
STATUTORY INSTRUMENTS

2006 No. 552

**The National Health Service (Local
Pharmaceutical Services etc.) Regulations 2006**

PART 1

GENERAL

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 and shall come into force on 1st April 2006.

(2) These Regulations apply in relation to England only⁽¹⁾.

Interpretation

2.—(1) In these Regulations—

“the 1990 Act” means the National Health Service and Community Care Act 1990⁽²⁾;

“the Abolition of the Tribunal Regulations” means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001⁽³⁾;

“the Act” means the National Health Service Act 1977;

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

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

“appliance” means an appliance which is included in a list for the time being approved by the Secretary of State for the purposes of section 41 of the Act (arrangements for pharmaceutical services);

“appropriate non-proprietary name” means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations (drugs, medicines and other substances not to be ordered under a general medical services contract) or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Contracts Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations (drugs, medicines and other substances that may be ordered only in certain circumstances);

(1) As regards Wales, the relevant functions of the Secretary of State under the Act were transferred to the National Assembly for Wales under [S.I. 1999/672](#), read with section 68(1) of the 2001 Act.

(2) 1990 c. 19.

(3) [S.I. 2001/3744](#).

“associated batch issue” means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;
“batch issue” means a form provided by a Primary Care Trust and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription which enables a contractor to receive payment for the provision of repeat dispensing services, which is in the format required by the NHS Business Services Authority, and which—

- (a) is generated by a computer and not signed by a repeatable prescriber;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and
- (d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);

“the Charges Regulations” means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(4);

“chemical reagent” means a chemical reagent included in a list for the time being approved by the Secretary of State for the purposes of section 41 of the Act(5);

“contractor” means the party or parties to an LPS scheme which is or are not the Primary Care Trust;

“dentist” means a dentist registered in the dentists register maintained under section 14 of the Dentists Act 1984(6);

“doctor” means a registered medical practitioner;

“drugs” includes medicines;

“Drug Tariff” means the statement compiled and published under regulation 56(1) of the Pharmaceutical Services Regulations (standards of, and payments for, drugs and appliances);

“electronic communication” has the meaning given in section 15 of the Electronic Communications Act 2000(7) (general interpretation);

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

“electronic prescription form” means a prescription which falls within (b) of the definition of “prescription form”;

“electronic repeatable prescription” means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription”;

“ETP service” means the electronic prescription service which forms part of the NHS Care Record Service;

“equivalent body” means—

- (a) a Local Health Board in Wales or, in relation to any time prior to 1st April 2003, a Health Authority in Wales;
- (b) a Health Board or NHS trust in Scotland;
- (c) a Health and Social Services Board in Northern Ireland; or

(4) S.I. 2000/620; as amended by S.I. 2000/2393 and 3189, 2001/746 and 2887, 2002/548 and 2352, 2003/699 and 1084, 2004/663, 696, 865 and 1771, and 2005/578 and 641.

(5) Section 41 was substituted by the 2001 Act, section 41, and amended by the 2002 Act, Schedule 2, paragraph 13, and by S.I. 2003/1590 and 2004/1771.

(6) 1984 c. 24.

(7) 2000 c. 7.

- (d) in relation to any time prior to 1st October 2002, a Health Authority in England;
- “FHSAA” means the Family Health Services Appeal Authority constituted under section 49S of the Act⁽⁸⁾ (the Family Health Services Appeal Authority);
- “the GMS Contracts Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004⁽⁹⁾;
- “Health and Social Services Board” means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972⁽¹⁰⁾;
- “Health Board” means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978⁽¹¹⁾ (Health Boards);
- “independent nurse prescriber” means a person—
- (a) who is registered in the Nursing and Midwifery Register; and
 - (b) in respect of whom is recorded in that register an annotation signifying that he is qualified to order drugs and appliances—
 - (i) until 30th April 2006, from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff,
 - (ii) until 30th April 2006, from the Nurse Prescribers' Extended Formulary in Part XVIIB(ii) of the Drug Tariff,
 - (iii) as an independent nurse prescriber, or
 - (iv) as a community practitioner nurse prescriber;
- “licensing or regulatory body” means a body that licenses or regulates any profession of which a person is or has been a member, and includes any body which licenses or regulates such a profession in a country other than the United Kingdom;
- “listed appliance” means an appliance which is listed from time to time in Parts IXA, IXB, IXC or X of the Drug Tariff;
- “Local Medical Committee” means a committee recognised under section 45A of the Act⁽¹²⁾ (Local Medical Committees);
- “Local Pharmaceutical Committee” means a committee recognised under section 44(B2)(b) of the Act⁽¹³⁾ (which relates to recognition of Local Pharmaceutical Committees);
- “national disqualification” means—
- (a) a decision made by the FHSAA under section 49N of the Act⁽¹⁴⁾ (national disqualification) in relation to a person who has been removed from a pharmaceutical list;
 - (b) a decision under provisions in force in Scotland or Northern Ireland corresponding to section 49N of the Act; or
 - (c) a decision by the Tribunal which is treated as a national disqualification by the FHSAA by virtue of regulation 4 of the Abolition of the Tribunal Regulations;
- “National Health Service Counter Fraud and Security Management Service” means the Special Health Authority of that name with responsibility for policy and operational matters relating to the prevention, detection and investigation of fraud or corruption and the management of

⁽⁸⁾ Section 49S was inserted by the 2001 Act, section 27(8)(b), and amended by the 2002 Act, Schedule 1, paragraph 18.

