STATUTORY INSTRUMENTS

2005 No. 893

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005

Made - - - -	*22nd March 2005*
Laid before Parliament	*24th March 2005*
Coming into force - -	*14th April 2005*

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 28E, 28S, 28V, 28W, 28X and 126(4) and (5) of the National Health Service Act 1977(**1**) and all other powers enabling him in that behalf, hereby makes the following Regulations:

PART 1

GENERAL

Citation, commencement, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005 and shall come into force on 14th April 2005.

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

(3) In these Regulations—

"the Act" means the National Health Service Act 1977;

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

(**1**) 1977 c. 49; section 28E was inserted by section 22(1) of the National Health Service (Primary Care) Act 1997 (c. 46) ("the 1997 Act") and was amended by the Health Act 1999 (c. 8) ("the 1999 Act"), section 65(2) and Schedule 5, the Health and Social Care Act 2001 (c. 15) ("the 2001 Act"), section 27(5)(a), the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act"), section 4(3), Schedule 3, paragraph 8 and the Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act"), section 177(7) to (11); sections 28S, 28V and 28W were inserted by section 175(1) of the 2003 Act; section 28X was inserted by section 179(1) of the 2003 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 1999 Act, Schedule 4, paragraph 37(6) and the 2001 Act, Schedule 5, paragraph 5(13)(b); section 126(5) was inserted by the 1990 Act, section 65(2) and amended by the 2001 Act, Schedule 5, paragraph 5(13)(d).

(**2**) S.I. 2004/291, as amended by S.I. 2004/906 and 2694 and 2005/28.

"PMS agreement" means an agreement for primary medical services made under section 28C of the Act(**3**);

"PMS Agreements Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2004(**4**);

"Performers Lists Regulations" means the National Health Service (Performers Lists) Regulations 2004(**5**); and

"relevant body" means—

(a) in a case where a contractor is a party to a PMS agreement with a Primary Care Trust, that Primary Care Trust, and

(b) in a case where a contractor is a party to a PMS agreement with a Strategic Health Authority, that Strategic Health Authority.

PART 2

AMENDMENT OF THE GMS CONTRACTS REGULATIONS

Amendment of regulation 2 of the GMS Contracts Regulations

2.—(1) Regulation 2(1) (interpretation) of the GMS Contracts Regulations shall be amended as provided in the following paragraphs.

(2) After the definition of "adjudicator", insert—

""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;".

(3) In the definition of "bank holiday", after "proclaimed as a bank holiday" insert "in England and Wales".

(4) In the definition of "batch issue"—

(a) before "prescriber", in each place where it occurs, insert "repeatable"; and

(b) for "repeatable prescription", in each place where it occurs, substitute "non-electronic repeatable prescription".

(5) After the definition of "core hours" insert—

""dispenser" means a chemist, medical practitioner or contractor whom a patient wishes to dispense his electronic prescriptions;".

(6) In the definition of "dispensing services", for "regulation 20" substitute "regulation 60".

(7) In the definition of "Drug Tariff", for "regulation 18" substitute "regulation 56".

(8) After the definition of "Drug Tariff", insert—

(**3**) Section 28C was inserted into the Act by the 1997 Act, section 21(1) and amended by the 1999 Act, Schedule 4, paragraph 15, the 2001 Act, Schedule 5, paragraph 11(4), the 2002 Act, Schedule 3, paragraph 7(2) and the 2003 Act, Schedule 11, paragraph 14.

(**4**) S.I. 2004/627, as amended by S.I. 2004/906 and 2694 and 2005/28.

(**5**) S.I. 2004/585 to which there are amendments not relevant to these Regulations.

""electronic communication" has the same meaning as in section 15 of the Electronic Communications Act 2000(**6**);

"electronic prescription" means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" means a prescription form which falls within paragraph (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";".

(9) After the definition of "essential services", insert—

""ETP service" means the electronic prescription service which forms part of the NHS Care Record Service;".

(10) Omit the definition of "NCAA".

(11) After the definition of "national disqualification" insert—

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

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

(12) After the definition of "the NHS Tribunal" insert—

""nominated dispenser" means a chemist, medical practitioner or contractor whom a patient has nominated in his NHS Care Record to dispense his electronic prescriptions;

"non-electronic prescription form" means a prescription form which falls within paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" means a prescription which falls within paragraph (a)(i) of the definition of "repeatable prescription";".

(13) After the definition of "normal hours" insert—

""NPSA" means the National Patient Safety Agency established as a Special Health Authority by the National Patient Safety Agency (Establishment and Constitution) Order 2001(**7**);".

(14) In the definition of "Pharmaceutical Regulations" for "National Health Service (Pharmaceutical Services) Regulations 1992" substitute "National Health Service (Pharmaceutical Services) Regulations 2005(**8**)".

(15) For the definition of "prescription form", substitute—

""prescription form" means—

(a) a form provided by the Primary Care Trust and issued by a prescriber, or

(b) where paragraph 39A(1) of Schedule 6 applies, data that are created in an electronic form, signed with a prescriber's advanced electronic signature and transmitted as an electronic communication to the ETP service,

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

(16) After the definition of "repeat dispensing services", insert—

""repeatable prescriber" means a prescriber who is—

(**6**) 2000 c. 7.
(**7**) S.I. 2001/1743 as amended by S.I. 2005/504.
(**8**) S.I. 2005/641.

(a) engaged or employed by a contractor which provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 of Schedule 6, or

(b) a party to a contract under which such services are provided;".

(17) For the definition of "repeatable prescription", substitute—

""repeatable prescription" means a prescription which—

(a) either—

(i) is contained in a form provided by the Primary Care Trust and issued by a repeatable prescriber which is in the format specified in Part 1 of Schedule 1 and which is generated by a computer and signed in ink by a repeatable prescriber; or

(ii) where paragraph 39A(1) of Schedule 6 applies, 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 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, medicines or appliances ordered on that prescription may be provided more than once and specifies the number of occasions on which they may be provided;".

(18) In the definition of "supplementary prescriber"—

(a) in paragraph (b)(ii), omit "or";

(b) in paragraph (b)(iii), for "and", in the second place where it occurs, substitute "or"; and

(c) after paragraph (b)(iii), insert—

"(iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(**9**) relating to—

(aa) chiropodists and podiatrists;

(bb) physiotherapists; or

(cc) radiographers: diagnostic or therapeutic, and".

Amendment of Schedule 5 to the GMS Contracts Regulations

3. In Schedule 5 (fees and charges) to the GMS Contracts Regulations, in paragraph (k), for "regulation 20" substitute "regulation 60".

Amendment of Schedule 6 to the GMS Contracts Regulations

4.—(1) Schedule 6 (other contractual terms) to the GMS Contracts Regulations shall be amended as provided in the following paragraphs.

(2) After paragraph 1 (premises), insert—

"**Telephone services**

1A.—(1) The contractor shall not be a party to any contract or other arrangement under which the number for telephone services to be used by—

(a) patients to contact the practice for any purpose related to the contract; or

(b) any other person to contact the practice in relation to services provided as part of the health service,

(**9**) S.I. 2002/254.

starts with the digits 087, 090 or 091 or consists of a personal number, unless the service is provided free to the caller.

(2) In this paragraph, "personal number" means a telephone number which starts with the number 070 followed by a further 8 digits.".

