

**2007 No. 3491**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Primary Medical Services)  
(Miscellaneous Amendments) Regulations 2007**

<i>Made</i> - - - -	<i>11th December 2007</i>
<i>Laid before Parliament</i>	<i>17th December 2007</i>
<i>Coming into force</i> - -	<i>28th January 2008</i>

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by sections 89, 94 and 272(7) and (8) of the National Health Service Act 2006(a):

**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 2007 and shall come into force on 28th January 2008.

(2) These Regulations apply in relation to England.

(3) In these Regulations—

“GMS Contracts Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004(b); and

“PMS Agreements Regulations” means the National Health Service (Personal Medical Services Agreements) Regulations 2004(c).

**PART 2**

**AMENDMENT OF THE GMS CONTRACTS REGULATIONS**

**Amendment of regulation 2 of the GMS Contracts Regulations**

2. In regulation 2(1) (interpretation) of the GMS Contracts Regulations—

(a) in the definition of “batch issue”—

(i) for “Prescription Pricing Authority”, substitute “Prescription Pricing Division of the NHS Business Services Authority”, and

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(a) 2006 c.41.

(b) S.I. 2004/291, as amended by S.I. 2004/906 and 2694, S.I. 2005/28, 893 and 3315 and S.I. 2006/1501.

(c) S.I. 2004/627, as amended by S.I. 2004/906 and 2694, S.I. 2005/28, 893 and 3315 and S.I. 2006/1501.

- (ii) for “version 1 dated June 2004” substitute “version 2 dated August 2006(a)”;
- (b) in the definition of “CCT”, omit “, including any such certificate awarded in pursuance of the competent authority functions of the Postgraduate Medical Education and Training Board specified in article 20(3)(a) of that Order”;
- (c) insert the following definitions after the definition of “health service body”—
  - ““home oxygen order form” means a form provided by the Primary Care Trust and issued by a health care professional to authorise a person to supply home oxygen services to a patient requiring oxygen therapy at home;
  - “home oxygen services” means any of the following forms of oxygen therapy or supply—
    - (a) ambulatory oxygen supply,
    - (b) urgent supply,
    - (c) hospital discharge supply,
    - (d) long term oxygen therapy, and
    - (e) short burst oxygen therapy;”; and
- (d) in the definition of “repeatable prescription”—
  - (i) for “Prescription Pricing Authority”, substitute “Prescription Pricing Division of the NHS Business Services Authority”, and
  - (ii) for “version 1 dated June 2004” substitute “version 2 dated August 2006”.

#### **Amendment of regulation 5 of the GMS Contracts Regulations**

**3.** In regulation 5 (general condition relating to all contracts) of the GMS Contracts Regulations, in paragraph (2)(i)(ii), after “Insolvency Act 1986” insert “or Schedule 2A to the Insolvency (Northern Ireland) Order 1989(b)”.

#### **Amendment of Schedule 6 to the GMS Contracts Regulations**

**4.** In Schedule 6 (other contractual terms) to the GMS Contracts Regulations—

- (a) in paragraph 15 (application for inclusion in a list of patients)—
  - (i) for sub-paragraph (4)(b), substitute—
    - “(b) on behalf of any adult who lacks the capacity to make such an application, or to authorise such an application to be made on their behalf, by a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005(c).”, and
  - (ii) in sub-paragraph (6)(b), for “incapable adult”, substitute “an adult who lacks capacity”;
- (b) in paragraph 17(3) (which relates to the refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident), for “incapable adult”, substitute “an adult who lacks capacity”;
- (c) in paragraph 18(1)(a) (which relates to patient preference of practitioner), for “incapable adult”, substitute “an adult who lacks capacity”;
- (d) for paragraph 19(5)(b) (which relates to removal from the list at the request of the patient), substitute—
  - “(b) in the case of an adult patient who lacks the capacity to make the relevant request or receive the relevant advice, information or notification, a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person

