STATUTORY INSTRUMENTS

2006 No. 552

NATIONAL HEALTH SERVICE, ENGLAND

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

Made - - - - -	*2nd March 2006*
Laid before Parliament	*8th March 2006*
Coming into force - -	*1st April 2006*

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CONTENTS

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 42(2A) and 126(4) of, and paragraphs 1(3), 2(1), 3 and 4 of Schedule 8A to, the National Health Service Act 1977(**a**) and sections 30, 34, 37(b), 41 and 65(1) and (2) of, and paragraph 1(2)(b) of Schedule 2 to, the Health and Social Care Act 2001(**b**).

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(**c**).

Interpretation

2.—(1) In these Regulations—

(**a**) 1977 c.49. Section 42(2A) was inserted by section 40(3) of the Health and Social Care Act 2001 (c.15) ("the 2001 Act"). Section 126(4) was amended by: the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"), section 65(2); the Health Act 1999 (c.8) ("the 1999 Act"), Schedule 4, paragraphs 3 and 37(6); the 2001 Act, Schedule 5, paragraphs 5 (13)(b); the National Health Service Reform and Health Care Professions Act 2002 (c.17) ("the 2002 Act"), section 6(3)(c) and Schedule 8, paragraphs 1 and 10(a); and the Health and Social Care (Community Health and Standards) Act 2003 (c.43) ("the 2003 Act"), section 184 and Schedule 11, paragraphs 7 and 38 and Schedule 14, Part 4. Schedule 8A was inserted by section 40(1) and (2) of, and Schedule 3 to, the 2001 Act, and has been amended by: the 2002 Act, Schedule 2, paragraph 81, and Schedule 9, Part 1; and the 2003 Act, Schedule 4, paragraph 44, and Schedule 11, paragraph 41. *See* section 128(1) of the Act, as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of "prescribed" and "regulations" which are relevant to the powers being exercised.

(**b**) 2001 c.15.

(**c**) 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.

"the 1990 Act" means the National Health Service and Community Care Act 1990(**a**);

"the Abolition of the Tribunal Regulations" means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001(**b**);

"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);

"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(**c**);

"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(**d**);

"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(**e**);

"doctor" means a registered medical practitioner;

"drugs" includes medicines;

(**a**) 1990 c.19.
(**b**) S.I. 2001/3744.
(**c**) 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.
(**d**) 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.
(**e**) 1984 c.24.

"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(**a**) (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

(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(**b**) (the Family Health Services Appeal Authority);

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

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(**d**);

"Health Board" means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(**e**) (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(**f**) (Local Medical Committees);

(**a**) 2000 c.7.
(**b**) Section 49S was inserted by the 2001 Act, section 27(8)(b), and amended by the 2002 Act, Schedule 1, paragraph 18.
(**c**) S.I. 2004/291; amended by S.I. 2004/2694 and 2005/893 and 3315.
(**d**) S.I. 1972/1265 (N.I. 14).
(**e**) 1978 c.29.
(**f**) Section 45A was inserted by the 2003 Act, Schedule 11, paragraph 23.

"Local Pharmaceutical Committee" means a committee recognised under section 44(B2)(b) of the Act(**a**) (which relates to recognition of Local Pharmaceutical Committees);

"national disqualification" means—

(a) a decision made by the FHSAA under section 49N of the Act(**b**) (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 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(**c**);

"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(**d**) (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

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(**a**) 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.

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

(**c**) S.I. 2005/2414.

(**d**) 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.

(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(**a**);

"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);

"Pharmaceutical Services Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005(**b**);

"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(**c**) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**d**); 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(**e**);

"primary care list" means—

(a) a list of persons performing primary medical or dental services under section 28X of the Act(**f**) (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(**g**) (which relate to regulations as to ophthalmic services, pharmaceutical services and persons authorised to provide pharmaceutical services);

(**a**) S.I. 2002/253; there are no relevant amending instruments.
(**b**) 2005/641; amended by S.I. 2005/1015, 1501 and 3315.
(**c**) 1954 c.61.
(**d**) S.I. 1976/1213 (N.I. 22).
(**e**) S.I. 2004/629, as amended by S.I. 2004/3215.
(**f**) Section 28X was inserted into the Act by the 2003 Act, section 179(1).
(**g**) 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,

(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(**a**) (which related to regulations as to general medical services and general dental services);

(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(**b**) (supplementary lists);

(e) a services list that fell within the meaning of section 8ZA of the National Health Service (Primary Care) Act 1977(**c**) (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(**d**) (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(**e**);

"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.

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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.

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

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

(**c**) 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.

(**d**) 2001 c.15.

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

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

"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(**a**) 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(**b**); 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(**c**),

(ii) regulations made under section 28DA (lists of persons who may perform personal medical services or personal dental services)(**d**) 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(**e**), and "suspends" and "suspension" shall be construed accordingly; and

"Tribunal" means the Tribunal constituted under section 46 of the Act(**f**) (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(**g**).

(**a**) S.I. 2002/254; there are no relevant amending instruments.
(**b**) 1989 (c.44).
(**c**) 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.
(**d**) 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.
(**e**) S.I. 2002/1920. These Regulations apply in relation to Wales only.
(**f**) Section 46 was substituted by the 1999 Act, section 40(1), and repealed by the 2001 Act, section 16.
(**g**) *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(**a**) (arrangements for pharmaceutical services), or by virtue of section 41A of that Act(**b**) (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(**c**) 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(**d**) 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;

(**a**) 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.
(**b**) Section 41A was inserted by the 1997 Act, section 27, and amended by the 2001 Act, section 43(1).
(**c**) 1993 c.46.
(**d**) *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(**a**) (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;

(f) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933(**b**) (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(**c**) (offences against children under the age of 17 years to which special provisions apply) committed on or after 1st April 2006;

(**a**) 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.

(**b**) 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.

(**c**) 1995 c.46.

(g) he has been convicted of an offence under Part 2 of the Sexual Offences Act 2003(**a**) 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(**b**),

(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(**c**);

(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(**d**) (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(**e**) or the Companies (Northern Ireland) Order 1986(**f**), 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.

(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.

(**a**) 2003 c.42.
(**b**) 1986 c.45. Schedule 4A was inserted by the Enterprise Act 2002 (c.40), section 257 and Schedule 20.
(**c**) Schedule B1 was inserted by the Enterprise Act 2002 (c.40), section 248 and Schedule 16.
(**d**) 1990 c.40.
(**e**) 1986 c.46, as amended by the Insolvency Act 2000 (c.39).
(**f**) S.I. 1986/1032 (N.I.6).

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(**a**) (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(**b**) (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—

(**a**) 1995 c.46.
(**b**) 1992 c.5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c.47).

(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,

on fitness to practise grounds, and if so, why and the name of that Primary Care Trust or equivalent body; or

(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.

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(**a**) 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.

(**a**) 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.

(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.