⁽⁹⁾ S.I. 2004/291; amended by S.I. 2004/2694 and 2005/893 and 3315.

⁽¹⁰⁾ S.I. 1972/1265 (N.I. 14).

⁽¹¹⁾ 1978 c. 29.

⁽¹²⁾ Section 45A was inserted by the 2003 Act, Schedule 11, paragraph 23.

⁽¹³⁾ Subsection (B2) was inserted into section 44 by the 2002 Act, section 5(4), and subsection (B2)(b) was inserted by S.I. 2002/2861 and applies with the modifications set out in paragraph 6 of Schedule 1 to these Regulations.

⁽¹⁴⁾ Section 49N was inserted by the 2001 Act, section 25, and amended by the 2002 Act, Schedule 2, paragraph 25.

security in the National Health Service, which was replaced on 1st April 2006 by the NHS Business Services Authority;

“NHS Business Services Authority” means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005⁽¹⁵⁾;

“NHS Care Record” means the records relating to an individual patient held by the NHS Care Record Service;

“NHS Care Record Service” means information technology systems procured by the Department of Health and used by the health service to hold medical records relating to patients;

“NHS dispute resolution procedure” means the procedure for disputes specified in Schedule 2, paragraph 22;

“nominated dispensing contractor” means—

- (a) a contractor;
- (b) a person included in a pharmaceutical list;
- (c) a party to a general medical services contract other than a Primary Care Trust; or
- (d) a party to section 28C arrangements other than a Primary Care Trust or a Strategic Health Authority,

whom a patient has nominated in his NHS Care Record to dispense his electronic prescriptions;

“non-electronic repeatable prescription” has the same meaning as in the Pharmaceutical Services Regulations;

“non-proprietary name”, in relation to a drug, means—

- (a) where—
 - (i) the drug is described in a monograph in the current edition, as defined in section 103(5) of the Medicines Act 1968⁽¹⁶⁾ (construction of references to specified publications), as in force at the time of the supply of the drug, of the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the British National Formulary, the International Pharmacopoeia, the Cumulative List of Recommended International Non-proprietary Names or the Dental Practitioners' Formulary, any name, or abbreviation of the name, at the head of that monograph, or
 - (ii) if that name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that publication; or
- (b) where the drug is not so described in a monograph, but has an approved name, being the name which appears in the current edition, as defined in section 103(5) of the Medicines Act 1968, of the list of names prepared and published under section 100 of that Act (lists of names), as in force at the time of the supply of the drug, its approved name;

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001⁽¹⁷⁾;

“Patients' Forum” means a body established under section 15(1) of the National Health Service Reform and Health Care Professions Act 2002 (establishment of Patients' forums);

⁽¹⁵⁾ S.I. 2005/2414.

⁽¹⁶⁾ 1968 c. 67. Section 103(5) was amended by the Health and Medicines Act 1988 (c. 49), section 22(6), and modified by S.I. 1994/3144.

⁽¹⁷⁾ S.I. 2002/253; there are no relevant amending instruments.

“Pharmaceutical Services Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005⁽¹⁸⁾;

“pharmaceutical list” shall be construed in accordance with regulation 4 of the Pharmaceutical Services Regulations (pharmaceutical lists);

“pharmacist independent prescriber” means a person—

- (a) who is registered in the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954⁽¹⁹⁾ or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽²⁰⁾; and
- (b) against whose name in that register is recorded an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

“prescriber” means a doctor, a dentist, an independent nurse prescriber, a pharmacist independent prescriber or a supplementary prescriber;

“prescription form” means—

- (a) a form provided by a Health Board, a Health and Social Services Board, a Local Health Board, a Primary Care Trust, an NHS Trust or an NHS Foundation Trust, and issued by a prescriber; or
- (b) data that are created in an electronic form, signed with a prescriber’s advanced electronic signature and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service,

to enable a person to obtain pharmaceutical services or local pharmaceutical services, and does not include a repeatable prescription;

“Prescription of Drugs Regulations” means the National Health Service (General Medical Services)(Prescription of Drugs etc.) Regulations 2004⁽²¹⁾;

“primary care list” means—

- (a) a list of persons performing primary medical or dental services under section 28X of the Act⁽²²⁾ (persons performing primary medical and dental services);
- (b) a list of persons undertaking to provide general ophthalmic services or, as the case may be, pharmaceutical services prepared in accordance with regulations made under section 39, 42 or 43 of the Act⁽²³⁾ (which relate to regulations as to ophthalmic services, pharmaceutical services and persons authorised to provide pharmaceutical services);
- (c) a list of persons who undertook to provide general medical services or general dental services prepared in accordance with regulations made under section 29 or 35 of the Act⁽²⁴⁾ (which related to regulations as to general medical services and general dental services);

⁽¹⁸⁾ 2005/641; amended by S.I. 2005/1015, 1501 and 3315.

