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STATUTORY INSTRUMENTS

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**2010 No. 915**

**NATIONAL HEALTH SERVICE,  
ENGLAND AND WALES**

**The National Health Service (Reimbursement of  
the Cost of EEA Treatment) Regulations 2010**

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|-------------------------------|---------|------------------------|
| <i>Made</i>                   | - - - - | <i>23rd March 2010</i> |
| <i>Laid before Parliament</i> |         | <i>26th March 2010</i> |
| <i>Coming into force</i>      | - -     | <i>1st June 2010</i>   |

The Secretary of State in the exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972<sup>(1)</sup> and by sections 7, 272(7) and 273(4) of the National Health Service Act 2006<sup>(2)</sup>, makes the following Regulations.

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to the National Health Service<sup>(3)</sup>.

**PART 1**

**INTRODUCTORY**

**Citation, commencement, extent and interpretation**

1.—(1) These Regulations may be cited as the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 and come into force on 1 June 2010.

(2) These Regulations extend to England and Wales only.

(3) In these Regulations—

“the NHS Act” means the National Health Service Act 2006,

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- (1) [1972 c.68](#). By virtue of the amendment to section 1(2) of the European Communities Act 1972 by section 1 of the European Economic Area Act 1993 ([c.51](#)), regulations may be made under section 2(2) of the European Communities Act to implement obligations of the United Kingdom created or arising by or under the EEA Agreement.
- (2) [2006 c. 41](#); by virtue of section 271 of the National Health Service Act 2006, the powers conferred on the Secretary of State by that Act, as exercised in these Regulations, are exercisable only in relation to England. *See* section 275(1) for the definition of “regulations”.
- (3) [S.I. 2001/3495](#).

“the NHS (Wales) Act” means the National Health Service (Wales) Act 2006(4).

## PART 2

### AMENDMENTS TO THE NATIONAL HEALTH SERVICE ACT 2006

#### Reimbursement of the costs of treatment in another EEA state (England)

2. After section 6 of the NHS Act, insert—

##### “Reimbursement of cost of services provided in another EEA state

**6A.**—(1) The Secretary of State must, on an application made by any person, reimburse to that person the amount of any qualifying EEA expenditure incurred by that person on or after 23 August 2010, but this is subject to subsections (5) and (6), to any limit applicable under subsection (8) and to any deduction applicable under subsection (9).

(2) For the purpose of this section, “qualifying EEA expenditure” is expenditure incurred on the provision by an authorised provider, in an EEA state other than the United Kingdom, to a person ordinarily resident in England (“the patient”) of a service as respects which condition A or condition B is met.

(3) Condition A is that the service—

- (a) was necessary to treat or diagnose a medical condition of the patient,
- (b) is the same as or equivalent to a service that the Secretary of State or a responsible authority would make or have made available to the patient under this Act in the circumstances of the patient’s case, and
- (c) is not a special service.

(4) Condition B is that before the service was provided the Secretary of State had given authorisation under section 6B for the provision of the service to the patient.

(5) The duty in subsection (1) does not apply where the applicant incurred the qualifying expenditure in connection with an arrangement which was entered into by the applicant in the course of business and under which the applicant has gained or might be expected to gain any financial benefit.

(6) This section does not apply in circumstances where Article 20 or 27(3) of Regulation (EC) No. 883/2004 apply.

(7) Subsections (8) and (9) apply where the service is the same as or equivalent to a service that the Secretary of State or a responsible authority would have made available to the patient under this Act in the circumstances of the patient’s case.

(8) The Secretary of State may limit the amount of any reimbursement under this section—

- (a) in relation to a service other than a dental service, to the cost that the Secretary of State or a responsible authority would have incurred if the same or an equivalent service had been made available by either of them, and
- (b) in relation to a dental service, to the average cost that the Secretary of State or a responsible authority would have incurred if the same or an equivalent service had been made available by either of them.

(9) The Secretary of State may deduct from any reimbursement under this section the amount of any NHS charge which would have been payable for the same service or an equivalent service if the service had been made available by the Secretary of State or a responsible authority; and in determining for this purpose the amount of any NHS charge regard shall be had to any entitlement the patient would have had—

- (a) to any payment or contribution by virtue of regulations made under section 180(1) or (3), or
- (b) to any remission or repayment by virtue of regulations made under section 182.

(10) The Secretary of State may determine—

- (a) the form in which an application under this section must be made, and
- (b) the information to be provided in support of the application.