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(a) This document is available at [http://www.ppa.org.uk/ppa/prescform\\_overspec.htm](http://www.ppa.org.uk/ppa/prescform_overspec.htm).  
 (b) S.I. 1989/2405 (N.I. 19).  
 (c) 2005 c. 9.

or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005.”;

(e) for paragraph 38 (prescribing), substitute—

“38. The contractor shall ensure that—

- (a) any prescription form or repeatable prescription for drugs, medicines or appliances issued or created by a prescriber; and
- (b) any home oxygen order form issued by a health care professional,

complies as appropriate with the requirements in paragraphs 39, 39A and 41 to 44.”;

(f) in paragraph 39 (which relates to prescribing)—

(i) in sub-paragraph (1), after “Subject to” insert “sub-paragraph (1A) and to”,

(ii) after sub-paragraph (1), insert—

“(1A) A health care professional shall order any home oxygen services which are needed for the treatment of any patient who is receiving treatment under the contract by issuing a home oxygen order form.”, and

(iii) after sub-paragraph (3B), insert—

“(3C) A home oxygen order form shall be signed by a health care professional.”;

(g) in paragraph 39A (electronic prescriptions)—

(i) after sub-paragraph (1) insert—

“(1A) A health care professional may not order home oxygen services by means of an electronic prescription.”,

(ii) in sub-paragraph (2), for “an adult incapable of nominating a dispenser”, substitute “an adult who lacks the capacity to nominate a dispenser”, and

(iii) for sub-paragraph (2)(b), substitute—

“in the case of an adult, that patient’s relative, primary carer, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005.”;

(h) for paragraph 66(2)(b) (which relates to signing of documents), substitute—

“(b) any other clinical documents, apart from—

- (i) home oxygen order forms, and
- (ii) those documents specified in sub-paragraph (3).”;

(i) in paragraph 93(b) (which relates to the making of complaints), for “is incapable of making a complaint”, substitute “lacks the capacity to make a complaint”;

(j) in paragraph 113(2)(j)(ii) (which relates to other grounds for termination by the Primary Care Trust), after “Insolvency Act 1986” insert “or Schedule 2A to the Insolvency (Northern Ireland) Order 1989”;

(k) in paragraphs 115(1) and (5) (which relate to termination by the Primary Care Trust: remedial notices and breach notices), for “specified in paragraphs 111 to 114” substitute “specified in paragraphs 111 to 114A”;

(l) in paragraph 120(1) (which relates to consultation with the Local Medical Committee), for sub-paragraphs (a) and (b) substitute—

“(a) terminating the contract pursuant to paragraph 112, 113, 114, 115(4) or (6) or 116;

(b) which of the alternative notices in writing available under the provisions of paragraph 114A it will serve; or

(c) imposing a contract sanction.”;

(m) in paragraph 121(1) (which relates to clinical governance), after “effective system of clinical governance” insert “which shall include appropriate standard operating procedures in relation to the management and use of controlled drugs”; and

(n) after paragraph 121 (clinical governance), insert the following—

“**121A.** The contractor shall co-operate with the Primary Care Trust in the discharge of any obligations of the Primary Care Trust or its accountable officer under the Controlled Drugs (Supervision of Management and Use) Regulations 2006(a).”.

## PART 3

### AMENDMENT OF THE PMS AGREEMENTS REGULATIONS

#### **Amendment of regulation 2 of the PMS Agreements Regulations**

**5.** In regulation 2 (interpretation) of the PMS Agreements Regulations—

(a) in the definition of “batch issue”—

(i) for “Prescription Pricing Authority”, substitute “Prescription Pricing Division of the NHS Business Services Authority”, and

(ii) for “version 1 dated June 2004” substitute “version 2 dated August 2006(b)”;

(b) in the definition of “CCT”, omit “, including any such certificate awarded in pursuance of the competent authority functions of the Postgraduate Medical Education and Training Board specified in article 20(3)(a) of that Order”;

(c) insert the following definitions after the definition of “health service body”—

““home oxygen order form” means a form provided by the Primary Care Trust and issued by a health care professional to authorise a person to supply home oxygen services to a patient requiring oxygen therapy at home;

“home oxygen services” means any of the following forms of oxygen therapy or supply—

(a) ambulatory oxygen supply,

(b) urgent supply,

(c) hospital discharge supply,

(d) long term oxygen therapy, and

(e) short burst oxygen therapy;”;

(d) in the definition of “repeatable prescription”—

(i) for “Prescription Pricing Authority”, substitute “Prescription Pricing Division of the NHS Business Services Authority”, and

(ii) for “version 1 dated June 2004” substitute “version 2 dated August 2006”.

