relevant body", in each place, substitute "the Board".

(68) The heading to paragraph 105 and paragraph 105 (termination by the relevant body on fitness grounds) are amended as follows—

- (a) in the heading to paragraph 105 and in sub-paragraph (1) of paragraph 105, for "the relevant body", substitute "the Board";
- (b) in sub-paragraph (1)(b)(ii), immediately before "legally and beneficially" insert "both";
- (c) in sub-paragraph (3)—

(i) in paragraph (c), for "the relevant body", substitute "the Board";

^{(30) 2007} c.28. Section 225 is amended by section 186(6) to (11) of, and paragraphs 148 and 151 of Schedule 5 and paragraphs 103 and 106 of Schedule 14 to, the 2012 Act.

- (ii) in paragraph (d), for "section 49F(2), (3) and (4) respectively", substitute "section 151(2), (3) and (4) of the 2006 Act respectively";
- (d) in sub-paragraph (4)—
 - (i) for "A relevant body", substitute "The Board";
 - (ii) for "the relevant body", substitute "the Board"; and
 - (iii) in paragraph (b)(i), immediately before "legally and beneficially" insert "both";
- (e) in sub-paragraph (5)—
 - (i) for "A relevant body", substitute, in each place, "The Board"; and
 - (ii) for "the relevant body", substitute "the Board"; and
- (f) in sub-paragraph (6)—
 - (i) for "A relevant body", substitute "The Board";
 - (ii) for "the relevant body", substitute "the Board"; and
 - (iii) in paragraph (b)(i), immediately before "legally and beneficially" insert "both".

(69) In the heading to paragraph 106 and in paragraph 106 (termination by the relevant body where there is a serious risk to the safety of patients or risk of financial loss to the relevant body), for "the relevant body", in each place, substitute "the Board".

- (70) In—
 - (a) the heading to paragraph 106A and in paragraph 106A (termination by the relevant body for unlawful sub-contracting) for "the relevant body", in each place, substitute "the Board"; and
 - (b) paragraph 106A, for "the relevant body's", substitute "the Board's".
- (71) In-
 - (a) the heading to paragraph 107 and in sub-paragraphs (1) to (3) and (5) to (8) of paragraph 107 (termination by the relevant body: remedial notices and breach notices) for "the relevant body", in each place, substitute "the Board"; and
 - (b) sub-paragraph (4) of paragraph 107—
 - (i) for "a relevant body", substitute "the Board"; and
 - (ii) for "the relevant body", substitute, in each place, "the Board".

(72) In the heading to paragraph 108 and in paragraph 108 (termination by the relevant body: additional provisions specific to agreements with qualifying bodies), for "the relevant body", in each place, substitute "the Board".

- (73) In paragraph 109 (agreement sanctions)—
 - (a) in sub-paragraph (2)—
 - (i) for "the relevant body", in each place, substitute "the Board"; and
 - (ii) for "the relevant body's" substitute "the Board's"; and
 - (b) in sub-paragraphs (3) to (5), for "the relevant body", in each place, substitute "the Board".

(74) In paragraph 110 (agreement sanctions and the NHS dispute resolution procedure), for "the relevant body", in each place, substitute "the Board".

(75) In paragraph 111 (termination and the NHS dispute resolution procedure) in sub-paragraphs (1) to (3) and (5), for "the relevant body", in each place, substitute "the Board".

(76) For paragraph 112A (clinical governance), substitute-

"**112A.** The contractor must co-operate with the Board in the discharge of any obligations of the Board or its accountable officers under section 17 (accountable officers and their responsibilities as to controlled drugs) and section 18 (co-operation between health bodies and other organisations) of the Health Act 2006.".

(77) Immediately after paragraph 112A, insert—

"Duty as to education and training

112B. The contractor must co-operate with the Secretary of State in the discharge of the duty under section 1F of the 2006 Act (duty as to education and training), or co-operate with Health Education England where Health Education England is discharging that duty by virtue of a direction under section 7.".

(78) In paragraph 115 (compliance with legislation and guidance), for sub-paragraph (b) substitute—

- "(b) have regard to all relevant guidance issued by the Board or the Secretary of State or Local Authorities in respect of the exercise of their functions under the 2006 Act.".
- (79) In paragraph 117 (gifts)—
 - (a) in sub-paragraph (2)(b)(i), immediately before "legally and beneficially" insert "both"; and
 - (b) in sub-paragraph (6), for "the relevant body", substitute "the Board".

Omission of Schedule 7

51. Schedule 7 (modification of patient provisions where the contractor is a Primary Care Trust) is omitted.

Amendment of Schedule 10

- 52.—(1) Schedule 10 (information to be included in a contractor's leaflet) is amended as follows.
- (2) For paragraph 16, substitute—

"16. Where the services referred to in paragraph 15 are not provided by the contractor, the fact that the Board is responsible for commissioning the services."

- (3) Omit paragraphs 17, 18 and 27.
- (4) For paragraph 26, substitute—

"26. The full name, postal and email address and telephone number of the Board.".