(11) In this section and section 6B—

“authorised provider”, in relation to any service provided in an EEA state other than the United Kingdom, means a person who is lawfully providing that service;

“NHS charge” means a charge payable under regulations made under section 172(1), 176(1) or 179(1);

“responsible authority” means, in relation to a patient, a Strategic Health Authority or Primary Care Trust responsible under or by virtue of this Act for providing or securing the provision of services for the benefit of the patient;

“special service” means—

- (a) a service that involves a stay in hospital accommodation for at least one night,
- (b) medical treatment that involves general anaesthesia, epidural anaesthesia or intravenously administered sedation,
- (c) dental treatment that involves general anaesthesia or intravenously administered sedation, or
- (d) a service whose provision involves the use of specialised or cost-intensive medical infrastructure or medical equipment;

“service” includes any goods, including drugs, medicines and appliances, which are used or supplied in connection with the provision of a service, but does not include accommodation other than hospital accommodation.

### **Prior authorisation for the purposes of section 6A**

**6B.**—(1) A person may apply to the Secretary of State under this section for prior authorisation for the purposes of section 6A in relation to the provision of a service (“the requested service”) to a person ordinarily resident in England (“the patient”).

(2) The requested service must be—

- (a) a special service, or
- (b) a service that is neither the same as nor equivalent to a service that the Secretary of State or a responsible authority would make available to the patient under this Act in the circumstances of the patient’s case.

(3) The Secretary of State may determine—

- (a) the form in which an application under this section must be made, and
- (b) the information to be provided in support of the application.

(4) The Secretary of State—

- (a) must authorise the provision of the requested service if it is a special service and the conditions in subsection (5) are met, and
  - (b) may authorise the provision of the requested service in any other case where the requested service is necessary to treat or diagnose a medical condition of the patient.
- (5) The conditions referred to in subsection (4)(a) are—
- (a) that the requested service is necessary to treat or diagnose a medical condition of the patient,
  - (b) that the requested service is the same as or equivalent to a service that the Secretary of State or a responsible authority would make available to the patient in the circumstances of the patient’s case, and
  - (c) that the Secretary or State or a responsible authority cannot provide to the patient a service that is the same as or equivalent to the requested service within a period of time that is acceptable on the basis of medical evidence as to the patient’s clinical needs, taking into account the patient’s state of health at the time the decision under this section is made and the probable course of the medical condition to which the service relates.
- (6) The matters to which the Secretary of State is to have regard in determining for the purpose of subsection (5)(c) whether the length of any delay is acceptable include—
- (a) the patient’s medical history,
  - (b) the extent of any pain, disability, discomfort or other suffering that is attributable to the medical condition to which the service is to relate,
  - (c) whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks, and
  - (d) the extent to which the provision of the service would be likely to alleviate, or enable the alleviation of, the pain, disability, discomfort or suffering.
- (7) Any authorisation under this section must be in writing.”.

### **Payment of travelling expenses**

3. In section 183 (payment of travelling expenses) of the NHS Act, for paragraph (a) substitute—
- “(a) for the payment by the Secretary of State, a Primary Care Trust, an NHS trust or an NHS foundation trust, in such cases as may be prescribed, of travelling expenses (including the travelling expenses of a companion) incurred or to be incurred for the purpose of their obtaining—
- (i) any services provided under this Act,
  - (ii) any services in respect of which the costs are reimbursable under section 6A, or
  - (iii) any services authorised to be received in another EEA state or Switzerland under Article 20 or Article 27(3) of Regulation (EC) No. 883/2004,”.

### **Interpretation**

4. In section 275(1) (interpretation) of the NHS Act, after the definition of “registered pharmacist” insert the following definition—

“Regulation (EC) No. 883/2004” means Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems,”<sup>(5)</sup>.

## PART 3

### AMENDMENTS TO THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

#### Reimbursement of the costs of treatment in another EEA state (Wales)

5. After section 6 of the NHS (Wales) Act, insert—

##### “Reimbursement of cost of services provided in another EEA state

**6A.**—(1) The Welsh Ministers must, on an application made by any person, reimburse to that person the amount of any qualifying EEA expenditure incurred by that person on or after 23 August 2010, but this is subject to subsections (5) and (6), to any limit applicable under subsection (8) and to any deduction applicable under subsection (9).