(3) After paragraph 11 (standards for out of hours services), insert—

"**Supply of medicines etc. by contractors providing out of hours services**

11A.—(1) In this paragraph—

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(**10**);

"complete course" means the course of treatment appropriate to the patient's condition, being the same as the amount that would have been prescribed if the patient had been seen during core hours;

"necessary drugs, medicines and appliances" means those drugs, medicines and appliances which the patient requires and for which, in the reasonable opinion of the contractor, and in the light of the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait until such time as he could obtain them during core hours;

"out of hours performer" means a prescriber, a person acting in accordance with a Patient Group Direction or any other health care professional employed or engaged by the contractor who can lawfully supply a drug, medicine or appliance, who is performing out of hours services under the contract;

"Patient Group Direction" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**11**); and

"supply form" means a form provided by a Primary Care Trust and completed by or on behalf of the contractor for the purpose of recording the provision of drugs, medicines or appliances to a patient during the out of hours period.

(2) Where a contractor whose contract includes the provision of out of hours services has agreed with the Primary Care Trust that its contract should also include the supply of necessary drugs, medicines and appliances to patients at the time that it is providing them with out of hours services, the contractor shall comply with the requirements in sub-paragraphs (3) to (5).

(3) The contractor shall ensure that an out of hours performer—

(a) only supplies necessary drugs, medicines and appliances;

(b) supplies the complete course of the necessary medicine or drug required to treat the patient; and

(c) does not supply—

(i) drugs, medicines or appliances which he could not lawfully supply,

(ii) appliances which are not listed in Part IX of the Drug Tariff,

(iii) restricted availability appliances, except where the patient is a person, or it is for a purpose, specified in the Drug Tariff, or

(iv) a drug, medicine or other substance listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004(**12**), or a drug, medicine or other substance listed in

(**10**) S.I. 2000/620.
(**11**) S.I. 1997/1830; relevant amending instruments are S.I. 2000/1917 and 2003/2915.
(**12**) S.I. 2004/629 as amended by S.I. 2004/3215.

Schedule 2 to those Regulations other than in the circumstances specified in that Schedule.

(4) The out of hours performer shall record on a separate supply form for each patient any drugs, medicines or appliances supplied to the patient provided that a single supply form may be completed where the out of hours performer supplies necessary drugs, medicines or appliances to two or more persons in a school or other institution in which at least 20 persons normally reside, when the out of hours performer may write on the supply form the name of the school or institution rather than the name of the individual patient.

(5) The out of hours performer shall—

(a) ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations(**13**) by virtue of either—

(i) entitlement to exemption under regulation 7(1) of the Charges Regulations(**14**), or

(ii) entitlement to remission of charges under regulation 5 of the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003(**15**),

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, and at the time of the declaration the out of hours performer already has such evidence available to him; and

(b) if no satisfactory evidence is produced to him (and, where it is relevant, none is already available to him as mentioned in paragraph (a)), endorse the supply form to that effect.

(6) Subject to sub-paragraph (7), nothing in this paragraph shall prevent an out of hours performer supplying a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(7) The provisions of regulation 24 (fees and charges) apply in respect of the supply of necessary drugs, medicines and appliances under this paragraph as they apply in respect of prescriptions for drugs, medicines and appliances.".

(4) In paragraph 38 (prescribing)—

(a) after "issued" insert "or created"; and

(b) after "paragraphs 39" insert ", 39A".

(5) In paragraph 39—

(a) in sub-paragraph (1), for the words from "by issuing to that patient" to the end substitute—

"by—

(a) issuing to that patient a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3); or

(b) where paragraph 39A(1) applies, creating and transmitting an electronic prescription,

and such a non-electronic prescription form, non-electronic repeatable prescription or electronic prescription shall not be used in any other circumstances.";

(b) in sub-paragraph (3)—

(i) for "such" substitute "non-electronic",

(**13**) Regulation 4(1) was amended by S.I. 2002/548 and 2004/663.
(**14**) Regulation 7(1) was amended by S.I. 2000/3189 and 2002/2352.
(**15**) S.I. 2003/2382 as amended by S.I. 2004/663 and 936.

(ii) before "repeatable prescription", in the first place that it occurs, insert "non-electronic", and

(iii) omit from the words "and—" to the end;

(c) after sub-paragraph (3), insert—

"(3A) A prescription form or repeatable prescription shall not refer to any previous prescription form or repeatable prescription.

(3B) A separate prescription form or repeatable prescription shall be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 44.";

(d) in sub-paragraph (4)—

(i) after "buprenorphine" insert "or diazepam", and

(ii) in paragraph (a), before "prescription form" insert "non-electronic";

(e) in sub-paragraph (5), before "prescription form" insert "non-electronic"; and

(f) in sub-paragraphs (6) and (7)—

(i) after "issued" insert "or created", and

(ii) for paragraph (c), substitute—

"(c) he undertakes to—

(i) furnish the chemist within 72 hours with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3), or

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

(6) After paragraph 39 insert—

"**Electronic prescriptions**

39A.—(1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if—

(a) the contractor holds a contract with a Primary Care Trust which is specified in directions issued by the Secretary of State under section 17 of the Act as being a Primary Care Trust which can authorise its contractors to use the ETP service(**16**);

(b) the patient to whom the prescription relates has—

(i) nominated one or more dispensers in his NHS Care Record,

(ii) confirmed that he intends to use that dispenser (or one of them) for the purposes of obtaining the drugs, medicines or appliances ordered on the electronic prescription in question, and

(iii) consents to the use of an electronic prescription on the particular occasion; and

(c) the prescription is not—

(**16**) These directions will be available on the website of the National Programme for IT (www.npfit.nhs.co.uk) and published in the Drug Tariff.

(i) for a controlled drug within the meaning of the Misuse of Drugs Act 1971(**17**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**18**),

(ii) for supply by instalments under paragraph 39(4), or

(iii) a bulk prescription issued for a school or institution under paragraph 44.

(2) In relation to a patient who is a child or an adult incapable of nominating a dispenser, sub-paragraph (1)(b) shall apply as if the reference to the patient to whom the prescription relates included a reference to—

(a) in the case of a child, that patient's parent or other person referred to in paragraph 15(4)(a); or

(b) in the case of an adult, that patient's relative or primary carer.

(3) A prescriber who orders drugs, medicines or appliances by means of an electronic prescription shall—

(a) in the case of an electronic repeatable prescription, issue the patient with a form provided by the Primary Care Trust for the purpose of recording details of that electronic repeatable prescription and linked to that electronic repeatable prescription by a number contained on the form; and

(b) in the case of an electronic prescription form, issue the patient, if he so requests, with a written record of the prescription which has been created.

Nomination of dispensers for the purpose of electronic prescriptions

39B.—(1) A contractor which operates the ETP service for its patients shall, if requested to do so by a patient, enter in that patient's NHS Care Record—

(a) where he does not have a nominated dispenser, the dispenser chosen by that patient; and

(b) where he does have a nominated dispenser—

(i) a replacement dispenser, or

(ii) a further dispenser,

chosen by that patient.

(2) Sub-paragraph (1)(b)(ii) shall not apply if the number of nominated dispensers would thereby exceed the maximum number permitted by the ETP service.

(3) Paragraph 15(4) shall apply in relation to requests under sub-paragraph (1) as it applies to applications for inclusion in a list of patients.

(4) A contractor—

(a) shall not seek to persuade a patient to nominate a dispenser recommended by the prescriber or the contractor; and

(b) shall, if asked by the patient to recommend a chemist whom he might nominate as his dispenser, provide the patient with the list of all the chemists in the area who provide an ETP service as given to the contractor by the Primary Care Trust.".

