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## DIRECTIONS

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### **NATIONAL HEALTH SERVICE ACT 1977**

#### **The National Health Service (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006**

The Secretary of State for Health gives the following directions in exercise of the powers conferred by sections 16D, 17, 41A, 41B and 126(4) of the National Health Service Act 1977(a) and paragraphs 2(3), (4) and (6), 4(6) and 7(1) and (4) of Schedule 2 to the Health and Social Care Act 2001(b).

#### **Citation, commencement and application**

1.—(1) These Directions may be cited as the National Health Service (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006, and—

- (a) except for directions 2(a), (c) and (d) and 3(2)(b) and (4) shall come into force on 1st April 2006;
- (b) directions 2(a), (c) and (d) and 3(2)(b) and (4) shall come into force on 1st May 2006.

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

#### **Amendment of the Primary Care Trusts Out of Hours Services (Supply of Medicines etc.) Directions 2005**

2. In direction 1(2) of the Primary Care Trusts Out of Hours Services (Supply of Medicines etc.) Directions 2005(c) (which relates to interpretation)—

- (a) in the definition of “independent nurse prescriber”, for paragraph (b) substitute the following paragraph—
  - “(b) against whose name in that register is recorded an annotation signifying that he is qualified to order drugs, medicines and appliances as a community practitioner nurse prescriber or as a nurse independent prescriber;”;
- (b) for the definition of “local pharmaceutical services” substitute the following definition—

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(a) 1977 c.49. Section 16D of the 1977 Act was substituted by the Health Act 1999 (c.8) (“the 1999 Act”), section 12(1), and amended by the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”), Schedule 1, paragraph 6. Section 17 of the 1977 Act is as substituted by the 1999 Act, section 12(1), and thereafter amended by the Health and Social Care Act 2001 (c.15) (“the 2001 Act”), Schedule 5, paragraph 5(3), and the 2002 Act, Schedule 1, paragraph 7. Section 41A of the 1977 Act was inserted into the 1977 Act by the National Health Service (Primary Care) Act 1997 (c. 46) (“the 1997 Act”), section 27(1); and has been amended by the 2001 Act, section 43(1) and the 2002 Act, Schedule 2, Part 1, paragraphs 1 and 14. Section 41B was inserted into the 1977 Act by the 1997 Act, section 28(1), and has been amended by the 2002 Act, Schedule 2, Part 1, paragraphs 1 and 15. Section 126(4) of the 1977 Act was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2). As regards Wales, the functions of the Secretary of State under the 1977 Act were transferred to the National Assembly for Wales by virtue of article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672), as amended by section 66(5) of the 1999 Act and as read with section 40(1) of the 2002 Act.

(b) 2001 c.15; relevant amendments have been made by the Health and Social Care (Community Health and Standards) Act 2003 (c.43) (“the 2003 Act”), Schedule 2, paragraphs 71 and 80.

(c) Available on [www.dh.gov.uk](http://www.dh.gov.uk).

““local pharmaceutical services” means such services of a kind which may be provided under section 41 of the Act or by virtue of section 41A of the Act (other than practitioner dispensing services) as are prescribed by regulations under paragraph 1(3) of Schedule 8A to the Act(a) or section 28 of the Health and Social Care Act 2001(b);”;

- (c) after the definition of “Patient Group Direction” insert the following definition—  
““pharmacist independent prescriber” has the meaning given in regulation 2(1) of the National Health Service (Pharmaceutical Services) Regulations 2005(c);”;
- (d) in the definition of “prescriber”, after paragraph (a) insert the following paragraph—  
“(aa) a pharmacist independent prescriber;”;
- (e) in paragraph (a) of the definition of “supplementary prescriber”, after sub-paragraph (i) insert the following sub-paragraph—  
“(ia) the register of optometrists maintained by the General Optical Council in pursuance of section 7 (register of opticians) of the Opticians Act 1989(d);”.

### **Amendment of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2005**

**3.**—(1) The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2005(e) are amended in accordance with this direction.

- (2) In direction 2 (interpretation)—
- (a) insert the following definition at the appropriate place in the alphabetical order—  
““financial year” means the period of twelve months ending on 31st March in any year;”;  
”; and
- (b) insert the following definition at the appropriate place in the alphabetical order—  
““pharmacist independent prescriber” has the meaning given in regulation 2(1) of the Pharmaceutical Services Regulations;”;

(3) In direction 3 (advanced services: Medicines Use Review and Prescription Intervention Service)—

- (a) for paragraph (4) substitute the following paragraphs—  
“(4) Subject to paragraph (4A), the second condition is that the MUR services are provided at an acceptable location, and for these purposes, an “acceptable location” means—  
(a) an area for confidential consultations within the pharmacist’s pharmacy, which is—  
(i) clearly designated as an area for confidential consultations,  
(ii) distinct from the general public areas of the pharmacy, and  
(iii) an area where both the person receiving MUR services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff),  
except that paragraphs (i) and (ii) shall not apply in circumstances where the pharmacy is closed to other members of the public;

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(a) Schedule 8A was inserted into the 1977 Act by the 2001 Act, section 40(2) and Schedule 3, and has been amended by the 2002 Act, Schedule 2, paragraph 8 and Schedule 9, Part 1, and by the 2003 Act, Schedule 11, paragraph 41.