(2) For the purpose of this section, “qualifying EEA expenditure” is expenditure incurred on the provision by an authorised provider, in an EEA state other than the United Kingdom, to a person ordinarily resident in Wales (“the patient”) of a service as respects which condition A or condition B is met.

(3) Condition A is that the service—

- (a) was necessary to treat or diagnose a medical condition of the patient,
- (b) is the same as or equivalent to a service that the Welsh Ministers or the Local Health Board in whose area the patient usually resides would make or have made available to the patient under this Act in the circumstances of the patient’s case, and
- (c) is not a special service.

(4) Condition B is that before the service was provided the Welsh Ministers had given authorisation under section 6B for the provision of the service to the patient.

(5) The duty in subsection (1) does not apply where the applicant incurred the qualifying expenditure in connection with an arrangement which was entered into by the applicant in the course of business and under which the applicant has gained or might be expected to gain any financial benefit.

(6) This section does not apply in circumstances where Article 20 or 27(3) of Regulation (EC) No. 883/2004 apply.

(7) Subsections (8) and (9) apply where the service is the same as or equivalent to a service that the Welsh Ministers or the Local Health Board in whose area the patient usually resides would have made available to the patient under this Act in the circumstances of the patient’s case.

(8) The Welsh Ministers may limit the amount of any reimbursement under this section—

- (a) in relation to a service other than a dental service, to the cost that the Welsh Ministers or the Local Health Board would have incurred if the same or an equivalent service had been made available by either of them, and

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<sup>(5)</sup> OJ L166, 30.4.2004, p.1.

(b) in relation to a dental service, to the average cost that the Welsh Ministers or the Local Health Board would have incurred if the same or an equivalent service had been made available by either of them.

(9) The Welsh Ministers may deduct from any reimbursement under this section the amount of any NHS charge which would have been payable for the same service or an equivalent service if the service had been made available by the Welsh Ministers or the Local Health Board; and in determining for this purpose the amount of any NHS charge regard shall be had to any entitlement the patient would have had—

(a) to any payment or contribution by virtue of regulations made under section 129(1) or (3), or

(b) to any remission or repayment by virtue of regulations made under section 130.

(10) The Welsh Ministers may determine—

(a) the form in which an application under this section must be made, and

(b) the information to be provided in support of the application.

(11) In this section and section 6B—

“authorised provider”, in relation to any service provided in an EEA state other than the United Kingdom, means a person who is lawfully providing that service;

“NHS charge” means a charge payable under regulations made under section 121(1), 125(1) or 128(1);

“special service” means—

(a) a service that involves a stay in hospital accommodation for at least one night,

(b) medical treatment that involves general anaesthesia, epidural anaesthesia or intravenously administered sedation,

(c) dental treatment that involves general anaesthesia or intravenously administered sedation, or

(d) a service whose provision involves the use of specialised or cost-intensive medical infrastructure or medical equipment;

“service” includes any goods, including drugs, medicines and appliances, which are used or supplied in connection with the provision of a service, but does not include accommodation other than hospital accommodation.

### **Prior authorisation for the purposes of section 6A**

**6B.—**(1) A person may apply to the Welsh Ministers under this section for prior authorisation for the purposes of section 6A in relation to the provision of a service (“the requested service”) to a person ordinarily resident in Wales (“the patient”).

(2) The requested service must be—

(a) a special service, or

(b) a service that is neither the same as nor equivalent to a service that the Welsh Ministers or the Local Health Board in whose area the patient usually resides would make available to the patient under this Act in the circumstances of the patient’s case.

(3) The Welsh Ministers may determine—

(a) the form in which an application under this section must be made, and

(b) the information to be provided in support of the application.

(4) The Welsh Ministers—

- (a) must authorise the provision of the requested service if it is a special service and the conditions in subsection (5) are met, and
  - (b) may authorise the provision of the requested service in any other case where the requested service is necessary to treat or diagnose a medical condition of the patient.
- (5) The conditions referred to in subsection (4)(a) are—
- (a) that the requested service is necessary to treat or diagnose a medical condition of the patient,
  - (b) that the requested service is the same as or equivalent to a service that the Welsh Ministers or the Local Health Board in whose area the patient usually resides would make available to the patient in the circumstances of the patient’s case, and
  - (c) that the Welsh Ministers or the Local Health Board cannot provide to the patient a service that is the same as or equivalent to the requested service within a period of time that is acceptable on the basis of medical evidence as to the patient’s clinical needs, taking into account the patient’s state of health at the time the decision under this section is made and the probable course of the medical condition to which the service relates.
- (6) The matters to which the Welsh Ministers are to have regard in determining for the purpose of subsection (5)(c) whether the length of any delay is acceptable include—
- (a) the patient’s medical history,
  - (b) the extent of any pain, disability, discomfort or other suffering that is attributable to the medical condition to which the service is to relate,
  - (c) whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks, and
  - (d) the extent to which the provision of the service would be likely to alleviate, or enable the alleviation of, the pain, disability, discomfort or suffering.
- (7) Any authorisation under this section must be in writing.”.