Transitional provisions

53. The transitional provisions set out in Schedule 2 have effect.

PART 4

MISCELLANEOUS AMENDMENTS

National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

54.—(1) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004(**31**) are amended as follows.

(2) In Schedule 2 (drugs, medicines and other substances that may be ordered only in certain circumstances)—

- (a) in column 1, omit the entry for "Cyanocobalamin Tablets" and the adjacent part which relates to the description of the patient (column 2) and the specified purpose (column 3);
- (b) for the entry for "Oseltamivir (Tamiflu)" which is referred to in column 1, in the part which relates to the description of the patient (as mentioned in column 2), in paragraph (1A) and (2A), for "are part of a Primary Care Trust's antivirals distribution service.", substitute "are part of an antiviral distribution service provided by the Board, Public Health England or a Local Authority."(32); and
- (c) for the entry for "Zanamivir (Relenza)" which is referred to in column 1, in the part which relates to "patient" (as mentioned in column 2), in paragraph (2) for "are part of a Primary Care Trust's antivirals distribution service.", substitute "are part of an antiviral distribution service provided by the Board, Public Health England or a Local Authority.".

Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004

55.—(1) The Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004(**33**) are amended as follows.

- (2) In regulation 2 (interpretation)-
 - (a) in paragraph (1)—
 - (i) after the definition of "the 1977 Act" insert-

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

"the 2012 Act" means the Health and Social Care Act 2012;";

(ii) for the definition of "APMS contractor", substitute-

"means a person with whom the Board has made arrangements under section 83(2) (primary medical services) of the 2006 Act for the provision of primary medical services or as a consequence of a scheme made under section 300 (transfer schemes) of the 2012 Act is a party to such arrangements;";

(iii) for the definition of "GMS contractor", substitute-

"means a person with whom the Board has entered into a general medical services contract under section 84 (general medical services contracts: introductory) of the 2006 Act or a default contract or as a consequence of a scheme made under section 300 of the 2012 Act is a party to such contracts;"; and

⁽³¹⁾ S.I. 2004/629. Relevant amending instruments are S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

⁽³²⁾ Public Health England is an Executive Agency of the Department of Health.

⁽³³⁾ S.I. 2004/906. There are no amendments.

(iv) for the definition of "PMS contractor", substitute-

"means a person with whom the Board has entered into a section 92 arrangement or as a consequence of a scheme made under section 300 of the 2012 Act is a party to a section 92 arrangement;".

- (b) in paragraph (2), for sub-paragraph (a), substitute—
 - "(a) recorded by the Board as being on the contractor's or performer's list of patients or on a list of patients maintained by the Board in respect of the contractor or performer; and".
- (3) Immediately after regulation 2, insert—

"Relevant area

2A. For the purposes of section 259(1) of the 2006 Act (sale of medical practices), the relevant area means the area which forms the area team area of the Board in which the performers or providers who are specified in regulation 3(1) (prohibition on the sale of goodwill in certain primary medical services practices) have provided or performed services at any time in accordance with arrangements or contract at that time.".

Signed by authority of the Secretary of State for Health.

Earl Howe Parliamentary Under-Secretary of State, Department of Health

15th February 2013

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULES

SCHEDULE 1

Regulation 29

Transitional provisions relating to GMS contracts

Application of Schedule 1

1. This Schedule applies to a GMS contract which is entered into before the appointed day, and the parties to the contract on or after the appointed day are the Contractor and the Board as a consequence of a property scheme transfer made under section 300 of the 2012 Act.

Interpretation

2. In this Schedule—

"2012 Act" means the Health and Social Care Act 2012(34);

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

"the appointed day" means 1st April 2013;

"the Board" means the National Health Service Commissioning Board (35);

"contractor" means—

- (a) in relation to a period before the appointed day, a party to a GMS contract, other than the Primary Care Trust; or
- (b) in relation to a period on or after the appointed day, a party to the GMS contract, other than the Board;

"GMS contract" means a contract entered into in accordance with section 84 of the 2006 Act (36);

"out of hours services" has the same meaning as in regulation 2 (interpretation) of the GMS Contracts Regulations;

"Primary Care Trust" means the Primary Care Trust which was established and which subsisted immediately before the coming into force of section 34 (abolition of Primary Care Trusts) of the 2012 Act;

"Strategic Health Authority" means the Strategic Health Authority which was established and which subsisted immediately before the coming into force of section 33 (abolition of Strategic Health Authorities) of the 2012 Act.

General transitional provisions relating to the terms of a GMS contract

3.—(1) The Contractor and the Board must as soon as is reasonably practicable on or after the appointed day, enter into discussions with each other with a view to agreeing variations to the GMS

⁽**34**) 2012 c.7.

⁽³⁵⁾ The National Health Service Commissioning Board is established by section 1H of the 2006 Act. Section 1H is inserted by section 9 of the 2012 Act.

⁽³⁶⁾ Section 84 is amended by section 55(1) of, and paragraph 31 of Schedule 4 to, the 2012 Act.

contract in order to ensure that the contract complies with the GMS Contracts Regulations on or after the appointed day.