#### **Amendment of regulation 5 of the PMS Agreements Regulations**

**6.** In regulation 5 (general condition relating to all agreements) of the PMS Agreements Regulations, in paragraph (3)(i)(ii), after “Insolvency Act 1986” insert “or Schedule 2A to the Insolvency (Northern Ireland) Order 1989”(c).

#### **Amendment of Schedule 5 to the PMS Agreements Regulations**

**7.** In Schedule 5 (other contractual terms) to the PMS Agreements Regulations—

(a) in paragraph 14 (application for inclusion in a list of patients)—

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

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(a) S.I. 2006/3148.

(b) This document is available at [http://www.ppa.org.uk/ppa/prescform\\_overspec.htm](http://www.ppa.org.uk/ppa/prescform_overspec.htm).

(c) S.I. 1989/2405 N.I. 19.

- “(b) on behalf of any adult who lacks the capacity to make such an application, or to authorise such an application to be made on their behalf, by a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005(a).”, and
- (ii) in sub-paragraph (6)(b), for “incapable adult”, substitute “an adult who lacks capacity”;
- (b) in paragraph 16(3) (which relates to the refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident), for “incapable adult”, substitute “an adult who lacks capacity”;
- (c) in paragraph 17(1)(a) (which relates to patient preference of practitioner), for “incapable adult”, substitute “an adult who lacks capacity”;
- (d) for paragraph 18(5)(b) (which relates to removal from the list at the request of the patient), substitute—
- “(b) in the case of an adult patient who lacks the capacity to make the relevant request or receive the relevant advice, information or notification, a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005.”;
- (e) for paragraph 37(1) (which relates to prescribing), substitute—
- “37.—(1) The contractor shall ensure that—
- (a) any prescription form or repeatable prescription for drugs, medicines or appliances issued or created by a prescriber; and
- (b) any home oxygen order form issued by a health care professional,
- complies as appropriate with the requirements in paragraphs 38, 38A and 40 to 43.”;
- (f) in paragraph 38 (which relates to prescribing)—
- (i) in sub-paragraph (1), after “Subject to” insert “sub-paragraph (1A) and to”,
- (ii) after sub-paragraph (1) insert—
- “(1A) A health care professional shall order any home oxygen services which are needed for the treatment of any patient who is receiving treatment under the contract by issuing a home oxygen order form.”, and
- (iii) after sub-paragraph (3B), insert—
- “(3C) A home oxygen order form shall be signed by a health care professional.”;
- (g) in paragraph 38A (electronic prescriptions)—
- (i) after sub-paragraph (1) insert—
- “(1A) A health care professional may not order home oxygen services by means of an electronic prescription.”,
- (ii) in sub-paragraph (2), for “an adult incapable of nominating a dispenser”, substitute “an adult who lacks the capacity to nominate a dispenser”, and
- (iii) for sub-paragraph (2)(b), substitute—
- “in the case of an adult, that patient’s relative, primary carer, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005.”;
- (h) in paragraph 45 (dispensing services: general), for “paragraph 49”, substitute “paragraphs 49 and 49A”;
- (i) for paragraph 49 (provision of dispensing services by Primary Care Trusts), substitute—

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(a) 2005 c. 9.