### **Payment of travelling expenses**

6. In section 131 (payment of travelling expenses) of the NHS (Wales) Act, for paragraph (a) substitute—

- “(a) for the payment by the Welsh Ministers, a Local Health Board or an NHS trust, in such cases as may be prescribed, of travelling expenses (including the travelling expenses of a companion) incurred or to be incurred for the purpose of their obtaining—
- (i) any services provided under this Act,
  - (ii) any services in respect of which the costs are reimbursable under section 6A, or
  - (iii) any services authorised to be received in another EEA state or Switzerland under Article 20 or Article 27(3) of Regulation (EC) No. 883/2004,”.

### **Interpretation**

7. In section 206(1) (interpretation) of the NHS (Wales) Act, after the definition of “registered pharmacist” insert the following definition—

““Regulation (EC) No. 883/2004” means Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems,”.

## PART 4

### AMENDMENTS TO REGULATIONS

#### **Amendment to NHS Functions Regulations**

**8.** In Part 2 of Schedule 1 to the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002<sup>(6)</sup> (Secretary of State functions exercisable by (A) Primary Care Trusts and (B) Strategic Health Authorities for specified purposes only), in the entry relating to the 2006 Act insert the following entries before the entry to Schedule 3, paragraph 11 (3) of that Act —

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| “section 6A | Determining requests for reimbursement and reimbursing the costs of services provided in an EEA state other than the United Kingdom and determining the form to be used for, and information to be provided with, an application for reimbursement. |
| section 6B  | Determining requests for prior authorisation and determining the form to be used for, and information to be provided with, an application for prior authorisation.”.  |

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Signed by authority of the Secretary of State for Health.

23rd March 2010

*Gillian Merron*  
Minister of State,  
Department of Health

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(6) [S.I. 2002/2375](#); relevant amending instruments are [S.I. 2006/1407](#), [2007/ 1818](#) and [2008/3166](#).



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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations give effect to the judgment of the European Court of Justice in Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* ([2006]ECR I-4325), which held that the obligation under Article 49 of the EC Treaty (this Article, now numbered Article 56 under the Treaty on the Functioning of the European Union, provides for the freedom to provide and receive services in another Member State of the European Union) to reimburse the cost of hospital treatment provided in another member State also applies to a tax-funded national health service, such as in England and Wales, which provides such treatment free of charge. These Regulations also cover non-hospital treatment.

The EEA (European Economic Area) consists of the member States of the European Union, together with Norway, Iceland and Liechtenstein.

Regulation 2 provides for the National Health Service Act 2006 (“the NHS Act”) to be amended by inserting new sections 6A and 6B. Regulation 5 provides for equivalent amendments to the National Health Service (Wales) Act 2006 (“the NHS (Wales) Act”) by inserting new sections 6A and 6B. Regulations 3 and 4 make consequential amendments to the NHS Act and regulations 6 and 7 make equivalent amendments to the NHS (Wales) Act.

The new section 6A of the NHS Act and the NHS (Wales) Act sets out the conditions for reimbursement of qualifying EEA expenditure (defined in subsection (2)) incurred on or after 23 August 2010, the limitations that may be imposed on the amount of the reimbursement and the NHS charges that may be deducted.

Section 6B provides for when an application for prior authorisation must be made to the Secretary of State or the Welsh Ministers and when authorisation must be given by the Secretary of State or Welsh Ministers.

Regulation 8 amends the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002, by inserting new entries into Part 2 of Schedule 1 (Secretary of State functions exercisable by (A) Primary Care Trusts and (B) Strategic Health Authorities, for specified purposes only). These new entries provide for the Secretary of State’s functions under the new sections 6A and 6B of the NHS Act to be exercisable by Primary Care Trusts.