(b) Section 28 has been amended by the 2002 Act, Schedule 2, paragraphs 71 and 73 and Schedule 9, Part 1, and the 2003 Act, Schedule 4, paragraphs 115 and 117, and Schedule 11, paragraphs 69 and 91.

(c) S.I. 2005/641. The relevant amendment will be introduced by the National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations 2006.

(d) 1989 c.44; section 7 was amended by S.I. 2005/848.

(e) Signed on 31st March 2005 and available on [www.dh.gov.uk](http://www.dh.gov.uk). These Directions were amended by the NHS Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2005, signed on 6th December and available on [www.dh.gov.uk](http://www.dh.gov.uk).

- (b) an area for confidential consultations which is not at the pharmacist's pharmacy but which—
    - (i) is clearly designated as an area for confidential consultations—
    - (ii) is distinct from the general public areas of the premises in which it is situated, and
    - (iii) is an area where both the person receiving MUR services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person, and the Primary Care Trust has approved the premises where the area is situated as being premises at which MUR services may be provided (and that approval has not been withdrawn); or
  - (c) premises to which neither sub-paragraph (a) or (b) applies, but which are —
    - (i) premises as regards which the pharmacist has obtained the approval of the Primary Care Trust to provide MUR services to a particular patient on a particular occasion, or
    - (ii) premises or a category of premises as regards which the pharmacist has obtained the approval of the Primary Care Trust (which has not been withdrawn) to provide MUR services to a particular category of patients, in such circumstances and subject to such conditions as the Primary Care Trust may have specified (which the Primary Care Trust may vary without withdrawing its approval).
- (4A) A pharmacist may provide MUR services other than at an acceptable location, if he does so—
- (a) by telephone to a particular patient on a particular occasion;
  - (b) in circumstances where the telephone conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer); and
  - (c) having obtained the approval of the Primary Care Trust to do so on that occasion.”;
- (b) for sub-paragraphs (b) to (d) of paragraph (6) substitute the following sub-paragraphs—
- “(b) MUR services are only provided—
- (i) at an acceptable location, except in the circumstances set out in paragraph (4A), and
  - (ii) at a location for which the PCT's approval is required by virtue of paragraph (4)(b) or (c) for the location to be considered acceptable, if the necessary approval has been given by the PCT and has not been withdrawn;
- (c) where MUR services are provided other than at an acceptable location, they are only provided by telephone, and with its approval, to a particular patient on a particular occasion;
- (d) no more than 250 MUR services consultations may be carried out under the arrangements with a pharmacist to provide those services, whether at an acceptable location or in the circumstances set out in paragraph (4A), in any financial year;”;
- (c) in sub-paragraph (e) of paragraph (6), after “an MUR service consultation” insert “which is not triggered by concerns over patient concordance”; and
- (d) omit paragraph (6A)(a).
- (4) In direction 4 (enhanced services)—
- (a) after paragraph (1), insert the following paragraph—

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(a) Inserted by the NHS Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2005, signed on 6th December and available on [www.dh.gov.uk](http://www.dh.gov.uk).

“(1A) Each Primary Care Trust is authorised to arrange for the provision of an Independent Prescribing Service, the underlying purpose of which is to provide a framework within which pharmacist independent prescribers may act as such under arrangements to provide an additional pharmaceutical service between the Primary Care Trust and a person included in the Primary Care Trust’s pharmaceutical list or in a pharmaceutical list of a neighbouring Primary Care Trust.”; and

(b) in paragraph (2), for “paragraph (1)” substitute “paragraphs (1) and (1A)”.

#### **Amendment of the National Health Service Litigation Authority (Functions) (England) Directions 2005**

**4.** In the National Health Service Litigation Authority (Functions) (England) Directions 2005(a)—

(a) in direction 2(1) (interpretation), for the definition of “local pharmaceutical services” substitute the following definitions—

““local pharmaceutical services” means such services of a kind which may be provided under section 41 of the Act or by virtue of section 41A of the Act (other than practitioner dispensing services) as are prescribed by regulations under paragraph 1(3) of Schedule 8A to the Act or section 28 of the Health and Social Care Act 2001;

“LPS scheme” has the meaning given in paragraph 1(2) of Schedule 8A to the Act;”;

(b) in direction 8 (exercise of miscellaneous functions by the Authority)—

(i) in paragraph (3)(d), after “pharmacy pilot scheme” insert “or an LPS scheme”, and

(ii) in paragraph (3)(e)(ii), for “the pilot scheme” substitute “a pharmacy pilot scheme or LPS scheme”; and