(2) Where the terms of the GMS contract have not been varied so as to include the terms which have the same effect as those terms specified in these Regulations, the GMS contract is deemed to have been so varied only to the extent that such terms are to have the same effect as those terms specified in these Regulations which have effect on or after the appointed day.

(3) The Contractor and the Board may not agree any variation to the GMS contract that is contrary to the GMS Contracts Regulations on or after the appointed day.

Continuing validity of forms

4. A form supplied by a Primary Care Trust continues to be a valid form in relation to the Board until it is cancelled or withdrawn by the Board.

Notification of reasons by a Primary Care Trust in respect of entering into contracts

5. Where a Primary Care Trust has given notification to a person under regulation 6 (reasons) of the GMS Contracts Regulations before the appointed day, the notification and the written views contained in that notification are to be treated, on or after that day, as notification by the Board and the written views of the Board.

Appeals relating to eligibility to enter into a contract

6. A person who has been served notice pursuant to regulation 6 of the GMS Contracts Regulations before the appointed day may on or after that day appeal to the First-tier Tribunal against the decision of the Primary Care Trust and that appeal must be treated as an appeal against a decision of the Board.

Finance

7. Any right that a Primary Care Trust had to set off against any amount payable to the contractor under the term that gives effect to regulation 22 (finance) of the GMS Contracts Regulations immediately before the appointed day, must be treated as a right of the Board under the term that gives effect to that regulation on or after the appointed day.

Opt outs of additional and out of hours services

8.—(1) Subject to the following provisions of this paragraph, a notification or approval given, or an agreement made, by a Primary Care Trust in accordance with the term of the contract that gives effect to—

- (a) regulation 17 (opt outs of additional and out of hours services) of the GMS Contracts Regulations;
- (b) regulation 31(3)(b) (out of hours services) of the GMS Contracts Regulations; or
- (c) paragraph 4 (out of hours opt outs where the opt out notice is served after 30th September 2004) of Schedule 3 to the GMS Contracts Regulations,

in respect of a period that commences on or after the appointed day, must be regarded for the purposes of the term of the GMS contract that give effect to that regulation or that paragraph as a notification or approval given, or agreement made, by the Board and is binding on the Board as if such notification or approval were given, or agreement were made, by it.

(2) Where a contractor informs the relevant Primary Care Trust that it wishes to withdraw an out of hours opt out notice where it has been approved by the Primary Care Trust and the Primary Care

Trust has not agreed to the withdrawal before the appointed day, the Board may, if it considers it appropriate, agree to the withdrawal of the out of hours opt out notice as if it had approved the notice.

Continuing application of published guidance and other documents

9. Where as a consequence of paragraph 11 (standards for out of hours services) or 125 (compliance with legislation and guidance) of Schedule 6 to the GMS Contracts Regulations a contractual term in a GMS contract requires a contractor to meet requirements set out in a document or have regard to, or comply with, guidance published before the appointed day which has effect immediately before that day, that contractual term continues to apply in respect of such documents and guidance on or after the appointed day—

- (a) as if references to a Primary Care Trust or Strategic Health Authority in that document or guidance were to the Board; and
- (b) until such time as the Board, or as the case may be, the Secretary of State, cancels or withdraws the document or guidance.

Arrangements for GP Registrars

10. A contractor which employs a GP Registrar in accordance with paragraph 64 (arrangements for GP Registrars) of Schedule 6 to the GMS Contracts Regulations immediately before the appointed day must continue to employ that GP Registrar and may only vary the terms and conditions to the extent necessary to comply with that paragraph and any other relevant provision relating to the 2006 Act which have effect on or after the appointed day.

Sub-contracting of clinical matters

11.—(1) A notification made to a Primary Care Trust by a contractor under the term of contract that had the same effect as the provision in sub-paragraph (1) of paragraph 69 (sub-contracting of clinical matters) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day, must be treated as notification to the Board.

(2) Notwithstanding a Primary Care Trust's request for further information in accordance with the term of the GMS contract that had the same effect as the provision in paragraph 69(4) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day, the Board may request such further information from the contractor relating to the proposed sub-contract if it considers it necessary in order to deal with the matter.

(3) Where a Primary Care Trust served notice of objection to the sub-contract in accordance with the term of the contract that had the same effect as the provision in paragraph 69(5) of the GMS Contracts Regulations as in force immediately before the appointed day, that notice and the reasons for objection is deemed to be notice of objection by, and reasons of, the Board.

(4) Where a Primary Care Trust has not objected to a proposed sub-contract and the 28 day period referred to in the term of the contract that had the same effect as the provision in paragraph 69(5) of the GMS Contracts Regulations as in force immediately before the appointed day has elapsed on or after that date, the Board and the contractor are deemed as having agreed a variation of the contract in accordance with paragraph 69(8) of the GMS Contracts Regulations as in force on or after the appointed day.

Sub-contracting of out of hours services

12.—(1) A written approval given by a Primary Care Trust to a contractor in respect of the term of the contract that had the same effect as the provision in paragraph 70(1) (sub-contracting of out of hours services) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day, must be treated as an approval given by the Board.