⁽¹⁹⁾ 1954 c. 61.

⁽²⁰⁾ S.I. 1976/1213 (N.I. 22).

⁽²¹⁾ S.I. 2004/629, as amended by S.I. 2004/3215.

⁽²²⁾ Section 28X was inserted into the Act by the 2003 Act, section 179(1).

⁽²³⁾ Section 39 has been amended by: the Health Services Act 1980 (c. 53) (“the 1980 Act”), sections 1 and 2 and Schedule 1, paragraph 51; the Health and Social Security Act 1984 (c. 48), sections 1 and 24 and Schedule 9; the 1999 Act, section 9; the 2001 Act, section 20; and the 2002 Act, Schedule 2, paragraph 12. Section 42 has been amended by: the National Health Service (Amendment) Act 1986 (c. 66), section 3; the Health Authorities Act 1995 (c. 17) (“the 1995 Act”), Schedule 1, paragraph 30; the 2001 Act, sections 20, 23, 43 and 67, and Schedule 6; and the 2002 Act, Schedule 2, paragraph 16. Section 43 has been amended by the 1980 Act, section 21; the 1990 Act, Schedule 9, paragraph 18; the 1995 Act, Schedule 1, paragraph 31; the 1997 Act, sections 29 and 41 and Schedule 2, paragraph 14; the 2001 Act, section 20; the 2002 Act, sections 2 and 42 and Schedule 2, paragraph 17; and the 2003 Act, Schedule 11, paragraph 19.

⁽²⁴⁾ Sections 29 and 36 were repealed by the 2003 Act, sections 175(2) and 196, and Schedule 14, Part 4.

- (d) a list of persons approved for the purposes of assisting in the provision of any services mentioned in paragraph (b) or (c) prepared in accordance with regulations made under section 43D of the Act⁽²⁵⁾ (supplementary lists);
- (e) a services list that fell within the meaning of section 8ZA of the National Health Service (Primary Care) Act 1977⁽²⁶⁾ (lists of persons who may perform personal medical services or personal dental services);
- (f) a list corresponding to a services list prepared by virtue of regulations made under section 41 of the Health and Social Care Act 2001⁽²⁷⁾ (corresponding provision and application of enactments); or
- (g) a list corresponding to any of the above lists in Scotland or Northern Ireland;

“professional conduct” includes matters relating both to professional conduct and professional performance;

“relevant scheme” shall be construed in accordance with regulation 4(3);

“relevant home Primary Care Trust” shall, as the context requires, be construed in accordance with regulation 17(5) or paragraph 17(2) of Schedule 2;

“Remission of Charges Regulations” means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003⁽²⁸⁾;

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

“repeatable prescriber” has the same meaning as in the Pharmaceutical Services Regulations;

“repeatable prescription” means a prescription which—

- (a) either—
 - (i) is contained in a form provided by a Primary Care Trust and issued by a repeatable prescriber which is in the format required by the NHS Business Services Authority, and which is generated by a computer and signed in ink by a repeatable prescriber, or
 - (ii) consists of data that are created in an electronic form, signed with a repeatable prescriber’s advanced electronic signature and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service;
- (b) is issued or created to enable a person to obtain pharmaceutical services or local pharmaceutical services; and
- (c) indicates that the drugs or appliances ordered on that prescription may be provided more than once, and specifies the number of occasions on which they may be provided;

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

“Scheduled drug” means a drug or other substance specified in—

- (a) Schedule 1 to the Prescription of Drugs Regulations; or
- (b) except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Contracts Regulations are satisfied, Schedule 2 to the Prescription of Drugs Regulations.

“superintendent” has the same meaning as it has in section 71 of the Medicines Act 1968 (bodies corporate);

⁽²⁵⁾ Section 43D was inserted into the Act by section 24 of the 2001 Act.

⁽²⁶⁾ 1997 c. 46. Section 8ZA was inserted by the 2001 Act, section 26(2), and repealed by the 2003 Act, section 196 and Schedule 14, Part 4.

⁽²⁷⁾ 2001 c. 15.

⁽²⁸⁾ S.I. 2003/2382, as amended by S.I. 2004/663 and 936.

“supplementary prescriber” means a person—

- (a) whose name is registered in—
 - (i) the Nursing and Midwifery Register,
 - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954,
 - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976,
 - (iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(29) relating to—
 - (aa) chiropodists and podiatrists,
 - (bb) physiotherapists, or
 - (cc) diagnostic or therapeutic radiographers, or
 - (v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(30); and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber;

“suspended” means—

- (a) suspended by a Primary Care Trust or equivalent body under —
 - (i) sections 49I (suspension) or 49J (suspension pending appeal) of the Act(31),
 - (ii) regulations made under section 28DA (lists of persons who may perform personal medical services or personal dental services)(32) or 43D of the Act (supplementary lists) of the Act, or
 - (iii) section 8ZA (lists of persons who may perform personal medical services or personal dental services) of the National Health Service (Primary Care) Act 1977; or
- (b) in relation to Scotland or Northern Ireland, suspended under provisions in force corresponding to those in or made under sections 28DA, 43D, 49I or 49J of the Act or under section 8ZA of the National Health Service (Primary Care) Act 1977,

and shall be treated as including a case where a person is treated as suspended by a Primary Care Trust or, prior to 1st October 2002, by a Health Authority by virtue of regulation 6(2) of the Abolition of the Tribunal Regulations, or, in Wales, by a Local Health Board, or prior to 1st April 2003, by a Health Authority by virtue of regulation 6(2) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002(33), and “suspends” and “suspension” shall be construed accordingly; and

“Tribunal” means the Tribunal constituted under section 46 of the Act(34) (the NHS tribunal) for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14th December 2001, and in relation to Wales only until 26th August 2002(35).