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

(a) in sub-paragraph (2)—

(**17**) 1971 c. 38. The relevant definition is in section 2 and Schedule 2 as amended by S.I. 1973/771, 1975/421, 1977/1243, 1979/299, 1983/765, 1984/859, 1985/1995, 1986/2230, 1989/1340, 1990/2589, 1995/1966, 1996/1300, 1998/750, 2001/3932 and 2003/1243 and 3201.

(**18**) S.I. 2001/3998; Schedule 4 was amended by S.I. 2003/1432.

(i) omit paragraph (a), and

(ii) in paragraph (b), before "repeatable prescriptions" insert "non-electronic"; and

(b) in sub-paragraph (7)(b), for "regulation 20" substitute "regulation 60".

(8) In paragraph 41 (repeatable prescriptions)—

(a) in sub-paragraph (1), before "repeatable prescription" insert "non-electronic"; and

(b) for sub-paragraphs (2) to (4) substitute—

"(2) Where a prescriber wishes to make any change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on a person's repeatable prescription he must—

(a) in the case of a non-electronic repeatable prescription—

(i) notify the person, and

(ii) make reasonable efforts to notify the chemist providing repeat dispensing services to that person,

that the original repeatable prescription should no longer be used to obtain or provide repeat dispensing services and make arrangements for a replacement repeatable prescription to be issued to that person; or

(b) in the case of an electronic repeatable prescription—

(i) arrange with the ETP service for the cancellation of the original repeatable prescription in the person's NHS Care Record, and

(ii) create a replacement electronic repeatable prescription relating to that person and notify him that he has done so.

(3) A prescriber who has created an electronic repeatable prescription for a person must as soon as practicable arrange with the ETP service for its cancellation in that person's NHS Care Record if, before the expiry of that prescription—

(a) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his electronic repeatable prescription or no longer appropriate or safe for him to continue to receive repeatable prescribing services;

(b) he has issued the person with a non-electronic repeatable prescription in place of the electronic repeatable prescription; or

(c) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.

(4) Where a prescriber has cancelled a person's electronic repeatable prescription in accordance with sub-paragraph (3) he must, as soon as is practicable, notify that person.

(5) A prescriber who has issued a non-electronic repeatable prescription in respect of a person must, as soon as practicable, make reasonable efforts to notify the chemist that that repeatable prescription should no longer be used to provide repeat dispensing services to that person, if, before the expiry of that repeatable prescription—

(a) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his repeatable prescription or no longer appropriate or safe for him to continue to receive repeatable prescribing services;

(b) he issues or creates a further repeatable prescription in respect of the person to replace the original repeatable prescription other than in the circumstances

referred to in sub-paragraph (2)(a) (for example, because the person wishes to obtain the drugs, medicines or appliances from a different chemist); or

(c) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.

(6) Where the circumstances in sub-paragraph (5)(a) to (c) apply, the prescriber must as soon as practicable notify the person on whose behalf the non-electronic repeatable prescription was issued that that repeatable prescription should no longer be used to obtain repeat dispensing services.".

(9) In paragraph 42 (restrictions on prescribing by medical practitioners)—

(a) in sub-paragraph (2)(c), for "endorses the form with" substitute "includes on the prescription form"; and

(b) in sub-paragraph (3)(b), for "endorses the face of the form with" substitute "includes on the prescription form".

(10) In paragraph 43 (restrictions on prescribing by supplementary prescribers)—

(a) in sub-paragraph (1)(a), for "give" substitute "issue or create";

(b) omit sub-paragraphs (2)(b), (4)(c) and (f) and (6);

(c) in sub-paragraph (2)(d)(iii), for "giving a prescription, he endorses the face of the form with" substitute "issuing or creating a prescription, he includes on the prescription form";

(d) in sub-paragraph (3), for "give" substitute "issue or create"; and

(e) in sub-paragraph (4), in paragraphs (e)(iii) and (h)(iii), for "giving the prescription, he endorses the face of the form with" substitute "issuing or creating the prescription, he includes on the prescription form".

(11) In paragraph 44 (bulk prescribing), in sub-paragraphs (1) and (2), before "prescription form" insert "non-electronic".

(12) In paragraph 47 (provision of dispensing services)—

(a) in sub-paragraph (1), for "regulation 20" substitute "regulation 60";

(b) in sub-paragraph (4)(b), for "regulation 12(15) or 13(13)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(5) or (6)" substitute "regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(5)";

(c) in sub-paragraph (9)(a), for "regulation 12(15) or 13(13) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(5) or (6)" substitute "regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(5)"; and

(d) in sub-paragraph (9)(b)(ii), for "regulation 9(10)" substitute "regulation 31(9)".

(13) In paragraph 48 (consent to dispense)—

(a) in sub-paragraph (2), for "by the Primary Care Trust in accordance with regulations 12 and 13 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraphs (5) and (6)), as though it were an application under regulation 21 of those Regulations" substitute "in accordance with regulations 18, 33, 34 and 36 to 38 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraph (5)), as though it were an application for outline consent under regulation 61 of those Regulations";

(b) in sub-paragraph (4), for "regulation 12(16)" substitute "regulation 39(12)"; and

(c) for sub-paragraphs (5) and (6) substitute—

"(5) Regulations 18, 20(2), 33, 34, 36 and 38 of the Pharmaceutical Regulations shall apply as if—

(a) in regulations 18(2), 33(2) and (3) and 36(1), (3) and (9), the references to provisions being "subject to regulations 25 and 26" were omitted;

(b) in regulations 18(2)(b) and (c), 33(2)(j) and 34(1)(a), for the references to "regulation 61" there were substituted references to this paragraph;

(c) in regulations 20(2) and 38(2)(c), for the references to "regulation 60" there were substituted references to paragraph 47; and

(d) in regulation 38(14)(b), for the reference to "arrangements under regulation 60 for the provision by a doctor of pharmaceutical services" there were substituted a reference to arrangements under paragraph 47 for the provision by a contractor of dispensing services.".

(14) In paragraph 50 (terms relating to the provision of dispensing services)—

(a) in sub-paragraph (2)(a), for "on a prescription form completed in accordance with paragraph 39(3);" substitute—

"on—

(i) a non-electronic prescription form completed in accordance with paragraph 39(3), or

(ii) if the contractor is the patient's nominated dispenser (or one of them), an electronic prescription form;";

(b) for sub-paragraph (4), substitute—

"(4) Where a patient—

(a) presents to a contractor who may provide dispensing services an order on a non-electronic prescription form for drugs, medicines or appliances signed by an independent nurse prescriber, or an order for a restricted availability appliance signed by and endorsed with the reference "SLS" by an independent nurse prescriber; or

(b) informs a contractor who may provide dispensing services and who is his nominated dispenser (or one of them) that an independent nurse prescriber has ordered drugs, medicines or appliances for him by means of an electronic prescription form,

the contractor may, provided, in a case to which paragraph (b) applies, it has received the electronic prescription form from the ETP service, provide to the patient such of the drugs, medicines or appliances so ordered as it supplies in the normal course of its practice."; and

(c) for sub-paragraph (8), substitute—

"(8) A contractor providing dispensing services shall comply with paragraph 5 of Schedule 2 (terms of service of dispensing doctors) to the Pharmaceutical Regulations, as if modified as follows—

(a) for "paragraph 3, or in the circumstances set out in paragraph 4" there were substituted "paragraph 50(2) or (4) of Schedule 6 to the GMS Regulations"; and

(b) for "the dispensing doctor", in each place where it occurs, there were substituted "the contractor providing dispensing services".".

(15) In paragraph 68 (appraisal and assessment), in sub-paragraph (1)(b), for "NCAA" substitute "NPSA".

(16) Omit paragraph 74 (access to records for the purpose of the Quality Information Preparation Scheme).