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(**a**) (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

Jane Kennedy
Minister of State,
Department of Health

2nd March 2006

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

SCHEDULE 1

Regulation 3

Modification and amendment of the National Health Service Act 1977 and modification of the Health Service Commissioners Act 1993

Duty of Primary Care Trust in relation to local pharmaceutical services

1. In section 15 of the Act(**a**) (which relates to the duties of Primary Care Trusts and Local Health Boards in relation to family health services)—

(a) subsection (1) shall apply as if after "the provision of" there were inserted "local pharmaceutical services,"; and

(b) omit subsections (1ZC) and (1ZD).

Supply of goods and services by the Secretary of State

2. In section 26 of the Act(**b**) (supply of goods and services by the Secretary of State)—

(a) subsection (2) shall apply as if for paragraph (c) there were substituted the following paragraph—

"(c) providing services under LPS arrangements or an LPS scheme,"; and

(b) subsection (4) shall apply as if for paragraph (ab) there were substituted the following paragraph—

"(ab) persons performing services under LPS arrangements or an LPS scheme, and".

Use of accommodation

3. In section 28I of the Act(**c**) (use of accommodation), paragraph (b) shall apply as if "in accordance with LPS arrangements" were omitted.

Persons performing primary medical and dental services

4. Section 28X of the Act(**d**) (persons performing primary medical and dental services) shall apply as if—

(a) after subsection (1) there were inserted the following subsection—

"(1A) Regulations may provide that a health care professional of a prescribed description may not perform any local pharmaceutical services for which a Primary Care Trust is responsible unless he is included in a list maintained by the Primary Care Trust."; and

(b) in subsection (3), after paragraph (b) there were inserted the following paragraph—

"(c) a Primary Care Trust is responsible for a local pharmaceutical service if it secures its provision, by or under any enactment.".

(**a**) Section 15 was amended by: the Health and Social Security Act 1984 (c.48), sections 5(2) and 24; the 1990 Act, section 12(1)(b); the 1995 Act, Schedule 1, paragraph 6; the 1997 Act, section 41(10) and Schedule 2, paragraphs 3 and 4; the 1999 Act, section 65 and Schedule 4, paragraphs 4 and 8; the 2002 Act, Schedule 2, paragraph 2 and Schedule 3, paragraph 11; and by S.I. 2002/2861.

(**b**) Relevant amendments to section 26 were made by: the 1980 Act, section 3(1); the 1995 Act, section 2 and Schedule 1, paragraph 14; the 1997 Act, section 41(10) and Schedule 2, paragraphs 3 and 5; the 1999 Act, section 65 and Schedule 4, paragraphs 4 and 11; the 2002 Act, Schedule 1, paragraph 12; S.I. 2002/2861; and the 2003 Act sections 184 and 196, and Schedule 11, paragraphs 7,13(1),(2)(a) and Schedule 14, Part 4.

(**c**) Section 28I was inserted by the 1997 Act, section 41(10), Schedule 2, paragraphs 3 and 7 and amended by: S.I. 2002/2861; and the 2003 Act, section 184, Schedule 11, paragraphs 7 and 17.

(**d**) Section 28X was inserted by the 2003 Act, section 179.

Assistance and Support

5. In Section 28Y of the Act(**a**) (assistance and support), subsection (1) shall apply as if, after paragraph (b), there were inserted the following paragraph—

"(c) any person providing local pharmaceutical services under LPS arrangements or an LPS scheme.".

Recognition of Local Pharmaceutical Committees

6. Section 44 of the Act(**b**) (which relates to the recognition of local representative committees) shall apply as if—

(a) in subsection (B2)(b), the "or" were omitted at the end of sub-paragraph (i) and after sub-paragraph (ii) there were inserted the following sub-paragraphs—

"(iii) the persons mentioned in sub-paragraph (i) above and the persons providing local pharmaceutical services under LPS arrangements in the Primary Care Trust's area, or

(iv) the persons mentioned in sub-paragraph (i) above and the persons providing local pharmaceutical services under LPS schemes in the Primary Care Trust's area,";

(b) after subsection (3), there were inserted the following subsection—

"(3A) Additionally, for the purposes of this section and section 45 below, a person who meets the condition in subsection (4) below is a person providing local pharmaceutical services in a Primary Care Trust's area if he provides those services under an LPS scheme." ; and

(c) in subsection (4), after "subsection (3)" there were inserted "and subsection (3A)".

Functions of Local Pharmaceutical Committees

7. In section 45 of the Act(**c**) (which relates to the functions of local representative committees)—

(a) subsection (1ZA) shall apply as if—

(i) "or" were added at the end of paragraph (aa) and omitted at the end of paragraph (a),

(ii) in paragraph (aa), for "section 44(B2)(b)(ii)" there were substituted "section 44(B2)(b)", and

(iii) after paragraph (aa) there were inserted the following paragraph—

"(ab) Primary Care Trusts, in the exercise of any of their functions which relate to LPS schemes, to consult committees recognised by them under section 44(B2)(b) above,"; and

(b) subsection (1C) shall apply as if, for "(B2)(b)(ii)" there were substituted "(B2)(b)(ii), (iii) or (iv)".

Special arrangement as to payment of remuneration

8. Section 103 of the Act(**d**) (special arrangement as to payment of remuneration), shall apply as if, in subsection (1)(a), after "or LPS" there were inserted "schemes or".

(**a**) Section 28Y was inserted by the 2003 Act, section 180.

(**b**) In section 44: subsection (B2) was inserted by the 2002 Act, section 5(4); subsection (B2)(b) was inserted by S.I. 2002/2861; and subsection (3) was inserted by the 1999 Act, section 11(1) and (4), and amended by the 2001 Act, Schedule 5, paragraph 5(7), the 2002 Act, section 5(6) and S.I. 2002/2861.

(**c**) In section 45: subsection (1ZA) was inserted by the 2002 Act, section 5(9); subsection (1ZA)(aa) and (e) were amended by SI 2002/ 2861; subsection (1C) was inserted by the 1999 Act, section 11(6), and amended by the 2002 Act, section 5(11); and subsection (4) was inserted by the 1999 Act, section 11(8).

(**d**) Section 103(1) was amended by the 1997 Act, section 41(10) and Schedule 2, paragraphs 3 and 25, and by S.I. 2002/2861.

Insertion of definitions of "local pharmaceutical services" and "LPS arrangements"

9. Subsection (1) of section 128 of the Act(**a**) (interpretation and construction) shall apply as if—

(a) in the definition of "local pharmaceutical services", after "Care Act 2001" there were inserted "or under paragraph 1(3) of Schedule 8A"; and

(b) after the definition of "LPS arrangements" there were inserted the following definition—

""LPS scheme" has the meaning given in paragraph 1(2) of Schedule 8A;".

Charges for the supply of drugs to treat venereal disease

10. In Schedule 12 to the Act(**b**) (additional provisions as to regulations for the making and recovery of charges), paragraph 1(1)(b) shall apply as if after "with LPS" there were inserted "schemes or".

Health Service Commissioner for England

11. In the Health Service Commissioners Act 1993(**c**), section 2A(**d**) (health services providers subject to investigation) shall apply as if in subsection (1)(d), after the words "Care Act 2001" there were inserted "or an LPS scheme made in accordance with the provisions of, and regulations under, Schedule 8A to the National Health Service Act 1977".