(29) S.I. 2002/254; there are no relevant amending instruments.

(30) 1989 (c. 44).

(31) Sections 49I and 49J were inserted by the 2001 Act, section 25, and were amended by the 2002 Act, Schedule 2, paragraphs 21 and 22.

(32) Section 28DA was inserted into the Act by the 2001 Act, section 26(1), and repealed by the 2003 Act, Schedule 14, Part 4, in relation to personal medical services.

(33) S.I. 2002/1920. These Regulations apply in relation to Wales only.

(34) Section 46 was substituted by the 1999 Act, section 40(1), and repealed by the 2001 Act, section 16.

(35) See S.I. 2001/3738, article 2(5) and (6)(b), which sets out the prescribed cases for England, and S.I. 2002/1919, article 2(2) and (3)(b), which sets out the prescribed cases for Wales.

(2) In these Regulations, “local pharmaceutical services” means services of a kind which may be provided under section 41 of the 1977 Act⁽³⁶⁾ (arrangements for pharmaceutical services), or by virtue of section 41A of that Act⁽³⁷⁾ (arrangements for providing additional pharmaceutical services), other than practitioner dispensing services.

Application of provisions of the Act and the Health Service Commissioners Act 1993 with modifications

3. Schedule 1 shall have effect (which applies with modifications provisions of the Act and the Health Service Commissioners Act 1993⁽³⁸⁾ and makes an amendment to the Act).

PART 2

DESIGNATION

Designation of priority neighbourhoods or premises

4.—(1) Subject to the following provisions of this regulation, a Primary Care Trust may designate neighbourhoods, premises or descriptions of premises for the purposes of paragraph 2 of Schedule 8A to the Act.

(2) Where a designation has been made or varied under this regulation, the Primary Care Trust may defer consideration of all other Part 2 applications⁽³⁹⁾ in respect of the designated neighbourhood, premises or descriptions of premises, until such time as the designation is cancelled.

(3) A designation must designate the neighbourhood in which, or the premises or description of the premises at which, local pharmaceutical services are to be provided under—

- (a) a proposal for an LPS scheme; or
- (b) LPS schemes that have been approved,

and the proposed scheme or the approved schemes (collectively) are referred to in this regulation as the “relevant scheme”.

(4) A designation must include details of the services to be provided under the relevant scheme, and must—

- (a) be made in writing and dated; and
- (b) include a map showing the location of the neighbourhood or premises that have been designated.

(5) A Primary Care Trust must give notice of a designation which it has made to—

- (a) any Local Pharmaceutical Committee formed for the area of that Primary Care Trust or of a neighbouring Primary Care Trust that is likely to be affected by the designation;
- (b) any Local Medical Committee formed for the area of that Primary Care Trust or of a neighbouring Primary Care Trust that is likely to be affected by the designation;
- (c) any person whose name is included in the pharmaceutical list of that Primary Care Trust or of a neighbouring Primary Care Trust that is likely to be affected by the designation;
- (d) any person who provides services under LPS arrangements or an LPS Scheme in the locality of the Primary Care Trust;

⁽³⁶⁾ Section 41 was substituted by the 2001 Act, section 42(1), and was amended by the 2002 Act, Schedule 2, paragraphs 13(1) to (3), the 2003 Act, Schedule 11, paragraph 18(1) and (2), and by *S.I. 2003/1590* and *2004/1771*.

⁽³⁷⁾ Section 41A was inserted by the 1997 Act, section 27, and amended by the 2001 Act, section 43(1).

⁽³⁸⁾ *1993 c. 46*.

⁽³⁹⁾ See paragraph 2(3) of Schedule 8A to the Act, which defines “Part 2 Applications” for the purposes of that Act.

- (e) any person whose name is included in the dispensing doctor list of that Primary Care Trust or of a neighbouring Primary Care Trust who, in the opinion of the Primary Care Trust, is likely to be affected by the designation; and
 - (f) any Patients' Forum serving the locality of the Primary Care Trust or of a neighbouring Primary Care Trust that is likely to be affected by the designation.
- (6) A Primary Care Trust may vary a designation under this paragraph if—
- (a) where the designation relates to a neighbourhood, the LP services to be provided under the relevant scheme are to be provided from part only of that neighbourhood;
 - (b) where the designation relates to premises, the LP services to be provided under the relevant scheme are to be provided from part only of those premises; or
 - (c) where the designation relates to a description of premises, the LP services to be provided under the relevant scheme are to be provided from certain parts only of the premises described.
- (7) A designation varied under paragraph (6) must designate the neighbourhood, premises or description of premises which are designated for the purposes of the designation and must satisfy the conditions specified in paragraph (4).
- (8) A Primary Care Trust must give notice of the variation to those persons listed in paragraph (5).
- (9) A Primary Care Trust must make available for inspection at its offices copies of all the designations which it has made, including any variations of such designations.