(17) In paragraph 79 (inquiries about prescriptions and referrals), in sub-paragraph (1)(a), after "issued" insert "or created".

(18) In paragraph 80 (reports to a medical officer), in sub-paragraph (1)(b), after "issued" insert "or created".

(19) In paragraph 85 (notice provisions specific to a contract with a company limited by shares)—

(a) in sub-paragraph (1), after paragraph (a) insert—

"(aa) a new director or secretary is appointed;"; and

(b) after sub-paragraph (2), insert—

"(3) A notice under sub-paragraph (1)(aa) shall confirm that the new director or, as the case may be, secretary meets the conditions imposed on directors and secretaries by virtue of regulation 5.".

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

(a) in sub-paragraph (4), omit the words from "sub-paragraphs (1), (2) and (3)" to the end and substitute "the remaining individual shall notify the Primary Care Trust in writing as soon as is reasonably practicable of the death of his partner and sub-paragraph (4A) or (4B) shall apply.";

(b) after sub-paragraph (4), insert—

"(4A) If the remaining individual is a general medical practitioner, the contract shall continue with that individual.

(4B) If sub-paragraph (4A) does not apply, the Primary Care Trust may, if it thinks fit, serve notice in writing on the remaining individual confirming that the Primary Care Trust will allow the contract to continue with that individual, for a period specified by the Primary Care Trust of up to six months (the "interim period") provided that he consents to the Primary Care Trust employing or supplying a general medical practitioner to him for the interim period to assist in the provision of clinical services under the contract.

(4C) Before deciding whether to serve a notice pursuant to paragraph (4B), the Primary Care Trust shall, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for its area.

(4D) If, during the interim period, the contractor withdraws his consent to the Primary Care Trust employing or supplying a general medical practitioner, the Primary Care Trust shall serve notice in writing on the contractor terminating the contract forthwith.

(4E) If, at the end of the interim period, the contractor has not entered into partnership with a general medical practitioner who is not a limited partner, the Primary Care Trust shall serve notice on the contractor terminating the contract forthwith.";

(c) in sub-paragraphs (5) and (6), for "(4)(b)" substitute "(4)"; and

(d) after sub-paragraph (7), add—

"(8) In this paragraph, "general medical practitioner" has the same meaning as in regulation 4(1).".

(21) After paragraph 107 (termination by agreement), insert—

"**Termination on the death of an individual medical practitioner**

107A.—(1) Where the contract is with an individual medical practitioner and that practitioner dies, the contract shall terminate at the end of the period of seven days after the date of his death unless, before the end of that period—

(a) the Primary Care Trust has agreed in writing with the contractor's personal representatives that the contract should continue for a further period, not exceeding 28 days after the end of the period of seven days; and

(b) the contractor's personal representatives have consented in writing to the Primary Care Trust employing or supplying one or more general medical practitioners to assist in the provision of clinical services under the contract throughout the period for which it continues.

(2) In sub-paragraph (1), "general medical practitioner" has the same meaning as in regulation 4(1).

(3) Sub-paragraph (1) does not affect any other rights to terminate the contract which the Primary Care Trust may have under paragraphs 112 to 115.".

(22) In paragraph 111 (termination by the Primary Care Trust for breach of conditions in regulation 4)—

(a) in sub-paragraph (1), insert at the beginning "Subject to sub-paragraph (1A),";

(b) after sub-paragraph (1) insert—

"(1A) Where the failure of an individual medical practitioner to continue to satisfy the condition specified in regulation 4(1) is the result of a suspension specified in sub-paragraph (3B), sub-paragraph (1) shall not apply unless—

(a) the contractor is unable to satisfy the Primary Care Trust that it has in place adequate arrangements for the provision of clinical services under the contract for so long as the suspension continues; or

(b) the Primary Care Trust is satisfied that the circumstances of the suspension are such that if the contract is not terminated forthwith—

(i) the safety of the contractor's patients is at serious risk, or

(ii) the Primary Care Trust is at risk of material financial loss.";

(c) in sub-paragraph (2), insert at the beginning "Except in a case to which paragraph 106(4) applies,";

(d) in sub-paragraph (3), for "of up to six months" substitute "in accordance with paragraph (3A)";

(e) after sub-paragraph (3) insert—

"(3A) The period specified by the Primary Care Trust under sub-paragraph (3)(b) shall not exceed—

(a) six months; or

(b) in a case where the failure of the contractor to continue to satisfy the condition in regulation 4(2)(a) or, as the case may be, 4(3)(a), is the result of a suspension referred to in sub-paragraph (3B), the period for which that suspension continues.

(3B) The suspensions referred to in sub-paragraphs (1A) and (3A)(b) are suspension—

(a) by a Fitness to Practise Panel under—

(i) section 35D (functions of a fitness to practise panel) of the Medical Act 1983(**19**) in a health case, other than an indefinite suspension under section 35D(6) of that Act, or

(ii) section 38(1) (power to order immediate suspension etc after a finding of impairment of fitness to practise) of that Act; or

(b) by a Fitness to Practise Panel or an Interim Orders Panel under section 41A (interim orders) of that Act.

(**19**) 1983 c. 54; section 35D was inserted by, and sections 38(1) and 41A substituted by S.I. 2002/3135.

(3C) In paragraph (3B), "health case" has the meaning given in section 35E(4) of the Medical Act 1983."; and

(f) after sub-paragraph (6), add—

"(7) In sub-paragraphs (3) and (5), "general medical practitioner" has the same meaning as in regulation 4(1).".

(23) In paragraph 112 (termination by the Primary Care Trust for the provision of untrue etc. information) for the words "by the contractor before the contract" to the end substitute—

"by the contractor—

(a) before the contract was entered into; or

(b) pursuant to paragraph 85(2) or (3) or 86(2),

in relation to the conditions set out in regulations 4 and 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.".

(24) In paragraph 113 (other grounds for termination by the Primary Care Trust), in sub-paragraph (1) after "the existence of the contract" insert "or, if later, on or after the date on which a notice in respect of his compliance with the conditions in regulation 5 was given under paragraph 85(2) or (3) or 86(2)".

(25) In paragraph 119 (termination and the NHS dispute resolution procedure), in sub-paragraph (1) for "or 115(4) or (6)" substitute "115(4) or (6) or 116(2)".

Amendment of Schedule 9 to the GMS Contracts Regulations

5. Schedule 9 (Primary Care Trusts specified for the purposes of repeatable prescribing) of the GMS Contracts Regulations is omitted.

PART 3

AMENDMENT OF THE PMS AGREEMENTS REGULATIONS

Amendment of regulation 2 of the PMS Agreements Regulations

6.—(1) Regulation 2 (interpretation) of the PMS Agreements Regulations shall be amended as provided in the following paragraphs.

(2) After the definition of "adjudicator", insert—

""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;".

(3) In the definition of "bank holiday", after "proclaimed as a bank holiday" insert "in England and Wales".

(4) In the definition of "batch issue"—

(a) before "prescriber", in each place where it occurs, insert "repeatable"; and

(b) for "repeatable prescription", in each place where it occurs, substitute "non-electronic repeatable prescription".

(5) After the definition of "core hours" insert—

""dispenser" means a chemist, medical practitioner or contractor whom a patient wishes to dispense his electronic prescriptions;".

(6) In the definition of "dispensing services", for "regulation 20" substitute "regulation 60".

(7) In the definition of "Drug Tariff", for "regulation 18" substitute "regulation 56".

(8) After the definition of "Drug Tariff", insert—

""electronic communication" has the same meaning as in section 15 of the Electronic Communications Act 2000(**20**);

"electronic prescription" means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" means a prescription form which falls within paragraph (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";".