(2) An application for approval made by a contractor to a Primary Care Trust under the term of the contract that has the same effect as the provisions in paragraph 70(1) and (3) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day which is pending, must be treated as an application made to the Board.

(3) Notwithstanding a Primary Care Trust's request for further information in accordance with the term of the contract that has the same effect as the provision in paragraph 70(4) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day, the Board may request such further information from the contractor relating to the proposed arrangements if it considers it necessary in order to deal with the matter.

(4) Where a Primary Care Trust informed the contractor by notice of its decision in accordance with the term of the contract that had the same effect as the provision in paragraph 70(7) of the GMS Contracts Regulations as in force immediately before the appointed day, that notice and (where it refuses an application) the statement of reasons for refusal is to be deemed as notice by, and (where there has been a refusal) the statement of reasons for refusal of, the Board.

Withdrawal and variation of approval relating to sub-contracting out of hours services

13. The Board may, at any stage, serve notice on a contractor withdrawing or varying an approval which was given by a Primary Care Trust in accordance with the term of the contract that had the same effect as paragraph 70(3) of the GMS Contracts Regulations as in force immediately before the appointed day, and for the purposes of the term of the contract that has the same effect as paragraphs 71 (withdrawal and variation of approval under paragraph 70) and 72 of the GMS Contracts Regulations, the approval is deemed to be approval by the Board.

Records, information, notifications and rights of entry

14.—(1) Where a Primary Care Trust gave consent, authorisation or notification or made a request under a term of the GMS contract that had the same effect as the provisions in Part 5 (records, information, notification and rights of entry) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day, such consent, authorisation, notification or request is deemed to be that of the Board for the purposes of the application of the terms of the GMS contract that have the same effect as the provisions in Part 5 of Schedule 6 to the GMS Contracts Regulations on or after the appointed day.

(2) The reference to a request and authorisation in paragraph (1) respectively includes any inquiries made in writing from the Primary Care Trust and appointments made by the Primary Care Trust in accordance with the terms of the GMS contract that have the same effect as the provisions in paragraph 79 (inquiries about prescriptions and referrals) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day.

Leaflets

15.—(1) This paragraph applies where a contractor has compiled a practice leaflet which complies with the requirements of paragraph 76 (practice leaflet) of Schedule 6 to the GMS Contracts Regulations immediately before the appointed day.

(2) Notwithstanding the requirements in paragraph 76 of Schedule 6 to the GMS Contracts Regulations as in force on or after the appointed day, a contractor must review its practice leaflet and make any amendments necessary so as to include the information specified in Schedule 10 to the GMS Contracts Regulations (information to be included in practice leaflets) not later than 1st July 2013.

Complaints

16.—(1) This paragraph applies where an investigation of a complaint under the procedure referred to in paragraph 92 of Schedule 6 to the GMS Contracts Regulations is not completed before the appointed day.

(2) A complaint of a kind referred to in paragraph (1) must continue to be dealt with in accordance with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(37)—

- (a) as if any reference to a Primary Care Trust in a document or form relating to the complaint were a reference to the Board; and
- (b) in respect of a complaint received prior to 1st April 2009, the contractor—
 - (i) must deal with the complaint as far as it is able, in accordance with those Regulations; and
 - (ii) may if it is unable to comply with those Regulations as a consequence of the length of time it has taken to deal with the complaint vary the procedure only to the extent that it is necessary in order to dispose of the matter in a just manner.

Co-operation with investigations

17. The contractor must continue to co-operate with an investigation of a complaint which is ongoing immediately before the appointed day in accordance with the terms of the GMS contract that give effect to paragraph 97 of Schedule 6 to the GMS Contracts Regulations as in force on or after the appointed day as if any act or omission by, or reference to, a Primary Care Trust or Strategic Health Authority were an act or omission by, or reference to, the Board.

Disputes

18.—(1) Any dispute arising out of or in connection with a GMS contract in respect of a contractor and Primary Care Trust that is on-going immediately before the appointed day is deemed to be a dispute in respect of that contractor and the Board.

(2) The terms of the contract which had the same effect as the provisions in Part 7 of Schedule 6 to the GMS Contracts Regulations as in force on or after the appointed day continue to apply to the dispute as if references to—

- (a) subject to paragraph (c), "Primary Care Trust" were to the "Board";
- (b) "the parties" mean to the contractor and the Board; and
- (c) "the Local Medical Committee for the area of the Primary Care Trust" were to "the Local Medical Committee for the area of the Primary Care Trust which was established and subsisted immediately before 1st April 2013".

Variation and termination of GMS contracts

19.—(1) This paragraph applies where a Primary Care Trust or a contractor has taken any steps in accordance with or in connection with a matter referred to in any of the provisions in Part 8 (variation and termination of contracts) of Schedule 6 to the GMS Contracts Regulations before the appointed day and had it not been for the coming into force of section 34 (abolition of Primary Care Trusts) of the 2012 Act that matter would continue to fall to the Primary Care Trust to be dealt with in accordance with Part 8.