SCHEDULE 2

Regulation14(2)

Contract Terms

General provisions

1.—(1) The contractor must comply with all relevant legislation, including—

(a) the provisions of these Regulations; and

(b) regulation 3 of the Patients' Forums (Functions) Regulations 2003(**e**) in so far as it relates to the entry and inspection of premises from where local pharmaceutical services are provided.

(2) The contractor must comply with the relevant provisions of the Drug Tariff.

(3) The contractor must have regard to all relevant guidance issued by—

(a) the Primary Care Trust;

(b) the relevant Strategic Health Authority; or

(c) the Secretary of State.

(4) To the extent that the provisions of the terms required by this Schedule impose a requirement on a contractor in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) if the contractor is a registered pharmacist—

(i) that registered pharmacist must comply with the requirement, or

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(**a**) Relevant amendments were made to section 128 by S.I. 2002/2861.
(**b**) In Schedule 12, paragraph 1(1)(b) was amended by the 1997 Act, section 41(10) and Schedule 2, paragraphs 3 and 31.
(**c**) 1993 c.46.
(**d**) Section 2A was inserted by the Health Service Commissioners (Amendment) Act 1996 (c.5), section 1; and amended by the 1997 Act, section 41(10) and Schedule 2, paragraph 68, the Health Service Commissioners (Amendment) Act 2000 (c.28), section 1 and S.I. 2002/2861.
(**e**) S.I. 2003/124; regulation 3 has been amended by S.I. 2004/540, 696 and 865.

(ii) if he employs or engages a registered pharmacist in connection with the provision of local pharmaceutical services under his LPS scheme, the contractor must either comply with that requirement or secure compliance with that requirement by the registered pharmacist he employs or engages; and

(b) if the contractor is not a natural person, that contractor must secure compliance with that requirement by the registered pharmacists it employs or engages,

and references in this Schedule to a contractor shall be construed accordingly.

Restrictions in an LPS scheme on supply

2.—(1) Where an LPS scheme is limited to the provision of specified drugs or appliances, the contractor must not provide other drugs or appliances at the premises from which he has undertaken to provide LPS services under that scheme.

(2) An LPS scheme must contain the following terms, where applicable—

(a) where the local pharmaceutical services to be provided include the supply of appliances—

(i) the only appliances which may be supplied are listed appliances, and

(ii) those appliances must be supplied in accordance with the provisions of the Notes, and the List of Technical Specifications, which appear at the beginning of Part IX of the Drug Tariff, which apply at the time of supply; and

(b) where the local pharmaceutical services to be provided include the supply of chemical reagents, the only chemical reagents which may be supplied are those listed from time to time in Part IXR of the Drug Tariff.

(3) Where an LPS scheme is limited to the provision of services—

(a) to a specified class of persons (for example persons who require the provision of local pharmaceutical services for the treatment of a specified disease or condition); or

(b) to persons residing in a particular place (for example persons in a specified residential home),

the contractor must not provide local pharmaceutical services to persons other than those so specified.

Dispensing

3.—(1) Subject to any provisions of an LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule, where—

(a) any person presents a non-electronic prescription form which contains—

(i) an order for a drug, not being a Scheduled drug, or for an appliance, not being a restricted availability appliance, signed by a prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, signed by a prescriber and including the reference "SLS", or

(iii) an order for restricted availability appliance, signed by a prescriber and including the reference "SLS"; or

(b) the contractor receives from the ETP service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii), and—

(i) any person requests the provision of a drug in accordance with that prescription, or

(ii) the contractor has previously arranged with the patient that it will dispense that prescription on receipt,

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

(2) Where an LPS scheme includes the provision of repeat dispensing services, subject to any provisions of the LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule—

(a) any person presents a non-electronic repeatable prescription which contains—

(i) an order for a drug, not being a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971(**a**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**b**), signed by a repeatable prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a repeatable prescriber and including the reference "SLS",

(iii) an order for an appliance, not being a restricted availability appliance, signed by a repeatable prescriber, or

(iv) an order for a restricted availability appliance, signed by a repeatable prescriber, and including the reference "SLS",

and also presents an associated batch issue; or

(b) the contractor receives from the ETP service an electronic repeatable prescription which contains an order of a kind specified in sub-paragraph (a)(i) to (iv) and—

(i) any person requests the provision of a drug or an appliance in accordance with that repeatable prescription, or

(ii) the contractor has previously arranged with the patient that it will dispense that repeatable prescription on receipt,

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

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

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

(a) the contractor has that prescription in his possession; and

(b) that person presents, or the contractor has in its possession, an associated batch issue.

(5) Where a contractor has made arrangements, as part of an LPS scheme, with a Primary Care Trust for the provision of an Independent Prescribing Service, and a pharmacist independent prescriber is authorised or required both to prescribe and to dispense a drug or appliance to a person under those arrangements, the pharmacist independent prescriber shall—

(a) do so in accordance with paragraphs 5 and 7 (as applicable);

(b) in connection with doing so, act in accordance with paragraphs 8 and 9;

(c) record the order on a prescription form;

(d) provide the drug or appliance in a suitable container;

(e) only provide a drug specified in Schedule 2 to the Prescription of Drugs Regulations where the conditions specified in paragraph 42(2) of Schedule 6 to the GMS Contracts Regulations are satisfied; and

(f) only provide a restricted availability appliance if the patient is a person, or it is for a purpose, specified in the Drug Tariff,

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(**a**) 1971 c.38; *see* section 2(1) of that Act, which defines "controlled drug" for the purposes of that Act.
(**b**) S.I. 2001/ 3998. Schedule 4 has been amended by S.I. 2003/1432.

but a contractor must not provide drugs or appliances ordered by a pharmacist independent prescriber under his LPS scheme unless it has made such arrangements.

(6) The contractor must only provide drugs and appliances ordered on a prescription form or a repeatable prescription, or by it or on its behalf by a pharmacist independent prescriber, in circumstances where the supervising pharmacist (whether or not he is the contractor) is not someone—

(a) who is suspended from a primary care list;

(b) who is subject to a national disqualification; or

(c) who—

(i) has been disqualified under section 46(**a**)(2)(b) of the Act (or under any corresponding provision in Scotland or Northern Ireland) from inclusion in the pharmaceutical list of a Primary Care Trust (or Local Health Board, Health Board or Health and Social Services Board), and

(ii) is the subject of a declaration under section 46(2)(c) of the Act (or any corresponding provision in Scotland or Northern Ireland) that he is not fit to be engaged in any capacity in the provision of pharmaceutical services.

Urgent supply without a prescription

4. Where, in case of urgency, a prescriber personally known to a contractor requests it to provide a drug, a contractor may provide that drug (where it would otherwise be able to provide that drug in accordance with the LPS scheme) before receiving a prescription form or repeatable prescription, provided that—

(a) the drug is not a Scheduled drug;

(b) the drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001; and

(c) the prescriber undertakes to—

(i) give the contractor a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug within 72 hours, or

(ii) transmit to the ETP service within 72 hours an electronic prescription.