(9) After the definition of "essential services", insert—

""ETP service" means the electronic prescription service which forms part of the NHS Care Record Service;".

(10) Omit the definitions of "FHSAA(SHA)" and "NCAA".

(11) After the definition of "national disqualification" insert—

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

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

(12) After the definition of "the NHS Tribunal" insert—

""nominated dispenser" means a chemist, medical practitioner or contractor whom a patient has nominated in his NHS Care Record to dispense his electronic prescriptions;

"non-electronic prescription form" means a prescription form which falls within paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" means a prescription which falls within paragraph (a)(i) of the definition of "repeatable prescription";".

(13) After the definition of "normal hours" insert—

""NPSA" means the National Patient Safety Agency established as a Special Health Authority by the National Patient Safety Agency (Establishment and Constitution) Order 2001(**21**);".

(14) In the definition of "Pharmaceutical Regulations" for "National Health Service (Pharmaceutical Services) Regulations 1992" substitute "National Health Service (Pharmaceutical Services) Regulations 2005(**22**)".

(15) For the definition of "prescription form", substitute—

""prescription form" means—

(a) a form provided by the Primary Care Trust and issued by a prescriber, or

(**20**) 2000 c. 7.
(**21**) S.I. 2001/1743 as amended by S.I. 2005/504.
(**22**) S.I. 2005/641.

(b) where paragraph 38A(1) of Schedule 5 applies, data that are created in an electronic form, signed with a prescriber's advanced electronic signature and transmitted as an electronic communication to the ETP service,

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

(16) After the definition of "repeat dispensing services", insert—

""repeatable prescriber" means a prescriber who is—

(a) engaged or employed by a contractor which provides repeatable prescribing services under the terms of its agreement which give effect to paragraph 39 of Schedule 5, or

(b) a party to an agreement under which such services are provided;".

(17) For the definition of "repeatable prescription", substitute—

""repeatable prescription" means a prescription which—

(a) either—

(i) is contained in a form provided by the Primary Care Trust and issued by a repeatable prescriber which is in the format specified in Part 1 of Schedule 1 and which is generated by a computer and signed in ink by a repeatable prescriber; or

(ii) where paragraph 38A(1) of Schedule 5 applies, 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 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, medicines or appliances ordered on that prescription may be provided more than once and specifies the number of occasions on which they may be provided;".

(18) In the definition of "supplementary prescriber"—

(a) in paragraph (b)(ii), omit "or";

(b) in paragraph (b)(iii), for "and", in the second place where it occurs, substitute "or"; and

(c) after paragraph (b)(iii), insert—

"(iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(**23**) relating to—

(aa) chiropodists and podiatrists;

(bb) physiotherapists; or

(cc) radiographers: diagnostic or therapeutic, and".

Amendment of Schedule 3 to the PMS Agreements Regulations

7. In Schedule 3 (fees and charges) to the PMS Agreements Regulations, in paragraph (k), for "regulation 20" substitute "regulation 60".

Amendment of Schedule 5 to the PMS Agreements Regulations

8.—(1) Schedule 5 (other contractual terms) to the PMS Agreements Regulations shall be amended as provided in the following paragraphs.

(2) After paragraph 2 (premises), insert—

(**23**) S.I. 2002/254.

"**Telephone services**

2A.—(1) The contractor shall not be a party to any contract or other arrangement under which the number for telephone services to be used by—

(a) patients to contact the practice for any purpose related to the agreement; or

(b) any other person to contact the practice in relation to services provided as part of the health service,

starts with the digits 087, 090 or 091 or consists of a personal number, unless the service is provided free to the caller.

(2) In this paragraph, "personal number" means a telephone number which starts with the number 070 followed by a further 8 digits.".

(3) After paragraph 9 (standards for out of hours services), insert—

"**Supply of medicines etc. by contractors providing out of hours services**

9A.—(1) In this paragraph—

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(**24**);

"complete course" means the course of treatment appropriate to the patient's condition, being the same as the amount that would have been prescribed if the patient had been seen during core hours;

"necessary drugs, medicines and appliances" means those drugs, medicines and appliances which the patient requires and for which, in the reasonable opinion of the contractor, and in the light of the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait until such time as he could obtain them during core hours;

"out of hours performer" means a prescriber, a person acting in accordance with a Patient Group Direction or any other health care professional employed or engaged by the contractor who can lawfully supply a drug, medicine or appliance, who is performing out of hours services under the agreement;

"Patient Group Direction" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**25**); and

"supply form" means a form provided by a Primary Care Trust and completed by or on behalf of the contractor for the purpose of recording the provision of drugs, medicines or appliances to a patient during the out of hours period.

(2) Where a contractor whose agreement includes the provision of out of hours services has agreed with the relevant body that its agreement should also include the supply of necessary drugs, medicines and appliances to patients at the time that it is providing them with out of hours services, the contractor shall comply with the requirements in sub-paragraphs (3) to (5).

(3) The contractor shall ensure that an out of hours performer—

(a) only supplies necessary drugs, medicines and appliances;

(b) supplies the complete course of the necessary medicine or drug required to treat the patient; and

(c) does not supply—

(i) drugs, medicines or appliances which he could not lawfully supply,

(**24**) S.I. 2000/620.
(**25**) S.I. 1997/1830; relevant amending instruments are S.I. 2000/1917 and 2003/2915.

(ii) appliances which are not listed in Part IX of the Drug Tariff,

(iii) restricted availability appliances, except where the patient is a person, or it is for a purpose, specified in the Drug Tariff, or

(iv) a drug, medicine or other substance listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004(**26**), or a drug, medicine or other substance listed in Schedule 2 to those Regulations other than in the circumstances specified in that Schedule.

(4) The out of hours performer shall record on a separate supply form for each patient any drugs, medicines or appliances supplied to the patient provided that a single supply form may be completed where the out of hours performer supplies necessary drugs, medicines or appliances to two or more persons in a school or other institution in which at least 20 persons normally reside, when the out of hours performer may write on the supply form the name of the school or institution rather than the name of the individual patient.

(5) The out of hours performer shall—

(a) ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations(**27**) by virtue of either—

(i) entitlement to exemption under regulation 7(1) of the Charges Regulations(**28**), or

(ii) entitlement to remission of charges under regulation 5 of the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003(**29**),

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, and at the time of the declaration the out of hours performer already has such evidence available to him; and

(b) if no satisfactory evidence is produced to him (and, where it is relevant, none is already available to him as mentioned in paragraph (a)), endorse the supply form to that effect.

(6) Subject to sub-paragraph (7), nothing in this paragraph shall prevent an out of hours performer supplying a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(7) The provisions of regulation 15 (fees and charges) apply in respect of the supply of necessary drugs, medicines and appliances under this paragraph as they apply in respect of prescriptions for drugs, medicines and appliances.".

(4) In paragraph 37 (prescribing)—

(a) after "issued" insert "or created"; and

(b) after "paragraphs 38" insert ", 38A".

(5) In paragraph 38—

(a) in sub-paragraph (1), for the words from "by issuing to that patient" to the end substitute—

"by—

(**26**) S.I. 2004/629 as amended by S.I. 2004/3215.
(**27**) Regulation 4(1) was amended by S.I. 2002/548 and 2004/663.
(**28**) Regulation 7(1) was amended by S.I. 2000/3189 and 2002/2352.
(**29**) S.I. 2003/2382 as amended by S.I. 2004/663 and 936.