(2) Any action taken or omission by a Primary Care Trust in accordance with or in connection with any of the provisions in Part 8 of Schedule 6 to the GMS Contracts Regulations is deemed to

⁽³⁷⁾ S.I.2009/309; amending instruments are S.I. 2009/1768, 2012/1909 and 2013/235.

be action taken or omitted by the Board for the purposes of the continuity of the application of those provisions that have effect on or after the appointed day.

(3) Where an agreement has been reached between a contractor and a Primary Care Trust in accordance with or in connection with the provisions in Part 8 of Schedule 6 to the GMS Contracts Regulations before the appointed day, that agreement is deemed to be an agreement made by that contractor and the Board.

(4) Where notice has been given by the contractor to the Primary Care Trust or notice has been given by the Primary Care Trust to the contractor in accordance with or in connection with the provisions in Part 8 of Schedule 6 to the GMS Contracts Regulations, that notice is deemed to have been given by that contractor to the Board, or as the case may be, notice given by the Board to that contractor.

(5) Notwithstanding the above paragraphs, the Board may, if it thinks necessary or desirable in order to dispose of a matter justly, review a decision or action taken that it is deemed to have made or taken as a consequence of this paragraph.

Consultation with the Local Medical Committee

20. Where a Primary Care Trust consulted the Local Medical Committee before the appointed day in accordance with the term of the contract that had the same effect as paragraph 120 (consultation with the Local Medical Committee) of Schedule 6 to the GMS Contracts Regulations as in force immediately before the appointed day, the Local Medical Committee, if it has not responded to the Primary Care Trust, must respond to the Board and treat the consultation as a consultation by the Board.

Supplementary transitional provision

21.—(1) Subject to the preceding provisions in this Schedule, any act or omission by, or in relation to, a Primary Care Trust before the appointed day in respect of—

- (a) the exercise of any functions of the Primary Care Trust under Part 4 of the 2006 Act; or
- (b) any rights or liabilities of the Primary Care Trust transferred as a consequence of a property transfer scheme made under section 300 of the 2012 Act,

in relation to a GMS contract, is deemed to have been an act or omission of, or in relation to the Board.

(2) Anything which, when these Regulations take effect, is in the process of being done by, or in relation to, the Primary Care Trust in respect of, or in connection with—

- (a) the exercise by the Primary Care Trust of any of its functions under Part 4 of the 2006 Act; or
- (b) any rights or liabilities of the Primary Care Trust transferred as a consequence of a property transfer scheme made under section 300 of the 2012 Act,

is deemed to have effect as if done by, or in relation to, and may be continued by, or in relation to, the Board.

(3) Where it is necessary for the contractor or the Board—

- (a) to take account of a period of time; or
- (b) to calculate a period of time which is required in accordance with the GMS Contracts Regulations as in force on or after the appointed day,

any period of time that occurred before the appointed day and which is relevant to the matter under consideration is to be taken into account or used in order to calculate any time period for the purposes of that consideration or applying provisions in these Regulations on or after the appointed day only

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if that period of time could have been taken into account or used in a calculation of a time period in respect of those mirror provisions as in force immediately before the appointed day.

SCHEDULE 2

Regulation 53

Transitional provisions relating to PMS agreements

Application of Schedule 2

1. This Schedule applies to a PMS agreement which is entered into before the appointed day, and the parties to the agreement on or after the appointed day are the Contractor and the Board as a consequence of a property scheme transfer made under section 300 of the 2012 Act.

Interpretation

- 2. In this Schedule—
 - "2012 Act" means the Health and Social Care Act 2012(38);

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

"the appointed day" means 1st April 2013;

"the Board" means the National Health Service Commissioning Board;

"contractor" means—

- (a) in relation to a period before the appointed day, a party to a PMS agreement, other than the Primary Care Trust; or
- (b) in relation to a period on or after the appointed day, a party to a PMS agreement, other than the Board;

"out of hours services" has the same meaning as in regulation 2 (interpretation) of the PMS Agreements Regulations;

"PMS agreement" means an agreement entered into in accordance with section 92 of the 2006 Act(**39**);

"Primary Care Trust" means the Primary Care Trust which was established and which subsisted immediately before the coming into force of section 34 (abolition of Primary Care Trusts) of the 2012 Act; and

"relevant body" means-

- (a) in a case where the contractor is a party to a PMS agreement with a Primary Care Trust, that Primary Care Trust, and
- (b) in a case where the contractor is a party to a PMS agreement with a Strategic Health Authority, that Authority; and

"Strategic Health Authority" means the Strategic Health Authority which was established and which subsisted immediately before the coming into force of section 33 (abolition of Strategic Health Authorities) of the 2012 Act.

^{(38) 2012 (}c.7).

⁽³⁹⁾ Section 92 is amended by section 55(1) of, and paragraph 36 of Schedule 4 to, the 2012 Act.

General Transitional provision relating to the terms of a PMS agreement

3.—(1) The Contractor and the Board must as soon as is reasonably practicable on or after the appointed day, enter into discussions with each other with a view to agreeing variations to the PMS agreement in order to ensure that the agreement complies with the PMS Agreements Regulations on or after the appointed day.