Preliminary matters before providing ordered drugs or appliances

5.—(1) If a person specified in paragraph (2) asks the contractor to do so—

(a) the contractor shall give an estimate of the time when the drugs or appliances will be ready; and

(b) if they are not ready by then, the contractor shall give a revised estimate of the time when they will be ready (and so on).

(2) A person referred to in paragraph (1) is a person—

(a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or

(b) requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, a contractor must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations by virtue of either—

(a) entitlement to exemption under regulation 7(1) of the Charges Regulations; or

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(**a**) Section 46 was repealed by the 2001 Act, Schedule 5, paragraph 5, and Schedule 6, Part 1.

(b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,

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

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

(5) In the case of an electronic prescription, the contractor must transmit to the ETP service—

(a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—

(i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and

(ii) whether or not satisfactory evidence was produced to it as required by sub-paragraph (3);

(b) in any case where a charge is due, confirmation that the relevant charge was paid; and

(c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Providing ordered drugs or appliances

6.—(1) Where a contractor is presented with, or receives from the ETP service, a prescription form or a repeatable prescription, the contractor must only provide the drugs or appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 3(1) or (2); and

(b) in accordance with the order on the prescription form or repeatable prescription,

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

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

(a) measuring the person named on the prescription form or repeatable prescription for the appliance; and

(b) fitting the appliance.

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

(4) If the order—

(a) is an order for a drug; but

(b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001,

and does not prescribe its quantity, strength or dosage, a contractor may provide the drug in such strength and dosage as in the exercise of its professional skill, knowledge and care it considers to

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(**a**) 1985 c.72.

be appropriate and, subject to sub-paragraph (5), in such quantity as it considers to be appropriate for a course of treatment for a period not exceeding 5 days.

(5) Where an order to which sub-paragraph (4) applies is for—

(a) an oral contraceptive substance;

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

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

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

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

(a) sterile;

(b) effervescent or hygroscopic;

(c) a liquid preparation for addition to bath water;

(d) a coal tar preparation;

(e) a viscous preparation; or

(f) packed at the time of its manufacture in a calendar pack or special container,

the contractor must, subject to sub-paragraph (7), provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(7) A contractor must not provide, pursuant to sub-paragraph (6), a drug in a calendar pack where, in its opinion, it was the intention of the prescriber who ordered the drug that it should be provided only in the exact quantity ordered.

(8) In this paragraph—

(a) "calendar pack" means a blister or strip pack showing the days of the week or month against each of the several units in the pack; and

(b) "special container" means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(9) Except as provided in sub-paragraph (10), a contractor must not provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription.

(10) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, a contractor may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is in a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(11) Where a drug which is ordered as specified in sub-paragraph (10) combines more than one drug, that sub-paragraph must apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(12) A contractor must provide any drug which it is required to provide under paragraph 3 in a suitable container.

Refusal to provide drugs or appliances ordered

7.—(1) A contractor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

(a) the contractor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because he reasonably believes it has been stolen or forged);

(b) it appears to the contractor that—

(i) there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber), or

(ii) in the circumstances, providing the drugs or appliances would be contrary to the contractor's clinical judgement;

(c) the contractor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person; or

(d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

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

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

(a) it has no record of that prescription;

(b) it does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to him;

(c) it is not signed by a repeatable prescriber;

(d) to do so would not be in accordance with any intervals specified in the prescription;

(e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than six months previously;

(f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) it has been informed by the repeatable prescriber that the prescription is no longer required.

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

(a) that the patient to whom the prescription relates—

(i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;

(b) that the medication regimen of the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

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

8. In connection with the services provided under paragraphs 3 to 7, a contractor must—

(a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—

(i) to enable them to utilise the drugs or appliances appropriately, and

(ii) to meet the patient's reasonable needs for general information about the drugs or appliances;

(b) provide appropriate advice to patients to whom they provide drugs or appliances on—

(i) the safe keeping of the drugs or appliances, and

(ii) returning unwanted drugs or appliances to the pharmacy for safe destruction;

(c) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;

(d) keep and maintain records—

(i) of drugs and appliances provided, in order to facilitate the continued care of the patient;

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and

(iii) of notes provided under sub-paragraph (c);

(e) if it provides a drug or appliance under an electronic prescription, provide the patient, if he so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed; and

(f) ensure that where a person is refused drugs or appliances pursuant to paragraphs 7(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice.

Additional requirements in relation to electronic prescribing

9.—(1) A contractor must, if requested to do so by any person—

(a) explain to him the ETP service, whether or not it is a service which is available through its pharmacy; and

(b) where the ETP service is not available through its pharmacy, provide him with contact details of at least two pharmacies in his area through which the service is available, if these details are known to the contractor.

(2) Where the ETP service is available through its pharmacy, the contractor must, if requested to do so by any person, enter in that person's NHS Care Record—

(a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; and

(b) where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person.

(3) Paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the ETP service.

Further activities in connection with the provision of dispensing services under a repeatable prescription and batch issues

10. In connection with the services provided under paragraphs 3 to 7, a contractor must—

(a) provide appropriate advice to patients to whom it provides drugs or appliances in accordance with a repeatable prescription, in particular on the importance of only requesting those items which they actually need;

(b) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;

(c) if it takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;

(d) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);

(e) destroy any surplus batch issues relating to drugs or appliances—

(i) which are not required, or

(ii) where a patient is refused the drugs or appliances pursuant to paragraph 7;

(f) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification; and

(g) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 7(2).

Information to be provided for the Primary Care Trust's lists

11. A contractor must ensure that it provides to its Primary Care Trust, an up to date record of—

(a) the services that it provides; and

(b) the days on which and times at which those services are provided.

Clinical governance

12. A contractor must participate, in the manner reasonably required by the Primary Care Trust, in an acceptable system of clinical governance.

13. In these Regulations "system of clinical governance" means a framework through which the contractor endeavours to improve continuously the quality of its services and safeguards high standards of care by creating an environment in which clinical excellence can flourish.

Professional Standards

14. A contractor must provide local pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc.

15.—(1) A contractor or its staff must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his—

(a) presenting an order for drugs or appliances on a non-electronic prescription form or non-electronic repeatable prescription; or

(b) nominating the contractor as its dispensing contractor (or one of them) in his NHS Care Record.

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

Duty to provide information about fitness to practise matters as they arise

16.—(1) Subject to paragraph 17, the contractor must within 7 days of its occurrence supply in writing information to the Primary Care Trust as to whether he (in the case of an individual who is a contractor), or in the case of a partnership, any partner in the partnership, or where the contractor is a body corporate, any of its directors, its chief executive, its company secretary or its superintendent pharmacist—

(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(**a**) (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(**b**) (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 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) has been suspended from such a list,

on fitness to practise grounds, and if so, why and the name of that Primary Care Trust or equivalent body; or

(m) is 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 or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

(**a**) 1995 c.46.
(**b**) 1992 c.5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c.47).

Home Primary Care Trust of bodies corporate

17.—(1) Where a contractor is a body corporate with a registered office in England, the information to be provided under paragraph 16 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 the other Primary Care Trusts—

(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.