(a) issuing to that patient a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3); or

(b) where paragraph 38A(1) applies, creating and transmitting an electronic prescription,

and such a non-electronic prescription form, non-electronic repeatable prescription or electronic prescription shall not be used in any other circumstances.";

(b) in sub-paragraph (3)—

(i) for "such" substitute "non-electronic",

(ii) before "repeatable prescription", in the first place that it occurs, insert "non-electronic", and

(iii) omit from the words "and—" to the end;

(c) after sub-paragraph (3), insert—

"(3A) A prescription form or repeatable prescription shall not refer to any previous prescription form or repeatable prescription.

(3B) A separate prescription form or repeatable prescription shall be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 43.".

(d) in sub-paragraph (4)—

(i) after "buprenorphine" insert "or diazepam", and

(ii) in paragraph (a), before "prescription form" insert "non-electronic";

(e) in sub-paragraph (5), before "prescription form" insert "non-electronic"; and

(f) in sub-paragraphs (6) and (7)—

(i) after "issued" insert "or created", and

(ii) for paragraph (c), substitute—

"(c) he undertakes to—

(i) furnish the chemist within 72 hours with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3), or

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

(6) After paragraph 38 insert—

"**Electronic prescriptions**

38A.—(1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if—

(a) the contractor holds an agreement with a Primary Care Trust which is specified in directions issued by the Secretary of State under section 17 of the Act as being a Primary Care Trust which can authorise its contractors to use the ETP service(**30**);

(b) the patient to whom the prescription relates has—

(i) nominated one or more dispensers in his NHS Care Record,

(**30**) These directions will be available on the website of the National Programme for IT (www.npfit.nhs.co.uk) and published in the Drug Tariff.

(ii) confirmed that he intends to use that dispenser (or one of them) for the purposes of obtaining the drugs, medicines or appliances ordered on the electronic prescription in question, and

(iii) consents to the use of an electronic prescription on the particular occasion; and

(c) the prescription is not—

(i) for a controlled drug within the meaning of the Misuse of Drugs Act 1971(**31**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**32**),

(ii) for supply by instalments under paragraph 38(4), or

(iii) a bulk prescription issued for a school or institution under paragraph 43.

(2) In relation to a patient who is a child or an adult incapable of nominating a dispenser, sub-paragraph (1)(b) shall apply as if the reference to the patient to whom the prescription relates included a reference to—

(a) in the case of a child, that patient's parent or other person referred to in paragraph 14(4)(a); or

(b) in the case of an adult, that patient's relative or primary carer.

(3) A prescriber who orders drugs, medicines or appliances by means of an electronic prescription shall—

(a) in the case of an electronic repeatable prescription, issue the patient with a form provided by the Primary Care Trust for the purpose of recording details of that electronic repeatable prescription and linked to that electronic repeatable prescription by a number contained on the form; and

(b) in the case of an electronic prescription form, issue the patient, if he so requests, with a written record of the prescription which has been created.

Nomination of dispensers for the purpose of electronic prescriptions

38B.—(1) A contractor which operates the ETP service for its patients shall, if requested to do so by a patient, enter in that patient's NHS Care Record—

(a) where he does not have a nominated dispenser, the dispenser chosen by that patient; and

(b) where he does have a nominated dispenser—

(i) a replacement dispenser, or

(ii) a further dispenser,

chosen by that patient.

(2) Sub-paragraph (1)(b)(ii) shall not apply if the number of nominated dispensers would thereby exceed the maximum number permitted by the ETP service.

(3) Paragraph 14(4) shall apply in relation to requests under sub-paragraph (1) as it applies to applications for inclusion in a list of patients.

(4) A contractor—

(a) shall not seek to persuade a patient to nominate a dispenser recommended by the prescriber or the contractor; and

(**31**) 1971 c. 38. The relevant definition is in section 2 and Schedule 2 as amended by S.I. 1973/771, 1975/421, 1977/1243, 1979/299, 1983/765, 1984/859, 1985/1995, 1986/2230, 1989/1340, 1990/2589, 1995/1966, 1996/1300, 1998/750, 2001/3932 and 2003/1243 and 3201.

(**32**) S.I. 2001/3998; Schedule 4 was amended by S.I. 2003/1432.

(b) shall, if asked by the patient to recommend a chemist whom he might nominate as his dispenser, provide the patient with the list of all the chemists in the area who provide an ETP service as given to the contractor by the Primary Care Trust.".

(7) In paragraph 39 (repeatable prescribing services)—

(a) in sub-paragraph (2)—

(i) omit paragraphs (a) and (b), and

(ii) in paragraph (c), before "repeatable prescriptions" insert "non-electronic"; and

(b) in sub-paragraph (7)(b), for "regulation 20" substitute "regulation 60".

(8) In paragraph 40 (repeatable prescriptions)—

(a) in sub-paragraph (1), before "repeatable prescription" insert "non-electronic"; and

(b) for sub-paragraphs (2) to (4) substitute—

"(2) Where a prescriber wishes to make any change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on a person's repeatable prescription he must—

(a) in the case of a non-electronic repeatable prescription—

(i) notify the person, and

(ii) make reasonable efforts to notify the chemist providing repeat dispensing services to that person,

that the original repeatable prescription should no longer be used to obtain or provide repeat dispensing services and make arrangements for a replacement repeatable prescription to be issued to that person; or

(b) in the case of an electronic repeatable prescription—

(i) arrange with the ETP service for the cancellation of the original repeatable prescription in the person's NHS Care Record, and

(ii) create a replacement electronic repeatable prescription relating to that person and notify him that he has done so.

(3) A prescriber who has created an electronic repeatable prescription for a person must as soon as practicable arrange with the ETP service for its cancellation in that person's NHS Care Record if, before the expiry of that prescription—

(a) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his electronic repeatable prescription or no longer appropriate or safe for him to continue to receive repeatable prescribing services;

(b) he has issued the person with a non-electronic repeatable prescription in place of the electronic repeatable prescription; or

(c) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.

(4) Where a prescriber has cancelled a person's electronic repeatable prescription in accordance with sub-paragraph (3) he must, as soon as is practicable, notify that person.

(5) A prescriber who has issued a non-electronic repeatable prescription in respect of a person must, as soon as practicable, make reasonable efforts to notify the chemist that that repeatable prescription should no longer be used to provide repeat dispensing services to that person, if, before the expiry of that repeatable prescription—

(a) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his repeatable prescription or no

longer appropriate or safe for him to continue to receive repeatable prescribing services;

(b) he issues or creates a further repeatable prescription in respect of the person to replace the original repeatable prescription other than in the circumstances referred to in sub-paragraph (2)(a) (for example, because the person wishes to obtain the drugs, medicines or appliances from a different chemist); or

(c) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.

(6) Where the circumstances in sub-paragraph (5)(a) to (c) apply, the prescriber must as soon as practicable notify the person on whose behalf the non-electronic repeatable prescription was issued that that repeatable prescription should no longer be used to obtain repeat dispensing services.".

(9) In paragraph 41 (restrictions on prescribing by medical practitioners)—

(a) in sub-paragraph (2)(c), for "endorses the form with" substitute "includes on the prescription form"; and

(b) in sub-paragraph (3)(b), for "endorses the face of the form with" substitute "includes on the prescription form".

(10) In paragraph 42 (restrictions on prescribing by supplementary prescribers)—

(a) in sub-paragraph (1)(a), for "give" substitute "issue or create";

(b) omit sub-paragraphs (2)(b), (4)(c) and (f) and (6);

(c) in sub-paragraph (2)(d)(iii), for "giving a prescription, he endorses the face of the form with" substitute "issuing or creating a prescription, he includes on the prescription form";

(d) in sub-paragraph (3), for "give" substitute "issue or create"; and

(e) in sub-paragraph (4), in paragraphs (e)(iii) and (h)(iii), for "giving the prescription, he endorses the face of the form with" substitute "issuing or creating the prescription, he includes on the prescription form".