Reviews of designations

- 5.—(1) A Primary Care Trust must regularly review a designation which it has made or varied under regulation 4.
- (2) A Primary Care Trust must conduct a review of a designation under regulation 4 before the end of the period of six months beginning with the date of that designation (or as the case may be) the date of the last review of that designation.
- (3) When conducting a review of a designation, a Primary Care Trust must take into account representations received from any persons listed in regulation 4(5).
- (4) A Primary Care Trust must notify those persons listed in regulation 4(5) of the outcome of the review.

Cancellation of designations by a Primary Care Trust

- 6.—(1) A Primary Care Trust may at any time cancel a designation which it has made or varied under regulation 4.
- (2) A Primary Care Trust must cancel a designation which it has made or varied—
- (a) if required to do so by a direction given by the Secretary of State;
 - (b) if, within a period of twelve months beginning with the date of the original designation, an application for an LPS scheme that relates to the designation has not been submitted to the Primary Care Trust for approval;
 - (c) if the only (or only remaining) application for an LPS scheme that relates to the designation has been rejected; or
 - (d) if there is a significant change to the neighbourhood in which, or the premises from which, the LP services are to be provided, other than a change which leads to a variation by virtue of regulation 4(6).

(3) A Primary Care Trust must give notice of cancellation of a designation to those persons listed in regulation 4(5).

(4) Where a Primary Care Trust has cancelled a designation, it may not designate the same neighbourhood, premises or description of premises within a period of six months beginning with the date of cancellation of the designation, except where the reason for the cancellation of the designation was the rejection of an application for an LPS scheme.

PART 3

CONTRACTORS

General condition relating to all LPS schemes

- 7.—(1) A Primary Care Trust may only enter into an LPS scheme with—
- (a) an individual, if that individual does not fall within paragraph (2);
 - (b) two or more individuals (whether or not practising in partnership), if each of those individuals does not fall within paragraph (2); and
 - (c) in the case of a body corporate, if—
 - (i) the body corporate, or
 - (ii) any director, chief executive, superintendent or company secretary of the body corporate,
 does not fall within paragraph (2).
- (2) A person falls within this paragraph if—
- (a) he is the subject of national disqualification;
 - (b) subject to paragraph (3), he is disqualified or suspended (other than by an interim suspension order or direction pending an investigation) from practising by any licensing or regulatory body anywhere in the world;
 - (c) he has within a period of five years prior to the date the scheme is to be commenced or, if earlier, the date on which the scheme is to be signed, been removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) of the Act⁽⁴⁰⁾ (disqualification of practitioners) respectively), unless his name has subsequently been included in such a list;
 - (d) he has been convicted in the United Kingdom of—
 - (i) murder, or
 - (ii) a criminal offence other than murder, committed on or after 1st April 2006, and has been sentenced to a term of imprisonment of over six months;
 - (e) subject to paragraph (4), he has been convicted elsewhere of an offence—
 - (i) which would, if committed in England and Wales, constitute murder, or
 - (ii) committed on or after the 1st April 2006 which would, if committed in England and Wales, constitute a criminal offence other than murder, and has been sentenced to a term of imprisonment of over six months;

⁽⁴⁰⁾ Section 49F was inserted by section 25 of the 2001 Act and amended by the 2002 Act, Schedule 2, paragraph 21, and the 2003 Act, Schedule 14, Part 4.

- (f) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933(41) (offences against children and young persons with respect to which special provisions of the Act apply) or Schedule 1 to the Criminal Procedure (Scotland) Act 1995(42) (offences against children under the age of 17 years to which special provisions apply) committed on or after 1st April 2006;
- (g) he has been convicted of an offence under Part 2 of the Sexual Offences Act 2003(43) committed on or after 1st April 2006;
- (h) he has—
 - (i) been adjudged bankrupt, or sequestration of his estate has been awarded, unless (in either case) he has been discharged or the bankruptcy order has been annulled,
 - (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(44),
 - (iii) made a composition or arrangement with, or granted a trust deed for, his creditors unless he has been discharged in respect of it, or
 - (iv) in the case of a body corporate, been wound up under Part IV of the Insolvency Act 1986;
- (i) there is—
 - (i) an administrator, administrative receiver or receiver appointed in respect of him, or
 - (ii) an administration order made in respect of him under Schedule B1 to the Insolvency Act 1986(45);
- (j) he has within the period of five years prior to the date the scheme is to be commenced or, if earlier, the date on which the scheme is to be signed—
 - (i) been removed from the office of charity trustee or trustee for the charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which he was responsible or to which he was privy, or which he by his conduct contributed or facilitated, or
 - (ii) been removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(46) (powers of the Court of Session to deal with management of charities) from being concerned in the management or control of any body;
- (k) he has within the period of five years prior to the date the scheme is to be commenced or, if earlier, the date on which the scheme is to be signed, been subject to a disqualification order under the Company Directors Disqualification Act 1986(47) or the Companies (Northern Ireland) Order 1986(48), or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order); or
- (l) he (in the case of an individual) has refused to comply with a request by the Primary Care Trust for him to be medically examined on the grounds that it is concerned that he is incapable of adequately providing services under the scheme.

