
STATUTORY INSTRUMENTS

2013 No.

NATIONAL HEALTH SERVICE

ENGLAND AND WALES

**The National Health Service (Cross-Border Health Care)
Regulations 2013**

<i>Made</i>	- - - -	2013
<i>Laid before Parliament</i>		***
<i>Coming into force</i>	- -	***

The Secretary of State, in exercise of the powers conferred by sections 2(2) of the European Communities Act 1972(a) and sections 6D and 272(7) and (8) of the National Health Service Act 2006(b), [and all other powers enabling him in that behalf], 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(c).

PART 1

INTRODUCTORY

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Cross-Border Health Care) Regulations 2013 and come into force on 25 October 2013.

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

(3) In these Regulations—

“the Directive” means Directive 2011/24/EU of the European Parliament and of the Council;

“health care” means health services provided by health professionals to patients to assess, maintain or restore their state of health, and includes the prescription, dispensing and provision of medicinal products and medical devices ;

“health care provider” means a person providing health care;

“health professional” has the meaning given by section 69 of the Data Protection Act 1998 ;

(a) 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.

(b) 2006 c.42.

(c) S.I.2001/3495.

“medical device” means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of—

- (a) the diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - (b) the diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
 - (c) the investigation, replacement or modification of the anatomy or of a physiological process,
 - (d) the control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

“medicinal product” means any substance or combination of substances—

- (a) presented for treating or preventing disease in human beings, or
- (b) which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings;

“the NCP” means the national contact point designated under regulation 2(1) or(2);

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

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

“prescription” means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the member State in which the prescription is issued;

“resident patient” means an individual who is entitled to receive health care in any part of the United Kingdom;

“visiting patient” means an individual who is entitled to receive health care in another Member State.

PART 2

NATIONAL CONTACT POINT

National contact point: designation

2.—(1) The Secretary of State must, in relation to England, designate a suitable person or body to be the national contact point for the purposes of the Directive.

(2) The Welsh Ministers must, in relation to Wales, designate a suitable person or body to be the national contact point for the purposes of the Directive.

(3) The Secretary of State, in relation to England, and the Welsh Ministers, in relation to Wales, must publish the identity and contact details of the NCP.

NCP: information about treatment in England and Wales

3.—(1) This regulation has effect for the purpose of enabling a visiting patient to exercise his or her rights in relation to access to health care in England or Wales.

(2) The NCP must ensure that information about each of the following is available or accessible by whatever means it thinks appropriate—

(a) 2006 c.42.

- (a) health care providers;
- (b) patients' rights;
- (c) complaints procedures and methods of seeking remedies;
- (d) legal and administrative options available to settle disputes, including in the event of harm arising from the provision of health care.

(3) The NCP must also ensure that information about each of the following is made available by whatever means it thinks appropriate to a visiting patient, on request—

- (a) a specific health care provider's right to provide services;
- (b) any restrictions on a specific providers right to provide services;
- (c) standards and guidelines on quality and safety;
- (d) provision about the supervision and assessment of health care providers;
- (e) health care providers who are subject to the standards mentioned in sub-paragraph (c);
- (f) accessibility of hospitals for persons with disabilities.

(4) Information provided under this regulation and regulation 4 must—

- (a) be easily accessible, and
- (b) be available by electronic means.

NCP: information about treatment in another member State

4.—(1) The NCP must ensure that information about each of the following is available to or accessible by resident patients and health care professionals—

- (a) the rights and entitlements of resident patients to receive health care in another member State;
- (b) the procedures for accessing and determining those entitlements;
- (c) the procedures for appeal and redress if patients consider that their rights have not been respected;
- (d) the terms and conditions for reimbursement of costs.

(2) Nothing in this regulation affects sections 6A to 6D of the Act so far as they relate to qualifying expenditure within the meaning of section 6A.

NCP: cross border co-operation

5.—(1) For the purposes of the Directive, the NCP must co-operate with—

- (a) the national contact points in other member States;
- (b) the NCP established for England or Wales (as the case may be);
- (c) the national contact points established for the purposes of the Directive in Northern Ireland and Scotland;
- (d) the Commission of the EU..

(2) In particular, the NCP—

- (a) must co-operate on standards and guidelines on quality and safety,
- (b) must facilitate the exchange of information mentioned in regulation 3(2) and (3); and
- (c) co-operate on the clarification of the content of invoices..

PART 3
TREATMENT IN ANOTHER STATE (ENGLAND)

Reimbursement of costs of treatment

6.—(1) Section 6A of the NHS Act (reimbursement of the cost of services provided in another EEA state) is amended as follows.

(2) For subsection (1) substitute—

“(1) The Secretary of State must, on an application made by a person, reimburse to that person the amount of any qualifying expenditure incurred by the person on or after 25 October 2013.

(1A) Subsection (1) is subject to—

- (a) subsections (5) and (6),
- (b) any limit applicable under subsection (8), and
- (c) any deduction applicable under subsection (9).”

(3) For subsections (2) to (4) substitute—

“(2A) For the purposes of this section, “qualifying expenditure” is expenditure incurred on the provision by an authorised provider of a relevant service, in an EEA State other than the United Kingdom, to a person ordinarily resident in England (“the patient”).