“49. A Primary Care Trust may provide dispensing services to its registered patients under the agreement only if one or more of the medical practitioners performing services under the agreement is authorised or required to provide pharmaceutical services under regulation 60 of the Pharmaceutical Regulations (arrangements for provision of pharmaceutical services by doctors) and only to the extent of such authorisation or requirement.”;

(j) after paragraph 49, insert—

**“Primary Care Trusts who have previously provided dispensing services with the consent of the Strategic Health Authority**

**49A.**—(1) This paragraph (which shall cease to have effect on 30th October 2009) applies where a Primary Care Trust, immediately prior to 28th January 2008, was providing dispensing services to some or all of its patients under the agreement with the consent of the Strategic Health Authority.

(2) In a case to which this paragraph applies the Primary Care Trust shall be regarded as providing such dispensing services in accordance with paragraph 49, and as though one or more of the medical practitioners performing services under the agreement were authorised or required to provide pharmaceutical services under regulation 60 of the Pharmaceutical Regulations (arrangements for provision of pharmaceutical services by doctors), to any patient—

(i) to whom, immediately before 28th January 2008, the Primary Care Trust provided dispensing services with the consent of the Strategic Health Authority, and

(ii) who wishes the Primary Care Trust to continue to provide him with such services.”;

(k) for paragraph 66(2)(b) (which relates to the signing of documents), substitute—

“(b) any other clinical documents, apart from—

(i) home oxygen order forms, and

(ii) those documents specified in sub-paragraph (3).”;

(l) in paragraph 87(b) (which relates to the making of complaints), for “is incapable of making a complaint”, substitute “lacks the capacity to make a complaint”;

(m) in paragraph 105(3)(i)(ii) (which relates to termination by the relevant body on fitness grounds), after “Insolvency Act 1986” insert “or Schedule 2A to the Insolvency (Northern Ireland) Order 1989”;

(n) in paragraphs 107(1) and (5) (which relate to termination by the relevant body: remedial notices and breach notices), for “specified in paragraphs 104 to 106” substitute “specified in paragraphs 104 to 106A”;

(o) in paragraph 112(1) (which relates to clinical governance), after “effective system of clinical governance” insert “which shall include appropriate standard operating procedures in relation to the management and use of controlled drugs”; and

(p) after paragraph 112 (clinical governance), insert—

**“112A.** The contractor (other than a contractor which is a Primary Care Trust) shall co-operate with the Primary Care Trust in the discharge of any obligations of the Primary Care Trust or its accountable officer under the Controlled Drugs (Supervision of Management and Use) Regulations 2006(a).”.

**Amendment of Schedule 7 to the PMS Agreements Regulations**

**8.** In Schedule 7 (modification of patient provisions where the contractor is a Primary Care Trust) to the PMS Agreements Regulations—

(a) in paragraph 3(b), for “incapable adult” in the substituted paragraph 14(6), substitute “an adult who lacks capacity”; and

(b) in paragraph 6, for the substituted paragraph 18(4)(b), substitute—

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(a) S.I. 2006/3148.

“(b) in the case of an adult patient who lacks the capacity to make the relevant request or receive the relevant advice, information or notification, a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005.”.

Signed by authority of the Secretary of State for Health

11th December 2007

*Ben Bradshaw*  
Minister of State  
Department of health

## 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) updates the definitions of “batch issue” and “repeatable prescription”;
- (b) makes changes relating to the method by which home oxygen services may be ordered;
- (c) makes amendments to references to “incapable adults”, and to those who may act on their behalf, to reflect the terms used in and the provisions of the Mental Capacity Act 2005;
- (d) makes amendments to the provisions relating to the contractor’s clinical governance system to provide that such systems must include standard operating procedures in relation to the management and use of controlled drugs and also makes amendments which require contractors to co-operate in the discharge of any obligations of the Primary Care Trust or its accountable officer in relation to the management and use of controlled drugs; and
- (e) makes minor changes to the restrictions on those who are eligible to contract to provide primary medical services and to the provisions relating to the service of remedial and breach notices.

Part 3 makes amendments to the National Health Service (Personal Medical Services Agreements) Regulations 2004 (“the PMS Agreements Regulations”) which mirror those made in the GMS Contracts Regulations. It also makes amendments to the procedure by which dispensing services may be provided to registered patients under the contract where the PMS provider is a Primary Care Trust.

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