(2) For these purposes, the "relevant home Primary Care Trust" means the Primary Care Trust in which the registered office of the contractor is located.

Charges for drugs and refunds

18.—(1) Subject to regulations made under section 77 of the Act(**a**) (charges for drugs, medicines or appliances, or pharmaceutical services), all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where a contractor supplies a container in response to an order for drugs signed by a prescriber, other than equipment specified in the Drug Tariff as not returnable to the contractor, the container and equipment must remain the property of the contractor.

(3) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents a contractor with a valid claim for the repayment within three months of the date on which the charge was paid, the contractor must make the repayment.

(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if duly made on form FP57 0405 or form FP57 0403(**b**), available from the Primary Care Trust.

Remuneration, overpayments etc.

19.—(1) The Primary Care Trust must ensure that the LPS scheme requires it to remunerate the contractor promptly, in accordance with remuneration arrangements provided for in the scheme, but subject to the arrangements for reductions of and deductions from payments provided for in the scheme.

(2) Where an LPS scheme requires a fee, allowance or other item of remuneration to be made in accordance with the Drug Tariff and the Drug Tariff provides that the fee, allowance or other item of remuneration is to be determined by a Primary Care Trust, that fee, allowance or other item of remuneration must be determined by the Primary Care Trust.

(3) The Primary Care Trust must ensure that the LPS scheme—

(a) allows it to recover any payment made to the contractor which should not have been made;

(b) provides that any such recovery of an overpayment is without prejudice to any investigation of any alleged breach of the scheme; and

(c) provides that the remuneration arrangements under the scheme, referred to in sub-paragraphs (1) and (2), are subject to any right the Primary Care Trust may have to set off against any amount payable to the contractor, any amount—

(i) owed by the contractor to it, or

(ii) which it is entitled to withhold under the terms of the scheme (including terms of the Drug Tariff applied by the scheme).

(**a**) Section 77 has been amended by the 2003 Act, Schedule 11, paragraph 28.

(**b**) These forms were originally issued by the Prescription Pricing Authority, which is now part of the NHS Business Services Authority.

Local resolution of disputes

20. In the case of any dispute arising out of, or in connection with, the scheme, the contractor and the Primary Care Trust must make every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

Dispute resolution: non-NHS contracts

21.—(1) In the case of a scheme which is not an NHS contract, any dispute arising out of or in connection with the scheme, except matters dealt with under the complaints procedure pursuant to this Schedule, may be referred for consideration and determination to the Secretary of State, if—

(a) the Primary Care Trust so wishes and the contractor has agreed in writing; or

(b) the contractor so wishes (even if the Primary Care Trust does not agree).

(2) In the case of a dispute referred to the Secretary of State under sub-paragraph (1)—

(a) the procedure to be followed is the NHS dispute resolution procedure; and

(b) the parties must agree to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

22.—(1) The procedure specified in the following sub-paragraphs and paragraph 23 applies in the case of any dispute arising out of or in connection with the scheme which is referred to the Secretary of State—

(a) in accordance with section 4(3) of the 1990 Act (where the scheme is an NHS contract); or

(b) in accordance with paragraph 21(1) (where the scheme is not an NHS contract).

(2) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send to the Secretary of State a written request for dispute resolution which must include or be accompanied by—

(a) the names and addresses of the parties to the dispute;

(b) a copy of the scheme; and

(c) a brief statement describing the nature and circumstances of the dispute.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (2) within a period of three years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(4) Where the dispute relates to a scheme which is not an NHS contract, the Secretary of State may determine the matter herself or, if she considers it appropriate, appoint a person or persons to consider and determine it(**a**).

(5) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (4) or under section 4(5) of the 1990 Act, the Secretary of State must, within the period of seven days beginning with the date on which a matter was referred to her, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.

(6) The Secretary of State must give, with the notice given under sub-paragraph (5), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.

(7) The Secretary of State must give a copy of any representations received from a party to the other party and must in each case request (in writing) a party to whom a copy of the

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(**a**) Where the dispute relates to a contract which is an NHS contract, section 4(5) of the 1990 Act applies.

representations is given to make within a specified period any written observations which it wishes to make on those representations.

(8) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (5) or (7), the Secretary of State must, if she decides to appoint a person or persons to hear the dispute—

(a) inform the parties in writing of the name of the person or persons whom she has appointed; and

(b) pass to the person or persons so appointed any documents received from the parties pursuant to sub-paragraph (2), (5) or (7).

(9) For the purpose of assisting him in his consideration of the matter, the adjudicator may—

(a) invite representatives of the parties to appear before him to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which he wishes them to give special consideration; or

(b) consult other persons whose expertise he considers will assist him in his consideration of the matter.

(10) Where the adjudicator consults another person under sub-paragraph (9)(b), he must notify the parties accordingly in writing and, where he considers that the interests of any party might be substantially affected by the result of the consultation, he must give to the parties such opportunity as he considers reasonable in the circumstances to make observations on those results.

(11) In considering the matter, the adjudicator must consider—

(a) any written representations made in response to a request under sub-paragraph (5), but only if they are made within the specified period;

(b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within the specified period;

(c) any oral representations made in response to an invitation under sub-paragraph (9)(a);

(d) the results of any consultation under sub-paragraph (9)(b); and

(e) any observations made in accordance with an opportunity given under sub-paragraph (10).

(12) In this paragraph, "specified period" means such period as the Secretary of State must specify in the request, being not less than two, nor more than four weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if she considers that there is good reason for doing so, extend any such period (even after it has expired) and, where she does so, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to the other provisions of this paragraph and paragraph 23, the adjudicator must have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

Determination of dispute

23.—(1) The adjudicator must record his determination, and the reasons for it, in writing and must give notice of the determination (including a record of the reasons) to the parties.

(2) In the case of a scheme referred for determination in accordance with paragraph 21(1), subsection (8) of section 4 of the 1990 Act must apply as that subsection applies in the case of a scheme referred for determination in accordance with subsection (3) of section 4 of that Act.

Disputes: supplemental

24.—(1) In this Schedule, "any dispute arising out of, or in connection with, the scheme" includes any dispute arising out of, or in connection with, the termination of the scheme.

(2) Any term of the scheme that makes provision in respect of the requirements in paragraphs 20 to 23 must survive even where the scheme has terminated.

Complaints

25. A contractor must have in place arrangements for the handling and consideration of complaints about any matter connected with its provision of local pharmaceutical services which are essentially the same as those set out in Part II of the National Health Service (Complaints) Regulations 2004(**a**).

Variation of schemes

26.—(1) Subject to sub-paragraph (2), no amendment or variation to the LPS scheme shall have effect unless it is in writing and signed by or on behalf of the Primary Care Trust and the contractor.

(2) The Primary Care Trust may vary the scheme without the contractor's consent where it—

(a) is reasonably satisfied that it is necessary to vary the scheme so as to comply with the Act, any regulations made under that Act, or any direction given by the Secretary of State under that Act; and

(b) notifies the contractor in writing of the wording of the proposed variation and the date upon which that variation is to take effect,

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect must be not less than 14 days after the date on which the notice under paragraph (b) is served on the contractor.