(41) 1933 c. 12; as amended by: the Domestic Violence, Crime and Victims Act 2004 (c. 28), section 58(1), Schedule 10, paragraph 2; the Sexual Offences Act 2003 (c. 42) section 139 and Schedule 6, paragraph 7; the Criminal Justice Act 1988 (c. 33), section 170 and Schedule 15, paragraph 8 and Schedule 16, paragraph 16; and the Sexual Offences Act 1956 (c. 69), sections 48 and 51 and Schedules 3 and 4 – and as modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

(42) 1995 c. 46.

(43) 2003 c. 42.

(44) 1986 c. 45. Schedule 4A was inserted by the Enterprise Act 2002 (c. 40), section 257 and Schedule 20.

(45) Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), section 248 and Schedule 16.

(46) 1990 c. 40.

(47) 1986 c. 46, as amended by the Insolvency Act 2000 (c. 39).

(48) S.I. 1986/1032 (N.I.6).

(3) A person shall not fall within paragraph (2)(b) where the Primary Care Trust is satisfied that the disqualification or suspension from practising imposed by a licensing or regulatory body outside the United Kingdom does not make the person unsuitable to be—

- (a) a party to an LPS scheme; or
- (b) in the case of an LPS scheme with a body corporate, a director, chief executive, superintendent or company secretary of a party to an LPS scheme.

(4) A person shall not fall within (2)(e) where the Primary Care Trust is satisfied that the conviction does not make the person unsuitable to be—

- (a) a party to an LPS scheme; or
- (b) in the case of an LPS scheme with a body corporate, a director, chief executive, superintendent or company secretary of a party to an LPS scheme.

Reasons

8. Where a Primary Care Trust is of the view that a person proposing to enter into an LPS scheme does not meet the conditions in regulation 7, it must notify that person in writing of its view, the reasons for that view and of his right of appeal under regulation 9.

Appeal

9. A person who has been served with a notice under regulation 8 may appeal to the FHSAA against the decision of the Primary Care Trust that the conditions in regulation 7 are not met by giving notice in writing to the FHSAA within the period of 28 days beginning on the day that the Primary Care Trust served its notice.

Health service body status

10.—(1) A contractor shall be treated as a health service body for the purposes of section 4 of the 1990 Act from the date it makes an LPS scheme unless, prior to making the scheme, it objected in a written notice served on the Primary Care Trust with which it subsequently made the scheme.

(2) Where a contractor is to be treated as a health service body for the purposes of section 4 of the 1990 Act pursuant to paragraph (1), any change in the parties comprising the contractor shall not affect the health service body status of the contractor.

(3) If, pursuant to paragraph (1) or (4), a contractor is to be treated as a health service body, that fact shall not affect the nature of, or any rights or liabilities arising under, any other scheme or contract with a health service body entered into by that contractor before the date on which the contractor is to be so regarded.

(4) A contractor may at any time request a variation of the LPS scheme to include or remove provision from the scheme that the scheme is an NHS contract, and if it does so—

- (a) the Primary Care Trust must agree to the variation; and
- (b) the procedure in paragraph 26 of Schedule 2 shall apply.

(5) Where, pursuant to paragraph (4), the Primary Care Trust agrees to a variation of the scheme, the contractor shall—

- (a) be treated; or
- (b) subject to paragraph (7), cease to be treated,

as a health service body for the purposes of section 4 of the 1990 Act from the date that variation takes effect.

(6) Subject to paragraph (7), a contractor that is to be treated as a health service body pursuant to paragraphs (1) or (4), as the case may be, shall cease to be treated as a health service body for the purposes of section 4 of the 1990 Act if the scheme is terminated.

- (7) Where a contractor ceases to be treated as a health service body pursuant to—
- (a) paragraph (5) or (6), it shall continue to be treated as a health service body for the purposes of being a party to any other NHS contract entered into after it was treated as a health service body but before the date on which the contractor ceased to be treated as a health service body (for which purposes it ceases to be such a body on the termination of that NHS contract);
 - (b) paragraph (5), it shall, if it or the Primary Care Trust has referred any matter to the NHS dispute resolution procedure before it ceases to be treated as a health service body, be bound by the determination of the adjudicator as if the dispute had been referred pursuant to paragraph 22 of Schedule 2; or
 - (c) paragraph (6), it must continue to be treated as a health service body for the purposes of the NHS dispute resolution procedure where that procedure has been commenced—
 - (i) before the termination of the scheme, or
 - (ii) after the termination of the scheme, whether in connection with, or arising out of, the termination of the scheme or otherwise,for which purposes it ceases to be such a body on the conclusion of that procedure.

Lists of LPS contractors

11. The Primary Care Trust shall publish lists of contractors who provide local pharmaceutical services in their area, together with information about—

- (a) services that each contractor provides; and
- (b) the days on which and times at which those services are provided.