(2) Where the terms of the PMS agreement have not been varied so as to include the terms which have the same effect as those terms specified in these Regulations, the PMS agreement is deemed to have been so varied only to the extent that such terms are to have the same effect as those terms specified in these Regulations that have effect on or after on or after the appointed day.

(3) The Contractor and the Board may not agree any variation to the PMS agreement that is contrary to the PMS Agreements Regulations on or after the appointed day.

Continuing validity of forms

4. A form supplied by a relevant body continues to be a valid form in relation to the Board until it is cancelled or withdrawn by the Board.

Notification of reasons by a relevant body in respect of entering into agreements

5. Where a relevant body has given notification to a person under regulation 6 (reasons) of the PMS Agreements Regulations before the appointed day, the notification and the written views contained in that notification are to be treated, on or after that day, as notification by the Board and the written views of the Board.

Appeals relating to eligibility to enter into a PMS agreement

6. A person who has been served notice pursuant to regulation 6 of the PMS Agreements Regulations before the appointed day may on or after that day appeal to the First-tier Tribunal against the decision of the relevant body and that appeal must be treated as an appeal against a decision of the Board.

Finance

7. Any right that a relevant body had to set off against any amount payable to the contractor under the term that gives effect to regulation 13 (finance) of the PMS Agreements Regulations immediately before the appointed day, must be treated as a right of the Board under the term that gives effect to that regulation on or after the appointed day.

Opt outs of out of hours services

8.—(1) Subject to the following provisions of this paragraph, a notification or approval given, or an agreement made, by a Primary Care Trust in accordance with the term of the agreement that gives effect to—

- (a) regulation 16 (opt outs of out of hours services) of the PMS Agreements Regulations; or
- (b) paragraph 1 (out of hours opt outs where the opt out notice is served after 30th September 2004) of Schedule 4 to the PMS Agreements Regulations,

in respect of a period that commences on or after the appointed day, must be regarded for the purposes of the term of the PMS agreement that gives effect to that regulation or that paragraph as a notification or approval given, or agreement made, by the Board and is binding on the Board as if such notification or approval were given, or agreement were made, by it.

(2) Where a contractor informs the relevant Primary Care Trust that it wishes to withdraw an out of hours opt out notice where it has been approved by the Primary Care Trust and the Primary Care Trust has not agreed to the withdrawal before the appointed day, the Board may, if it considers it appropriate, agree to the withdrawal of the out of hours opt out notice as if it had approved the notice.

Right to a general medical services contract

9. Where notice is given to a relevant body prior to the appointed day in accordance with regulation 19 (right to a general medical services contract) of the PMS Agreements Regulations as in force immediately before the appointed day, that notice must be treated as notice given to the Board for the purposes of the application of that regulation as in force on or after the appointed day.

Arrangements for GP Registrars

10. A contractor which employs a GP Registrar in accordance with paragraph 63 (arrangements for GP Registrars) of Schedule 5 to the PMS Agreements Regulations immediately before the appointed day must continue to employ that GP Registrar and may only vary the terms and conditions to the extent necessary to comply with that paragraph and any other relevant provision relating to the 2006 Act which have effect on or after the appointed day.

Continuing application of published guidance and other documents

11. Where as a consequence of paragraph 9 (standards for out of hours services) or 115 (compliance with legislation and guidance) of Schedule 5 to the PMS Agreements Regulations a contractual term in a PMS agreement requires a contractor to meet requirements set out in a document or have regard to, or comply with, guidance published before the appointed day which has effect immediately before that day, that contractual term continues to apply in respect of such documents and guidance on or after the appointed day—

- (a) as if references to a Primary Care Trust or Strategic Health Authority in that document or guidance were to the Board; and
- (b) until such time as the Board, or as the case may be, the Secretary of State, cancels or withdraws the document or guidance.

Sub-contracting of clinical matters

12.—(1) Where a contractor has informed a relevant body that it has sub-contracted its rights and has provided the relevant information in accordance with paragraph 69 (sub-contracting of clinical matters) of Schedule 5 to the PMS Agreements Regulations as in force immediately before the appointed day, the contractor is deemed to have informed the Board and provided the Board with the relevant information.

(2) Notwithstanding paragraph (1), the Board may request from the contractor such further information relating to the proposed sub-contract if it considers it necessary in order to deal with the matter.

Records, information, notifications and rights of entry

13.—(1) Where a Primary Care Trust has given consent, authorisation or notification or made a request under a term of the contract that has the same effect of the provisions in Part 5 (records, information, notification and rights of entry) of Schedule 5 to the PMS Agreements Regulations as in force immediately before the appointed day, such consent, authorisation, notification or request is deemed to be that of the Board for the purposes of the application of the terms of the contract that have the same effect as the provisions in Part 5 of Schedule 5 to the PMS Agreements Regulations on or after the appointed day.