Termination by agreement

27. The Primary Care Trust and the contractor may agree in writing to terminate the scheme, and if the parties so agree, they must agree the date upon which that termination should take effect and any further terms upon which the scheme should be terminated.

Termination by notice

28.—(1) Either the contractor or the Primary Care Trust may terminate the scheme by serving notice of not less than six months in writing to the other party.

(2) Where a notice is served pursuant to sub-paragraph (1), the scheme must terminate on the expiry of the notice period.

Termination by the Primary Care Trust on grounds of suitability etc.

29.—(1) The Primary Care Trust may serve notice in writing on the contractor terminating the scheme with immediate effect, or from such date as may be specified in the notice, if, in the case of a scheme entered into—

(a) with an individual as a party, that individual;

(b) with more than one individual (whether or not practising in partnership), any of those individuals; or

(c) with a body corporate—

(i) the body corporate, or

(ii) any director, chief executive, superintendent or company secretary of the body corporate,

falls within sub-paragraph (2) during the existence of the scheme.

(2) A person falls within this sub-paragraph if—

(a) he is the subject of a national disqualification;

(**a**) S.I. 2004/1768.

(b) subject to sub-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 is 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(**a**) (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 sub-paragraph (4), he has been convicted outside the United Kingdom of an offence—

(i) which would, if committed in England and Wales, constitute murder, or

(ii) committed on or after 1st April 2006, which would if committed in England and Wales, constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;

(f) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933(**b**) (offences against children and young persons with respect to which special provisions of this Act apply) or Schedule 1 to the Criminal Procedure (Scotland) Act 1995(**c**) (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(**d**) 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(**e**), unless that order has ceased to have effect or has been annulled,

(iii) made a composition or arrangement with, or granted a trust deed for, his or its creditors unless he or it has been discharged in respect of it, or

(iv) 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(**f**);

(j) he has been—

(i) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct

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(**a**) 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.

(**b**) 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.

(**c**) 1995 c.46.

(**d**) 2003 c.42.

(**e**) 1986 c.45; Schedule 4A was inserted by the Enterprise Act 2002 (c.40), section 257 and Schedule 3 .

(**f**) Schedule B1 was inserted by the Enterprise Act 2002, section 248 of and Schedule 16.

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 to or facilitated, or

(ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(**a**) (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 is subject to a disqualification order under the Company Directors Disqualification Act 1986(**b**), the Companies (Northern Ireland) Order 1986(**c**) or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order);

(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; or

(m) it comes to the attention of the Primary Care Trust that information provided to it pursuant to regulation 12 or 17, or in accordance with a term of the scheme required by paragraph 16, was, when given, untrue or inaccurate in a material respect.

(3) A Primary Care Trust shall not terminate the scheme pursuant to sub-paragraph (2)(b) where it is satisfied that the disqualification or suspension imposed by a licensing or regulatory body outside the United Kingdom does not make the person unsuitable to be—

(a) a contractor; or

(b) in the case of a scheme with a body corporate, a director, chief executive, superintendent or company secretary of the body corporate.

(4) A Primary Care Trust shall not terminate the scheme pursuant to sub-paragraph (2)(e) where it is satisfied that the conviction does not make the person unsuitable to be—

(a) a contractor; or

(b) in the case of a scheme with a body corporate, a director, chief executive, superintendent or company secretary of a contractor.

Termination by the Primary Care Trust: patient safety and material financial loss

30. The Primary Care Trust may serve notice in writing on the contractor terminating the scheme with immediate effect or with effect from such date as may be specified in the notice if—

(a) the contractor has breached the scheme and as a result of that breach, the safety of the contractor's patients is at serious risk if the scheme is not terminated; or

(b) the contractor's financial situation is such that the Primary Care Trust considers that the Primary Care Trust is at risk of material financial loss.

Termination and the NHS dispute resolution procedure

31.—(1) Where the Primary Care Trust is entitled to serve written notice on the contractor terminating the scheme pursuant to paragraph 29 or 30, it must, in the notice served on the contractor pursuant to those provisions, specify a date on which the scheme terminates that is not less than 28 days after the date on which the Primary Care Trust has served that notice on the contractor, unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the Primary Care Trust is satisfied that a period less than 28 days is necessary in order to—

(a) protect the safety of the contractor's patients; or

(b) protect itself from material financial loss.

(3) In a case falling within sub-paragraph (1), where—

(**a**) 1990 c.40.
(**b**) 1986 c.46, as amended by the Insolvency Act 2000 (c.39).
(**c**) S.I. 1986/1032 (N.I. 6).

(a) the exceptions in sub-paragraph (2) do not apply;

(b) the contractor invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1); and

(c) the contractor notifies the Primary Care Trust in writing that it has done so,

subject to paragraph (5), the scheme shall not terminate at the end of the notice period but instead shall only terminate in the circumstances specified in sub-paragraph (4).

(4) Subject to paragraph (5), the scheme shall only terminate if and when—

(a) there has been a determination of the dispute pursuant to paragraph 23 and that determination permits the Primary Care Trust to terminate the scheme; or

(b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the Primary Care Trust is satisfied that it is necessary to terminate the scheme before the NHS dispute resolution procedure is concluded in order to—

(a) protect the safety of the contractor's patients; or

(b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the Primary Care Trust shall be entitled to confirm, by written notice to be served on the contractor, that the scheme will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 29(1) or 30.

Third party rights

32. The scheme shall not create any right enforceable by any person not a party to it.

SCHEDULE 3

Regulation 20

Amendments to secondary legislation

PART 1

Amendment of the Pharmaceutical Services Regulations

Amendment of the Pharmaceutical Services Regulations

1. The Pharmaceutical Services Regulations are amended in accordance with this Part.

Amendment of regulation 2

2. In regulation 2(**a**) (interpretation), in paragraph (1)—

(a) in the definition of "batch issue" for from "set out" to "June 2004," substitute "required by the NHS Business Services Authority,";

(b) after the definition of "equivalent lists", insert the following definition—

""ESP pilot scheme" means an Essential Small Pharmacies Local Pharmaceutical Services pilot scheme;";

(c) for the definition of "local pharmaceutical services", substitute the following definition—

""local pharmaceutical services" means local pharmaceutical services under—

(a) an LPS scheme established under paragraph 1(1) of Schedule 8A to the Act; or

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(**a**) Amended by S.I. 2005/1051 and 3315.

(b) an ESP pilot scheme;";

(d) in the definition of "LPS chemist", after "a pharmacy pilot scheme", insert "or an LPS scheme";

(e) after the definition of "LPS chemist", insert the following definition—

""LPS scheme" has the same meaning as in paragraph 1(2) of Schedule 8A of the Act;" ;

(f) in the definition of "National Health Service Counter Fraud and Security Management Service", after "in the National Health Service" add ", which was replaced on 1st April 2006 by the NHS Business Services Authority";

(g) after the definition of "National Health Service Counter Fraud and Security Management Service" insert the following definition—

""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(**a**);";

(h) in the definition of "pharmacy", at the end of paragraph (a) omit "or" and after paragraph (b)(ii) add—

"; or

(c) in accordance with an LPS scheme.";

(i) in the definition of "repeatable prescription" for from "set out" to "June 2004," substitute "required by the NHS Business Services Authority,"; and

(j) in the definition of "supplementary prescriber"—

(i) substitute a comma for ". or" at the end of paragraph (a)(iii),

(ii) substitute ", or" for "; and" at the end of paragraph (a)(iv)(cc), and

(iii) in paragraph (a), after sub-paragraph (iv) add the following sub-paragraph—

"(v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(**b**); and".