(11) In paragraph 43 (bulk prescribing), in sub-paragraphs (1) and (2), before "prescription form" insert "non-electronic".

(12) In paragraph 46 (provision of dispensing services by contractors other than Primary Care Trusts)—

(a) in sub-paragraph (1), for "regulation 20" substitute "regulation 60";

(b) in sub-paragraphs (4)(b) and (9)(a), for "regulation 12(15) or 13(13) of the Pharmaceutical Regulations as they apply pursuant to paragraph 47(5) or (6)" substitute "regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 47(5)"; and

(c) in sub-paragraph (9)(b)(ii), for "regulation 9(10)" substitute "regulation 31(9)".

(13) In paragraph 47 (consent to dispense)—

(a) in sub-paragraph (2), for "by the Primary Care Trust in accordance with regulations 12 and 13 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraphs (5) and (6)), as though it were an application under regulation 21 of those Regulations" substitute "in accordance with regulations 18, 33, 34 and 36 to 38 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraph (5)), as though it were an application for outline consent under regulation 61 of those Regulations";

(b) in sub-paragraph (4), for "regulation 12(16)" substitute "regulation 39(12)"; and

(c) for sub-paragraphs (5) and (6) substitute—

"(5) Regulations 18, 20(2), 33, 34, 36 and 38 of the Pharmaceutical Regulations shall apply as if—

(a) in regulations 18(2), 33(2) and (3) and 36(1), (3) and (9), the references to provisions being "subject to regulations 25 and 26" were omitted;

(b) in regulations 18(2)(b) and (c), 33(2)(j) and 34(1)(a), for the references to "regulation 61" there were substituted references to this paragraph;

(c) in regulations 20(2) and 38(2)(c), for the references to "regulation 60" there were substituted references to paragraph 46; and

(d) in regulation 38(14)(b), for the reference to "arrangements under regulation 60 for the provision by a doctor of pharmaceutical services" there were substituted a reference to arrangements under paragraph 46 for the provision by a contractor of dispensing services.".

(14) In paragraph 50 (terms relating to the provision of dispensing services)—

(a) in sub-paragraph (2)(a), for "on a prescription form completed in accordance with paragraph 38(3);" substitute—

"on—

(i) a non-electronic prescription form completed in accordance with paragraph 38(3), or

(ii) if the contractor is the patient's nominated dispenser (or one of them), an electronic prescription form;";

(b) for sub-paragraph (4), substitute—

"(4) Where a patient—

(a) presents to a contractor who may provide dispensing services an order on a non-electronic prescription form for drugs, medicines or appliances signed by an independent nurse prescriber, or an order for a restricted availability appliance signed by and endorsed with the reference "SLS" by an independent nurse prescriber; or

(b) informs a contractor who may provide dispensing services and who is his nominated dispenser (or one of them) that an independent nurse prescriber has ordered drugs, medicines or appliances for him by means of an electronic prescription form,

the contractor may, provided, in a case to which paragraph (b) applies, it has received the electronic prescription form from the ETP service, provide to the patient such of the drugs, medicines or appliances so ordered as it supplies in the normal course of its practice."; and

(c) for sub-paragraph (8), substitute—

"(8) A contractor providing dispensing services shall comply with paragraph 5 of Schedule 2 (terms of service of dispensing doctors) to the Pharmaceutical Regulations, as if modified as follows—

(a) for "paragraph 3, or in the circumstances set out in paragraph 4" there were substituted "paragraph 50(2) or (4) of Schedule 5 to the PMS Regulations"; and

(b) for "the dispensing doctor", in each place where it occurs, there were substituted "the contractor providing dispensing services".".

(15) In paragraph 68 (appraisal and assessment), in sub-paragraph (1)(b), for "NCAA" substitute "NPSA".

(16) In paragraph 75 (inquiries about prescriptions and referrals), in sub-paragraph (1)(a), after "issued" insert "or created".

(17) In paragraph 76 (reports to a medical officer), in sub-paragraph (1)(b), after "issued" insert "or created".

(18) In paragraph 78 (notifications to the relevant body), in sub-paragraph (b), omit "103,".

(19) In paragraph 80 (notice provisions specific to an agreement with a qualifying body)—

(a) in sub-paragraph (1), after paragraph (a) insert—

"(aa) a new director or secretary is appointed;";

(b) in sub-paragraph (2)(a), for "(d) and (f)" substitute "(d) or (f)"; and

(c) after sub-paragraph (2), insert—

"(3) A notice under sub-paragraph (1)(aa) shall confirm that the new director or, as the case may be, secretary meets the conditions imposed on directors and secretaries by virtue of regulation 5.".

(20) After paragraph 99 (termination by agreement), insert—

"**Termination on death**

99A.—(1) Where the agreement is with a single individual and that individual dies, the agreement shall terminate at the end of the period of seven days after the date of his death unless, before the end of that period the Primary Care Trust has agreed in writing with the contractor's personal representatives that the agreement should continue for a further period, not exceeding 28 days after the end of the period of seven days.

(2) Sub-paragraph (1) does not affect any other rights to terminate the agreement which the Primary Care Trust may have under paragraphs 104 to 107.".

(21) In paragraph 104 (termination by the relevant body for the provision of untrue etc information) for the words "by the contractor before the agreement" to the end substitute —

"by the contractor—

(a) before the agreement was entered into; or

(b) pursuant to paragraph 80(2) or (3),

in relation to the conditions set out in regulation 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.".

(22) In paragraph 105 (termination by the relevant body on fitness grounds), in sub-paragraph (1) after "the existence of the agreement" insert "or, if later, on or after the date on which a notice in respect of his compliance with the conditions in regulation 5 was given under paragraph 80(2) or (3)".

(23) In paragraph 107 (termination by the relevant body: remedial notices and breach notices), in sub-paragraphs (1) and (5), for "paragraphs 103 to 106" substitute "paragraphs 104 to 106".

(24) In paragraph 114 (insurance)—

(a) renumber the existing provision as sub-paragraph (1); and

(b) after that provision, insert—

"(2) In this paragraph, "insurance" has the same meaning as in paragraph 113.".

Amendment of Schedule 9 to the PMS Agreements Regulations

9. Schedule 9 (Primary Care Trusts specified for the purposes of repeatable prescribing) of the PMS Agreements Regulations is omitted.

PART 4

AMENDMENT OF THE PERFORMERS LISTS REGULATIONS

Amendment of regulation 4 of the Performers Lists Regulations

10. In regulation 4 (application for inclusion in a performers list) of the Performers Lists Regulations, for paragraph (4)(d) and (e) substitute—

"(d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995(**33**) (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(**34**) (penalty as alternative to prosecution);

(e) has, in proceedings in Scotland for an offence, been the subject of an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995 discharging him absolutely;".

Amendment of regulation 6 of the Performers Lists Regulations

11. In regulation 6 (decisions and grounds for refusal) of the Performers Lists Regulations, in paragraph (4)(f), for "to which Part I of the Sexual Offences Act 1997 applies, or if it had been committed in England or Wales, would have applied" substitute "for the purposes of Part 2 of the Sexual Offences Act 2003(**35**), or if it had been committed in England and Wales, would have been such an offence".