PART 4

LPS SCHEMES

Proposals

12.—(1) A Primary Care Trust may make payments of financial assistance in respect of developing LPS schemes with a view to their being included in a proposal for an LPS scheme.

(2) Any person proposing to enter into an LPS scheme must supply with their proposal in writing information as to whether he, or in the case of a partnership the partners in the partnership, or where the person is a body corporate, the body corporate or any of its directors, its chief executive, its company secretary or its superintendent—

- (a) has any criminal convictions in the United Kingdom;
- (b) has accepted a police caution in the United Kingdom;
- (c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995⁽⁴⁹⁾ (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a

⁽⁴⁹⁾ 1995 c. 46.

penalty under section 115A of the Social Security Administration Act 1992⁽⁵⁰⁾ (penalty as alternative to prosecution);

- (e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (f) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (g) has been subject to any investigation into his professional conduct by any licensing or regulatory body, where the outcome was adverse;
- (h) is currently subject to any investigation into his professional conduct by any licensing or regulatory body;
- (i) is, or has been where the outcome was adverse, the subject of any investigation into his professional conduct in respect of any current or previous employment;
- (j) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any primary care list;
- (k) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service or the NHS Business Services Authority in relation to fraud;
- (l) either—
 - (i) has been removed or contingently removed from, refused admission to, or conditionally included in, any primary care list kept by another Primary Care Trust or equivalent body, or
 - (ii) is currently suspended from such a list,
- (m) is, or ever has been, subject to a national disqualification,

and if so, he must give details of any investigation or proceedings which are being or were undertaken or brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings commenced, and any outcome.

Health service contract

13. If the contractor is to be treated as a health service body, the LPS scheme must state that the scheme is an NHS contract.

LPS schemes: general

14.—(1) An LPS scheme must specify—

- (a) the dispensing and other services to be provided; and
- (b) the address of each of the premises to be used by the contractor for the provision of LP services.

(2) A scheme must, unless it is of a type and nature to which the particular term does not apply, contain the terms, or terms which make provision having the same effect as the terms, specified in Schedule 2.

⁽⁵⁰⁾ 1992 c. 5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c. 47).

Right of return to pharmaceutical lists

15.—(1) Before a Primary Care Trust enters into an LPS scheme, it must determine pursuant to this regulation whether the contractor is to be given a right of return, subject to the conditions specified in regulation 10(2) of the Pharmaceutical Services Regulations, if it makes an application for its name to be included in a Primary Care Trust’s pharmaceutical list after ceasing to provide LP services.

(2) Before an LPS scheme is varied so as to permit the provision of LP services from different, or additional premises, the Primary Care Trust must consider how the variation affects (if at all) a determination under this regulation, and may make a further determination varying or cancelling a determination under this regulation.

(3) The Primary Care Trust may at any time make a determination under this regulation varying a determination about a contractor if it is asked to do so by the contractor.

(4) Before making any determinations under this regulation, the Primary Care Trust must publish the principles by reference to which it will make such determinations, and it may amend those principles from time to time.

(5) The Primary Care Trust must notify—

- (a) contractors providing local pharmaceutical services in its locality;
- (b) any person included in its pharmaceutical list;
- (c) any Local Pharmaceutical Committee formed for its area;
- (d) any Local Medical Committee formed for its area;
- (e) any Primary Care Trust or Local Health Board any part of whose locality is within two kilometres of the premises of the relevant contractor; and
- (f) any Patient’s Forum serving the locality of the Primary Care Trust,

in writing of any determination under this regulation.

(6) Different determinations may be made under this regulation with respect to different contractors providing LP services under the same LPS scheme.

Sharing of information received

16.—(1) Where a relevant home Primary Care Trust receives information pursuant to a term of an LPS scheme set by virtue of paragraph 16 of Schedule 2, or pursuant to regulation 17, it must consider that information and decide whether this raises any question about—

- (a) the contractor’s suitability to be a contractor; or
- (b) the fitness to practise of a pharmacist employed or engaged by the contractor.

(2) If a home Primary Care Trust is of the opinion that the information does raise such a question, it must pass the information it has received to—

- (a) any other Primary Care Trust with which the contractor has entered into, or has applied to enter into, LPS arrangements or an LPS scheme;
- (b) any other Primary Care Trust on whose pharmaceutical list the contractor is included or has applied to be included; and
- (c) where appropriate, to the Royal Pharmaceutical Society of Great Britain.

(3) If any Primary Care Trust receives information (whether pursuant to a term of an LPS scheme or otherwise) that raises any question about the fitness to practise of a pharmacist employed or engaged by a contractor or potential contractor, it must pass that information, where appropriate, to the Royal Pharmaceutical Society of Great Britain.

PART 5

TRANSITIONAL AND CONSEQUENTIAL PROVISIONS

Duty to provide information about suitability etc.