Amendment of regulation 5

3. In regulation 5 (applications in respect of pharmaceutical lists), in paragraph (3)(a) omit "or" and after sub-paragraph (a) insert the following sub-paragraph—

"(aa) pursuant to a determination made by the Secretary of State under regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006; or".

Amendment of regulation 10

4. In regulation 10(**c**) (right to return)—

(a) for paragraph (1), substitute the following paragraph—

"(1) Subject to regulation 69A, this regulation applies if the Secretary of State makes a determination—

(a) under regulation 4 of the National Health Service (Local Pharmaceutical Services) (No. 2) Regulations 2002; or

(b) under regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006,

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(**a**) S.I. 2005/2414.
(**b**) 1989 c.44.
(**c**) As amended by S.I. 2005/1015.

that a person is to be given the right of return to a Primary Care Trust's pharmaceutical list on making an application for his name to be included in that list after ceasing to provide local pharmaceutical services, subject to the conditions referred to in paragraph (2) being satisfied."; and

(b) in paragraph (3), after "a pharmacy pilot scheme" insert "or an LPS scheme".

Amendment of regulation 12

5. In regulation 12(**a**) (necessary or desirable test), in paragraph (2)(a)(ii), after "a pharmacy pilot scheme" insert "or an LPS scheme".

Amendment of Regulation 19

6. In regulation 19 (refusal: fitness to practise grounds), after "Security Management Service" insert "or the NHS Business Services Authority".

Amendment of regulation 20

7. In regulation 20 (imposition of conditions), in paragraph (3), after "a pharmacy pilot scheme" insert "or an LPS scheme".

Amendment of regulation 24

8. In regulation 24 (determination of applications)—

(a) in paragraph (2)(b), for "National Health Service Counter Fraud and Security Management Service" substitute "NHS Business Services Authority"; and

(b) in paragraph (6), in sub-paragraph (f) omit "or" and after sub-paragraph (g) insert—

"; or

(h) who is a party (other than a Primary Care Trust) to an LPS scheme, or an officer or an employee of such a person who provides or assists in providing local pharmaceutical services under an LPS scheme,".

Amendment of regulation 25

9. In regulation 25 (deferral of applications), at the end of paragraph (5) insert "or under regulation 4 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006".

Amendment of regulation 26

10. In regulation 26 (deferral of consideration of applications on fitness to practise grounds), in paragraph (1)(h) and (i), for "National Health Service Counter Fraud and Security Management Service" substitute "NHS Business Services Authority".

Amendment of regulation 28

11. In regulation 28 (notifications by Primary Care Trusts to other persons), in paragraph (2)(i), for "National Health Service Counter Fraud and Security Management Service" substitute "NHS Business Services Authority".

Amendment of regulation 36

12. In regulation 36 (determination of applications in respect of controlled localities)—

(**a**) As amended by S.I. 2005/1015.

(a) in paragraph (3)(b), for "National Health Service Counter Fraud and Security Management Service" substitute "NHS Business Services Authority"; and

(b) in paragraph (8), in sub-paragraph (f) omit "or" and after sub-paragraph (g) insert—

"; or

(h) who is a party (other than a Primary Care Trust) to an LPS scheme, or an officer or an employee of such a person who assists in providing local pharmaceutical services under an LPS scheme,".

Amendment of regulation 38

13. In regulation 38 (appeals in connection with determinations of controlled localities), in paragraph (3)(a)(iii), after "a pharmacy pilot scheme" insert "or an LPS scheme".

Amendment of regulation 45

14. In regulation 45 (removal from pharmaceutical lists), in paragraph (3), after "a pharmacy pilot scheme" insert "or an LPS scheme".

Amendment of regulation 54

15. In regulation 54 (temporary provision of services during a period of suspension), in paragraph (7)(b), after "Security Management Service" insert "or the NHS Business Services Authority".

Amendment of Schedule 1

16. In Schedule 1 (terms of service of pharmacists), in paragraph 30 (duty to provide information about fitness to practise matters as they arise), in paragraphs (1)(k) and (2)(f), for "National Health Service Counter Fraud and Security Management Service" substitute "NHS Business Services Authority".

Amendment of Schedule 3

17. In Schedule 3 (terms of service of suppliers of appliances), in paragraph 17 (duty to provide information about fitness to practise matters as they arise), in paragraphs (1)(k) and (2)(f), for "National Health Service Counter Fraud and Security Management Service" substitute "NHS Business Services Authority".

Amendment of Schedule 4

18. In paragraph 4 of Part 3 of Schedule 4 (which relates to the information to be provided by applicants for inclusion, or temporary inclusion, in a pharmaceutical list), after "Security Management Service" insert "or the NHS Business Services Authority".

PART 2

Amendments to other secondary legislation

Amendment of the National Health Service Trusts (Membership and Procedure) Regulations 1990

19. In the National Health Service Trusts (Membership and Procedure) Regulations 1990(**a**), in regulation 1(2) (interpretation), in paragraph (a) of the definition of "health service body", after

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(**a**) S.I. 1990/2024; the relevant amending instruments are S.I. 1996/1755, 1998/646, 2000/2434, 2001/3786 and 2002/2469.

"Care Act 2001" insert "or a contractor which is treated as a health service body pursuant to regulation 10 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006".

Amendment of the National Health Service Litigation Authority Regulations 1995

20. In the National Health Service Litigation Authority Regulations 1995(**a**), in regulation 1(2) (interpretation), in the definition of "health service body", after "Care Act 2001" insert "or a contractor which is treated as a health service body pursuant to regulation 10 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006".

Amendment of the Primary Care Trusts (Membership, Procedure and Administration Arrangements) Regulations 2000

21. In the Primary Care Trusts (Membership, Procedure and Administration Arrangements) Regulations 2000(**b**)—

(a) in regulation 1(2) (interpretation), in the definition of "health service body", after "Care Act 2001" insert "or a contractor which is treated as a health service body pursuant to regulation 10 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006"; and

(b) in regulation 5(1)(i) (disqualification for appointment: chairman and non-officer members), after "Care Act 2001" insert "or a contractor which is treated as a health service body pursuant to regulation 10 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006".

Amendment of the Charges Regulations

22. In the Charges Regulations(**c**), in regulation 2 (interpretation), in the definition of "local pharmaceutical services" for sub-paragraph (b) substitute—

"(b) provided under an LPS scheme as defined in paragraph 1(2) of Schedule 8A to the Act;".

Amendment of the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000

23. In the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000(**d**), in regulation 2(1) (interpretation), in the definition of "supply", after "Care Act 2001" insert "or under an LPS scheme as defined in paragraph 1(2) of Schedule 8A to the Act".