Amendment of regulation 9 of the Performers Lists Regulations

12. In regulation 9 (requirements with which a performer in a performers list must comply) of the Performers Lists Regulations, for paragraph (1)(d) and (e) substitute—

"(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, in proceedings in Scotland for an offence, been the subject of an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995 discharging him absolutely;".

Amendment of regulation 11 of the Performers Lists Regulations

13. In regulation 11 (criteria for a decision on removal) of the Performers Lists Regulations, in paragraph (2)(f), for "to which Part I of the Sexual Offences Act 1997 applies, or if it had been committed in England and Wales, would have applied" substitute "for the purposes of Part 2 of the Sexual Offences Act 2003, or if it had been committed in England and Wales, would have been such an offence".

(**33**) 1995 c. 46.
(**34**) 1992 c. 5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c. 47).
(**35**) 2003 c. 42.

PART 5

TRANSITIONAL PROVISIONS

Transitional arrangements in relation to telephone services and general medical services contracts

14.—(1) Where—

(a) pursuant to paragraph 104 of Schedule 6 to the GMS Contracts Regulations, a general medical services contract has been varied to include a term which gives effect to paragraph 1A of Schedule 6 to the GMS Contracts Regulations (as inserted by regulation 4(2) of these Regulations); and

(b) as a result of that variation, a contractor is, by virtue of a contract or other arrangement for the provision of telephone services which it entered into before the date on which that variation took effect, in breach of its general medical services contract,

no action shall be taken against the contractor by the Primary Care Trust in respect of that breach, provided that it complies with the conditions specified in paragraph (2).

(2) The conditions referred to in paragraph (1) are that the contractor—

(a) provides, within the time specified in the request, such details of the contract or other arrangement for telephone services as the Primary Care Trust may request; and

(b) varies or terminates that contract or other arrangement when required to do so by the Primary Care Trust in accordance with directions from the Secretary of State under section 17 of the Act.

Transitional arrangements in relation to telephone services and PMS agreements

15.—(1) Where—

(a) pursuant to paragraph 98 of Schedule 5 to the PMS Agreements Regulations, a PMS agreement has been varied to include a term which gives effect to paragraph 2A of Schedule 5 to the PMS Agreements Regulations (as inserted by regulation 8(2) of these Regulations); and

(b) as a result of that variation, a contractor is, by virtue of a contract or other arrangement for the provision of telephone services which it entered into before the date on which that variation took effect, in breach of its PMS agreement,

no action shall be taken against the contractor by the relevant body in respect of that breach, provided that it complies with the conditions specified in paragraph (2).

(2) The conditions referred to in paragraph (1) are that the contractor—

(a) provides, within the time specified in the request, such details of the contract or other arrangement for telephone services as the relevant body may request; and

(b) varies or terminates that contract or other arrangement when required to do so by the relevant body in accordance with directions from the Secretary of State under section 17 of the Act.

PART 6

REVOCATIONS

16. The National Health Service (General Medical Services Contracts) (Personal Medical Services Agreements) and (Pharmaceutical Services) (Amendment) Regulations 2005 (S.I. 2005/28) are revoked.

Signed on behalf of the Secretary of State

John Hutton
Minister of State,
Department of Health

22nd March 2005

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to certain regulations relating to primary medical services.

Part 2 amends the National Health Service (General Medical Services Contracts) Regulations 2004 ("the GMS Contracts Regulations"). In particular, it:

(a) provides for the introduction of electronic prescribing (regulations 2(2), (4)(b), (5), (8), (9), (11), (12), (15) and (17) and 4(4) to (6), (7)(a)(ii), (8), (9), (10)(a) and (c) to (e), (11), (14)(a) and (b), (17) and (18));

(b) makes amendments consequential on the repeal of the National Health Service (Pharmaceutical Regulations) 1992 and their replacement by the National Health Service (Pharmaceutical Regulations) 2005 (regulations 2(6), (7) and (14), 3 and 4(7)(b), (12), (13) and (14)(c));

(c) replaces references to the National Clinical Assessment Authority (which will cease to exist on 31st March 2005) with references to the National Patient Safety Agency (regulations 2(10) and (13) and 4(15));

(d) amends the definition of supplementary prescriber to include further health professionals (regulation 2(18));

(e) bans the use of telephone services for the purposes of general medical services contracts which make use of national rate numbers (starting with 087), premium rate numbers (starting with 090) or personal numbers starting with 070 (regulation 4(2));

(f) inserts provisions to enable the supply of medicines to patients by providers of out of hours services where certain conditions are met (regulation 4(3));

(g) extends the requirements for supply by instalments to diazepam (regulation 4(5)(d)(i));

(h) removes the requirement that contractors can only provide repeatable prescribing services if they hold a contract with specified Primary Care Trusts (regulations 4(7)(a)(i) and 5);

(i) removes the restrictions preventing supplementary prescribers from prescribing controlled drugs or unlicensed medicines (regulation 4(10)(b));

(j) removes the provision relating to the Quality Information Preparation Scheme which will cease to exist on 31st March 2005 (regulation 4(16));

(k) requires contractors who are companies limited by shares to notify the Primary Care Trust of a change of director or secretary and enables the Primary Care Trust to terminate the contract if untrue information is given about the compliance of that director or secretary with the conditions in regulation 5 of the GMS Contracts Regulations (regulation 4(19) and (23));

(l) enables a Primary Care Trust to vary a contract to allow it to continue at least for an interim period after the death of partner in a two-handed partnership even where the remaining individual is not a medical practitioner (regulation 4(20));

(m) provides that a contract with an individual medical practitioner shall terminate seven days after that practitioner's death unless before then arrangements have been made for it to continue for a further short period (regulation 4(21));

(n) enables a Primary Care Trust to continue a contract for a limited period with a medical practitioner who no longer meets the conditions in regulation 4 of the GMS Contracts Regulations if:

(i) the reason for that failure is an immediate or interim suspension or health suspension under the Medical Act 1983,

(ii) adequate arrangements are in place to provide clinical services during the period of suspension, and

(iii) immediate termination is not necessary on grounds of patient safety or to protect public funds (regulation 4(22)); and

(o) clarifies that the grounds for termination of the contract in paragraph 113 of Schedule 6 to the GMS Contracts Regulations only apply to partners, shareholders and directors who join the contracting body after the start of the contract in respect of circumstances which arise after they have so joined (prior circumstances being covered by paragraphs 85, 86 and 112 of that Schedule) (regulation 4(24)).

Part 3 of the Regulations makes amendments to the National Health Service (Personal Medical Services Agreements) Regulations 2004 ("the PMS Agreements Regulations") which, where relevant, mirror those made to the GMS Contracts Regulations. In addition, regulation 8(24) provides that the definition of insurance in paragraph 113 of Schedule 5 to the PMS Agreements Regulations also applies to paragraph 114. This is necessary to reflect the fact that some NHS bodies bear their own risks under a statutory scheme rather than taking out insurance.

Part 4 of the Regulations amends the National Health Service (Performers Lists) Regulations 2004. Regulations 10 and 12 amend references to Scottish legislation in regulations 4 and 9 of those Regulations. Regulations 11 and 13 replace references to Part 1 of the Sexual Offences Act 1997 (which has been repealed) with references to Part 2 of the Sexual Offences Act 2003.

Part 5 makes transitional arrangements in relation to general medical services contracts and personal medical services agreements where the contractor has, before the coming into force of these Regulations, entered into a contract or other arrangement for the provision of telephone services which will breach the ban on certain types of telephone services inserted by regulations 4(2) and 8(2) of these Regulations. Such contractors will be required to vary or terminate their existing telephone arrangements in accordance with directions from the Secretary of State.