17.—(1) Subject to paragraphs (3) and (4), a contractor who provides services under a pilot scheme must by 1st October 2006 supply to its Primary Care Trust information as to whether he (in the case of an individual who is a contractor), or in the case of a partnership, the partners, or where the contractor is a body corporate, any director, chief executive, superintendent or company secretary of it—

- (a) has any criminal convictions in the United Kingdom;
- (b) has accepted a police caution in the United Kingdom;
- (c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995 (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992 (penalty as alternative to prosecution);
- (e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (f) has been charged with an offence and is currently the subject of any proceedings which might lead to a conviction, which have not yet been notified to the Primary Care Trust;
- (g) has been subject to any investigation into his professional conduct by any licensing or regulatory body, where the outcome was adverse;
- (h) is currently subject to any investigation into his professional conduct by any licensing or regulatory body;
- (i) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service or the NHS Business Services Authority in relation to fraud;
- (j) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any primary care list;
- (k) is, or has been where the outcome was adverse, subject to an investigation into his professional conduct in respect of any current or previous employment;
- (l) either—
 - (i) has been removed or contingently removed from, refused admission to, or conditionally included in, any primary care list kept by another Primary Care Trust or equivalent body, or
 - (ii) is currently or has been suspended from such a list,
 - on fitness to practise grounds, and if so, why and the name of the Primary Care Trust or equivalent body; or
- (m) is, or ever has been, the subject of a national disqualification,

and if so, he must give details of any investigation or proceedings which are being or were undertaken or brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings commenced, and any outcome.

(2) A person to whom sub-paragraph (1) applies must consent to a request being made by the Primary Care Trust to any employer, former employer or licensing or regulatory body in the United

Kingdom or elsewhere, for information relating to a current investigation or an investigation where the outcome was adverse.

(3) Where a contractor is a body corporate with a registered office in England, the information to be provided under paragraph (1) may be provided instead to the relevant home Primary Care Trust, if the contractor also provides the relevant home Primary Care Trust with details of any other Primary Care Trust—

- (a) with which it has entered or applied to enter into LPS arrangements or an LPS scheme; or
- (b) which has included it or to which it has applied to be included in a pharmaceutical list.

(4) No information need be provided under paragraph (1) by a contractor that is a corporate body where that corporate body has already provided the information that it would otherwise provide under paragraph (1) to a relevant home Primary Care Trust—

- (a) as part of a Part 2 application; or
- (b) under Part 3 of Schedule 4 to the Pharmaceutical Services Regulations.

(5) For the purposes of this regulation, the “relevant home Primary Care Trust” means the Primary Care Trust in which the registered office in England of the contractor is located.

Transitional agreements for existing pilot schemes

18.—(1) Any pilot scheme agreement, except a pilot scheme that is an “ESP pilot scheme” for the purposes of the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005⁽⁵¹⁾ that—

- (a) has effect on 31st March 2006 shall continue to have effect on 1st April 2006 but as an LPS scheme; or
- (b) has been agreed prior to 1st April 2006 but is not to take effect until on or after 1st April 2006, but before 1st October 2006, shall take effect on the date it is due to take effect but as an LPS scheme.

(2) Any LPS scheme that has taken or takes effect by virtue of paragraph (1) is, for the purposes of these Regulations, also a “transitional agreement”.

(3) The parties to a transitional agreement shall, as soon as is reasonably practicable, enter into discussions with a view to agreeing variations to the agreement that ensure that it complies with the requirements of these Regulations.

(4) If the parties have not agreed those variations by 1st October 2006, the Primary Care Trust must vary the transitional agreement without the consent of the other party so as to ensure that the agreement complies with the requirements of these Regulations.

(5) Any variations under paragraph (4) shall not take effect until at least 14 days after the date on which they are notified to the other party.

(6) Pending the taking effect of variations made by virtue of this regulation, a transitional agreement shall apply as if the terms of the agreement were terms required by virtue of these Regulations.

(7) Once the variations made by virtue of this regulation have taken effect, the LPS scheme ceases to be a transitional agreement, but where the parties to the transitional agreement were in dispute (other than with regard to the terms of the variations to be made by virtue of this regulation), resolution of that dispute shall be in accordance with the provisions of the transitional agreement, notwithstanding that the scheme has ceased to be such an agreement.

⁽⁵¹⁾ Signed on 28th October 2005, as amended by the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) Directions 2005 and the Pharmaceutical Services (Miscellaneous Amendments) Directions 2006. All these directions are available on www.dh.gov.uk.

Transitional arrangements for existing designations

19. Any designation made under regulation 3 (or varied under regulation 4) of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002⁽⁵²⁾ (designation of priority neighbourhoods or premises), except one that relates to a pilot scheme that is an “ESP pilot scheme” for the purposes of the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005—

- (a) shall be treated for all purposes as a designation made or varied under regulation 4 (whether or not it has been made or varied in accordance with the requirements set out in that regulation); and
- (b) accordingly, regulation 4(6) to (9), 5 and 6 shall apply to that designation as those provisions apply to a designation made from 1st April 2006 under regulation 4.

Consequential amendments to secondary legislation

20. Schedule 3, which makes consequential amendments to secondary legislation, shall have effect.

Signed by authority of the Secretary of State for Health

2nd March 2006

Jane Kennedy
Minister of State,
Department of Health

⁽⁵²⁾ S.I. 2002/888; relevant amendments were made by S.I. 2002/2469 and 2005/641.