Amendment of the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001

24. In the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001(**e**), in regulation 2(1) (interpretation), in the definition of "supply", after "Care Act 2001" insert "or under an LPS scheme as defined in paragraph 1(2) of Schedule 8A to the National Health Service Act 1977".

(**a**) S.I. 1995/2801; the relevant amending instruments are S.I. 1998/646, 2000/696 and 2002/2469.
(**b**) S.I. 2000/89; the relevant amending instruments are S.I. 2001/3787 and 2002/557 and 2469.
(**c**) The relevant amending instrument is S.I. 2002/2352.
(**d**) S.I. 2000/1763; the relevant amending instrument is S.I. 2002/2861.
(**e**) S.I. 2001/3798; the relevant amending instrument is S.I. 2002/2861.

Amendment of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002

25. In the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(**a**)—

(a) in regulation 3(1)(**b**) (designation of priority neighbourhoods or premises), after "a Primary Care Trust may" insert "until 31st March 2006";

(b) omit regulations 7(**c**) (which relates to requests to Primary Care Trusts for preparation of proposals) and 7A(**d**) (consultation on proposals); and

(c) in regulation 8(1)(**e**) (provision of financial assistance), after "a Primary Care Trust may" insert "until 31st March 2006".

Amendment of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No.2) Regulations 2002

26. In regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No.2) Regulations 2002(**f**) (right of return to pharmaceutical lists), for paragraph (1) substitute the following paragraph—

"(1) Before the Secretary of State approves a pilot scheme under paragraph 3(1)(a) or (b) of Schedule 2 to the Act, he must determine pursuant to this regulation whether the pilot scheme provider is to be given a right of return, subject to the conditions specified in regulation 10(2) of the principal Regulations, if he makes an application for his name to be included in a Primary Care Trust's pharmaceutical list after ceasing to provide local pharmaceutical services under the pilot scheme.".

Amendment of the Delayed Discharges (England) Regulations 2003

27. In the Delayed Discharges (England) Regulations 2003(**g**), in regulation 2 (interpretation), in paragraph (e) of the definition of "health service body" after "Care Act 2001" insert "or a contractor which is treated as a health service body pursuant to regulation 10 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006".

Amendment of the National Health Service (Complaints) Regulations 2004

28. In the National Health Service (Complaints) Regulations 2004(**h**), in regulation 2(2) (interpretation), in sub-paragraph (h) after "Care Act 2001" insert "or in accordance with an LPS scheme as defined in paragraph 1(2) of Schedule 8A to the 1977 Act".

(**a**) S.I. 2002/888.
(**b**) Amended by S.I. 2002/2469 and 2005/641.
(**c**) Amended by S.I. 2002/2469.
(**d**) Inserted by S.I. 2002/2861.
(**e**) Amended by S.I. 2002/2469.
(**f**) S.I. 2002/2016.
(**g**) S.I. 2003/2277.
(**h**) S.I.2004/1768.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations govern the arrangements for the provision of local pharmaceutical services in England under agreements, known as LPS schemes, between Primary Care Trusts, who commission the services, and independent contractors, who provide them. LPS schemes have to be made in accordance with the provisions of these Regulations and of Schedule 8A to the National Health Service Act 1977 ("the 1977 Act"). Previously, local pharmaceutical services could only be provided under pilot schemes established under Chapter 1 of Part 2 of the Health and Social Care Act 2001, but as a result of these Regulations, most pilot schemes will become LPS schemes, and new proposals for pilot schemes will no longer be accepted.

Part 1 contains general provisions, including interpretation provisions – and, together with Schedule 1, provides for the application with modifications of certain provisions of the 1977 Act and the Health Service Commissioners Act 1993 that already deal with arrangements for personal medical or dental services (and with local pharmaceutical services pilot schemes) so that those provisions apply in relation to LPS schemes in a similar way.

Part 2 deals with designation of priority neighbourhoods or premises, and the review, variation and cancellation of such designations. Where a neighbourhood, premises or type of premises are designated, Primary Care Trusts may defer consideration of applications for inclusion in a pharmaceutical list (under the National Health Service (Pharmaceutical Services) Regulations 2005 ("the 2005 Regulations")) in relation to the same neighbourhood or premises. Notice of designations, and of the variation and cancellation of designations, has to be given to the interested parties listed in regulation 4(5).

Part 3 sets out the general requirements in relation to contractors. Specified categories of individuals, partnerships and companies are prevented from entering into LPS schemes (regulation 7) and if the Primary Care Trust determines that an applicant falls within one of those categories, the applicant has a right to the reasons for that determination and a right of appeal (regulations 8 and 9). Contractors are given health service body status, meaning that their contract is an NHS contract, unless they elect otherwise (regulation 10).

Part 4 sets out the general requirements in relation to LPS schemes. These include a requirement for certain information relating to the suitability of the applicant to be included in the proposal (regulation 12) and requirements as to the terms to be specified (regulation 14). The latter include the mandatory terms in Schedule 2, which relate to such matters as the dispensing arrangements, clinical governance, professional standards, inducements, the provision of information about fitness to practise matters, NHS charges, remuneration, complaints, dispute resolution and termination. The Primary Care Trust must also determine whether any potential contractor is to be given a right of return to its pharmaceutical list kept under the 2005 Regulations (regulation 15). The pharmaceutical list is a list of providers of pharmaceutical services who provide such services on the basis of the statutory terms of service set out in the 2005 Regulations rather than on the basis of a locally negotiated LPS scheme. Determinations of rights of return have to be sent to a list of interested parties.

There are arrangements which allow Primary Care Trusts to share information that they receive about the suitability of contractors or the fitness to practise of pharmacists under the Regulations with other Primary Care Trusts and, where appropriate, the Royal Pharmaceutical Society of Great Britain (regulation 16).

Part 5 contains transitional and consequential provisions. These include a duty on former pilot scheme contractors to provide Primary Care Trusts with certain information about their suitability to be a contractor, although some corporate bodies are exempt from this requirement (regulation 17). Generally, pilot scheme agreements all become LPS schemes (or for a transitional period, transitional agreements), but pilot schemes that come under the special arrangements for essential small pharmacies will continue as pilot schemes. The pilot schemes that become LPS schemes must, however, be modified so that they comply with the requirements of these Regulations (regulation 18). There are also transitional arrangements for the scheme for the designation of

neighbourhoods and premises (similar to the scheme in Part 2) that was in operation for pilot schemes. A number of consequential amendments are also made to other secondary legislation to take account of the arrangements set out in these Regulations. In addition, some consequential amendments are made to the 2005 Regulations to take account of the replacement of the Prescription Pricing Authority and the NHS Counter Fraud and Security Management Service by the NHS Business Services Authority, and the definition of "supplementary prescriber" is updated (regulation 20 and Schedule 3).

A full regulatory impact assessment of the effect that this instrument will have on the costs to business is available from the Medicines, Pharmacy and Industry Division, Department of Health, Skipton House, 80 London Road, London SE1 6LH. Copies have also been placed in the libraries of both Houses of Parliament.

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