(c) after direction 8 insert the following direction—

#### **“Functions relating to local pharmaceutical services**

**8A.**—(1) The following functions of the Secretary of State shall be exercisable on his behalf by the Authority—

(a) subject to paragraph (2), the functions of the Secretary of State under the terms of LPS schemes specified in accordance with paragraphs 21 (dispute resolution: non-NHS contracts), 22 (NHS dispute resolution procedure) and 23 (determination of dispute) of Schedule 2 to the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (“the LPS Regulations”);

(b) the function of determining an appeal by a qualifying pharmacist in accordance with paragraph 25(9) to (11) (determination of pharmacy opening hours instigated by the pharmacist) of Schedule 1 to the National Health Service (Pharmaceutical Services) Regulations 2005(b), as that paragraph applies in relation to pharmacy pilot schemes by virtue of direction 9(3) (hours of opening) of the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005 (“the LPS ESP Directions”); and

(c) the functions under the terms included in LPS agreements in accordance with direction 18 (disputes) of the Primary Care Trusts Preparation of Proposals and Implementation of Pilot Schemes (Local Pharmaceutical Services) Directions 2005(c) (“the Pilot Schemes Directions”) of—

(i) appointing an adjudicator under paragraph 1, and

(ii) receiving requests for dispute resolution under paragraph 2,

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(a) Signed on 31st March 2005 and available on [www.dh.gov.uk](http://www.dh.gov.uk).

(b) S.I. 2005/641.

(c) Signed on 29th April 2005 and available at [www.dh.gov.uk](http://www.dh.gov.uk).

of Schedule 2 to the Pilot Schemes Directions, as those paragraphs apply in relation to pharmacy pilot schemes by virtue of direction 20 of the LPS ESP Directions 2005.

(2) The Authority shall not, pursuant to paragraph (1)(a) exercise the Secretary of State's functions in relation to any dispute relating to termination by the Primary Care Trust pursuant to a term required by virtue of paragraph 29 of Schedule 2 to the LPS Regulations (termination by a Primary Care Trust on grounds of suitability etc.), in so far as the dispute requires a determination as to whether a person falls within paragraph 29(2)."

### **Revocation of the Primary Care Trusts Preparation of Proposals and Implementation of Pilot Schemes (Local Pharmaceutical Services) Directions 2005, and saving provision**

**5.**—(1) The Primary Care Trusts Preparation of Proposals and Implementation of Pilot Schemes (Local Pharmaceutical Services) Directions 2005 ("the LPS Directions") are revoked.

(2) But by virtue of directions 3(1) and 20 of the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005 ("the LPS ESP Directions"), the following provisions of the LPS Directions continue to apply, as modified by direction 3(2) of the LPS ESP Directions, as regards ESP pilot schemes—

- (a) direction 7 (publication of pilot schemes);
- (b) direction 10 (charges for the provision of local pharmaceutical services);
- (c) direction 14 (endorsement and dispatch of prescription forms);
- (d) direction 15 (endorsement and dispatch of repeatable prescriptions and batch issues);
- (e) direction 16 (overpayments); and
- (f) direction 18 (disputes) and Schedule 2 (dispute resolution procedure),

and for these purposes the references in directions 14(b) and 15(b) to the Prescription Pricing Authority shall be construed as references to the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(a);

### **Amendment of the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005**

**6.** In the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005(b)—

- (a) in direction 1(3) (which relates to interpretation)—
  - (i) in the definition of "LPS Directions", after "29th April 2005" insert ", as they had effect on 31st March 2006", and
  - (ii) insert the following definition at the appropriate place in the alphabetical order—

““NHS Business Services Authority” means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005;”;
- (b) in direction 2(a) (which relates to the application of the Directions, after "EPS pilot schemes" insert "(proposals have to have been submitted by 31st October 2005(c))";
- (c) for paragraph (1) of direction 3 (application of LPS Directions, the Pharmaceutical Regulations and Advanced and Enhanced Services Directions) substitute the following paragraph—

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(a) S.I. 2005/2414.

(b) Signed on 28th October 2005 and amended by the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) Directions 2005. The Directions are available at [www.dh.gov.uk](http://www.dh.gov.uk).

(c) See direction 6(1) of the amended Directions.

“(1) The LPS Directions continue to apply to ESP pilot schemes and the implementation of them, but only as expressly provided for in direction 20.”; and

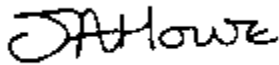
(d) in the following provisions—

- (i) direction 14(5) (remuneration),
  - (ii) direction 19 (notifications to Prescription Pricing Authority), and in the heading of that direction, and
  - (iii) direction 21(4) (termination),
- for “Prescription Pricing Authority” substitute “NHS Business Services Authority”.

**Revocation of the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2005**

7. The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2005(a) are revoked.

Signed by authority of the Secretary of State for Health



*J.A. Howe*  
A member of the Senior Civil Service  
Department of Health

8 March 2006

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(a) Signed on 6th December 2005 and available at [www.dh.gov.uk](http://www.dh.gov.uk).