(2) The reference to a request and authorisation in paragraph (1) respectively includes any inquiries made in writing from the Primary Care Trust and appointments made by the Primary Care Trust in accordance with the terms of the PMS agreement that have the same effect as the provisions in paragraph 75 (inquiries about prescriptions and referrals) of Schedule 5 to the PMS Agreements Regulations as in force immediately before the appointed day.

Leaflets

14.—(1) This paragraph applies where a contractor has compiled a practice leaflet which complies with the requirements of paragraph 72 (contractor's leaflet) of Schedule 5 to the PMS Agreements Regulations immediately before the appointed day.

(2) Notwithstanding the requirements in paragraph 72 of Schedule 5 to the PMS Agreements Regulations as in force on or after the appointed day, a contractor must review its practice leaflet and make any amendments necessary so as to include the information specified in Schedule 10 to the PMS Agreements Regulations (information to be included in practice leaflets) not later than 1st July 2013.

Complaints

15.—(1) This paragraph applies where an investigation of a complaint under the procedure referred to in paragraph 86 of Schedule 5 to the PMS Agreements Regulations is not completed before the appointed day.

(2) A complaint of a kind referred to in paragraph (1) must continue to be dealt with in accordance with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(40)—

- (a) as if any reference to a relevant body in a document or form relating to the complaint were a reference to the Board; and
- (b) in respect of a complaint received prior to 1st April 2009, the contractor—
 - (i) must deal with the complaint as far as it is able, in accordance with those Regulations; and
 - (ii) may if it is unable to comply with those Regulations as a consequence of the length of time it has taken to deal with the complaint vary the procedure only to the extent that it is necessary in order to dispose of the matter in a just manner.

Co-operation with investigations

16. The contractor must continue to co-operate with an investigation of a complaint which is ongoing immediately before the appointed day in accordance with the terms of the PMS agreement that give effect to paragraph 91 of Schedule 5 to the PMS Agreements Regulations as in force on or after the appointed day as if any act or omission by, or reference to, a relevant body, Primary Care Trust or Strategic Health Authority were an act or omission by, or reference to the Board.

Disputes

17.—(1) Any dispute arising out of or in connection with a PMS agreement in respect of a contractor and relevant body that is on-going immediately before the appointed day is deemed to be a dispute in respect of that contractor and the Board.

(2) The terms of the PMS agreement which have the same effect as the provisions in Part 7 of Schedule 5 to the PMS Agreements Regulations as in force on or after the appointed day apply to

⁽⁴⁰⁾ S.I.2009/309; amending instruments are S.I. 2009/1768, 2012/1909 and 2013/235.

the dispute as if any act, omission by, or in relation to, the relevant body is an act, omission by, or in relation to the Board.

Variation and termination of PMS agreements

18.—(1) This paragraph applies where a relevant body or a contractor has taken any steps in accordance with or in connection with a matter referred to in any of the provisions in Part 8 (variation and termination of agreements) of Schedule 5 to the PMS Agreements Regulations before the appointed day and had it not been for the coming into force of section 33 (abolition of Strategic Health Authorities) or section 34 (abolition of Primary Care Trusts) of the 2012 Act that matter would continue to fall to the relevant body to be dealt with in accordance with Part 8.

(2) Any action taken or omission by a relevant body in accordance with or in connection with any of the provisions in Part 8 of Schedule 5 to the PMS Agreements Regulations is deemed to be action taken or omitted by the Board for the purposes of the continuity of the application of those provisions that have effect on or after the appointed day.

(3) Where an agreement has been reached between a contractor and a relevant body in accordance with or in connection with the provisions in Part 8 of Schedule 5 to the PMS Agreements Regulations before the appointed day, that agreement is deemed to be an agreement made by that contractor and the Board.

(4) Where notice has been given by the contractor to the relevant body or notice has been given by the relevant body to the contractor in accordance with or in connection with the provisions in Part 8 of Schedule 5 to the PMS Agreements Regulations, that notice is deemed to have been given by that contractor to the Board, or as the case may be, notice given by the Board to that contractor.

(5) Notwithstanding the above paragraphs, the Board may, if it thinks necessary or desirable in order to dispose of a matter justly, review a decision or action taken that it is deemed to have made or taken as a consequence of this paragraph.

Supplementary transitional provision

19.—(1) Subject to the preceding provisions in this Schedule, any act or omission by, or in relation to, the relevant body before the appointed day in respect of—

- (a) the exercise of any functions of the relevant body under Part 4 of the 2006 Act; or
- (b) any rights or liabilities of the relevant body transferred as a consequence of a property transfer scheme made under section 300 of the 2012 Act,

in relation to section 92 arrangements, is deemed to have been an act or omission of, or in relation to the Board.

(2) Anything which, when these Regulations take effect, is in the process of being done by, or in relation to, the relevant body in respect of, or in connection with—

- (a) the exercise by the relevant body of any of its functions under Part 4 of the 2006 Act; or
- (b) any rights or liabilities of the relevant body transferred as a consequence of a property transfer scheme made under section 300 of the 2012 Act,

is deemed to have effect as if done by, or in relation to, and may be continued by, or in relation to, the Board.

- (3) Where it is necessary for the contractor or the Board—
 - (a) to take account of a period of time; or
 - (b) to calculate a period of time which is required in accordance with the PMS Agreements Regulations as in force on or after the appointed day,

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

any period of time that occurred before the appointed day and which is relevant to the matter under consideration is to be taken into account or used in order to calculate any time period for the purposes of that consideration or applying provisions in these Regulations on or after the appointed day only if that period of time could have been taken into account or used in a calculation of a time period in respect of those mirror provisions as in force immediately before the appointed day.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Services Contracts) Regulations 2004 ("the GMS Contracts Regulations"), the National Health Service (Personal Medical Services Agreements) Regulations 2004 ("the PMS Agreements Regulations"), the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 ("the Prescription of Drugs Regulations") and the Primary Medical Services (Sales of Goodwill and Restrictions on Sub-contracting) Regulations 2004 ("the Sale of Goodwill Regulations"). These Regulations largely make amendments which are as a consequence of the transfer of primary medical services contracts and agreements to the National Health Service Commissioning Board ("the Board") from Primary Care Trusts and as a consequence of the abolition of Strategic Health Authorities and Primary Care Trusts upon the coming into force of sections 33 and 34 of the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). These Regulations also make other minor amendments to the GMS Contracts Regulations, PMS Agreements Regulations and the Prescription of Drugs Regulations.

Part 2 contains amendments to the GMS Contracts Regulations. The majority of these amendments are made in consequence of the transfer of GMS contracts from Primary Care Trusts to the Board, the abolition of Primary Care Trusts and Primary Care Trust's areas. In addition, minor amendments are made as a consequence of amendments to Part 4 of the National Health Service Act 2006 (c.41) by section 202(1) (medical services: minor amendments) of the 2012 Act coming into force. However–

regulation 12 amends regulation 15 of the GMS Contracts Regulations to ensure that a contractor under its contractual terms is not required to provide essential services during any period in respect of which the Care Quality Commission has suspended the contractor as a service provider. Regulation 3 makes a consequential amendment by the insertion of a new definition of "service provider" into regulation 2 of the GMS Contracts Regulations;

regulation 15 inserts a new provision into the GMS Contracts Regulations providing that contracts are to contain a term requiring a contractor to be a member of a clinical commissioning group and requiring a contractor to appoint one individual to act on its behalf. Regulation 3 makes a consequential amendment by the insertion of a new definition of "CCG" into regulation 2 of the GMS Contracts Regulations;

regulation 20 omits the provisions relating to the Patient Choice Scheme that comes to an end on 31st March 2013. A new Patient Choice Extension Scheme is established and a variation of contractual terms in respect of entering into arrangements under that scheme are provided for by new regulation 26B which is inserted into the GMS Contracts Regulations by regulation 20. Regulation 3 makes a consequential amendment by the insertion of a new definition of "Patient Choice Extension Scheme" into regulation 2 of the GMS Contracts Regulations;

Regulation 27 makes additional amendments to Schedule 6 to the GMS Contracts Regulations-

paragraphs (33), (34) and (36) make amendments in relation to electronic prescriptions which are required as a consequence of the National Health Service IT infrastructure changes which include the electronic system that enables the transmission of digitally signed prescriptions and prescription messages to dispensing contractors. Regulation 3 makes consequential amendments;

paragraph (41) makes an updating amendment as a consequence of changes relating to postgraduate education and training and requirements relating to the medical performers list which is established and maintained by the Board;

paragraph (42) amends paragraph 64 of Schedule 6 and paragraph 86 inserts a new paragraph 121B into Schedule 6 as a consequence of the newly established Special Health Authority known as Health Education England;

paragraph (43) amends paragraph 65 of Schedule 6 as a consequence of chiropodists and podiatrists and physiotherapists being able to be recorded on the register maintained under article 5 of the Health and Social Work Professions Order 2001 as independent prescribers.

paragraphs (60) and (61) respectively omit paragraph 91A and insert a new paragraph 91B as a consequence of the abolition of local involvement networks and the establishment of Local Healthwatch organisations in accordance with section 222(2A) of the Local Government and Public Involvement in Health Act 2007 (c.28) as amended by section 183(2) of the 2012 Act.

Schedule 1 makes transitional provisions in respect of GMS contracts which are transferred from Primary Care Trusts to the Board on 1st April 2013.

Part 3 and Schedule 2 make amendments to the PMS Agreements Regulations and transitional provision relating to agreements made under those Regulations which mirror those made to the GMS Contracts Regulations.

Part 4 makes miscellaneous amendments. Regulation 54 amends the Prescription of Drugs Regulations-

- (a) to omit the entry for Cyanocobalamin Tablets from the list of drugs that may be ordered in respect of specified persons in certain circumstances, and
- (b) in respect of the circumstances in which Oseltamivir and Zanamivir may be ordered for a person as part of an antiviral distribution service as a consequence of the abolition of Primary Care Trusts, the establishment of the Board and Public Health England and the public health functions of Local Authorities.

Regulation 55 amends the Sale of Goodwill Regulations as a consequence of the abolition of Primary Care Trusts and Strategic Health Authorities.