(2B) A relevant service is a service which—

- (a) is necessary to treat or diagnose a medical condition of the patient, and
- (b) subject to section 6B(2)(b), is the same as or equivalent to a service that the Secretary of State, the Board or a responsible authority would make or have made available to the patient under this Act in the circumstances of the patient’s case.

(2C) A service within subsection (2D) is not a relevant service unless, before the service was provided, the Secretary of State had given authorisation under section 6B for the provision of the service to the patient.

(2D) A service is within this section if—

- (a) it is a planning requirement service and—
 - (i) involves overnight hospital accommodation of the patient for at least one night, or
 - (ii) requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment, or
- (b) it involves treatments presenting a particular risk for the patient or the population, or
- (c) it is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.

(2E) For the purposes of subsection (2D), a service is a planning requirement service if it is subject to special planning requirements relating to—

- (a) the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment, or
- (b) the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

(2F) The Secretary of State may, by directions given to the National Health Service Commissioning Board or a clinical commissioning group, specify services to which are within subsection (2B).”

(4) In subsection (8)—

- (a) in paragraph (a) omit “ in relation to a service other than a dental service”;
- (b) omit “and” after paragraph (a) and omit paragraph (b).
- (5) In subsection (11) omit the definition of “special service”.

Prior authorisation of treatment

7.—(1) Section 6B of the NHS Act (prior authorisation for the purposes of section 6A) is amended as follows.

(2) In subsection (2) for paragraph (a) substitute—

- (a) “(a) a service which is within section 6A(2D), or”.

(3) For subsections (4) and (5) substitute—

“(4) The Secretary of State must authorise the provision of the requested service if—

- (a) the service is within section 6A(2D), and
- (b) the Secretary of State, the Board 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.

(4A) The Secretary of State may authorise the provision of the requested service if it is a service to which subsection (4) does not apply.”

(4) In subsection (6), for “subsection (5)(c)” substitute “subsection (4)(b)”.

(5) After subsection (6) insert—

“(6A) But subsection (4) does not apply if the requested service is a service within section 6A(2D) and any of the following conditions is met—

- (a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the requested service;
- (b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the requested service;
- (c) the requested service is to be provided by a health care provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the member State in which the service will be provided;

[(d) the health care can be provided [by the Secretary of State, the Board or a responsible authority] within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of the patient.”.]**[NOTE “(d)” is included for the purpose of illustration. Please refer to pages 35 – 39 of the consultation document and associated consultation question for discussion]**

Information on rights and entitlements

8.—(1) For the purpose of enabling the Secretary of State to comply with the obligation under Article 5(b) of the Directive, the National Health Service Commissioning Board or a clinical commissioning group must ensure that information on the rights and entitlements mentioned in that Article is provided for patients in respect of whom the United Kingdom is the Member State of affiliation (within the meaning of the Directive).

(2) The Commissioning Board and clinical commission groups must exercise their functions under subsection (1) in accordance with directions given by the Secretary of State.

Treatment for certain pensioners and members of their family who are resident in another Member State

9.—(1) The Secretary of State, the Board or a responsible authority must provide health care to a person (P) who is within paragraph (2) if—

- (a) the provision of the health care is not subject to prior authorisation pursuant to Article 8 of the Directive,
- (b) the health care is not provided in accordance with Article 20 or Article 27(3) of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004, and

(2) P is within this paragraph if P is—

- (a) the insured person is a pensioner residing in a Member State other than the United Kingdom for whom the United Kingdom is the competent Member State under Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004, or
- (b) a member of the insured person's family who resides in a Member State other than the United Kingdom.

(3) The following expressions have the same meaning in this regulation as they have for the purposes of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004—

- (a) competent Member State;
- (b) prior authorisation;
- (c) insured person;
- (d) member of the family;
- (e) pensioner.

Review

10.—(1) The Secretary of State must from time to time carry out a review of regulation 2(1) and(3) and regulations 3 to 5 (National Contact Point) as they apply to England and regulations 6 to 9 (treatment in another State (England)).

(2) The Secretary of State must—

- (a) set out the conclusions of the review carried out in accordance with paragraph (1) in a report, and
- (b) publish the report.

(3) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other Member States.

(4) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these regulations;
- (b) assess the extent to which these objectives are achieved; and
- (c) assess whether these objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(5) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(6) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

PART 4
TREATMENT IN ANOTHER STATE (WALES)

NOTE

Regulations to implement the Directive in Wales will be inserted following consideration by the Welsh Government of responses to the Welsh Government's consultation on the implementation in Wales of Directive 2011/24 EU on the application of patients' rights in cross border healthcare (Number WG 17276) issued on 21 December 2012 .

PART 5
TRANSITIONAL

Non-EU states

11.—(1) This paragraph applies in the case of expenditure incurred in any of the following EEA States—

- (a) Iceland;
- (b) Lichtenstein;
- (c) Norway.

(2) The amendments to sections 6A and 6B of the NHS Act and made by regulations 6 and 7 and sections 6A and 6B of the NHS (Wales) Act by regulations 10 and 11 do not have effect in relation to expenditure to which paragraph (1) applies unless the Directive applies to the States specified in that paragraph in accordance with the Agreement done at Brussels on 17 March 1993 (the EU/EFTA Agreement).

Expenditure incurred before 25 October 2013

12.—(1) This regulation applies to an application under section 6A or 6B of the NHS Act or sections 6A and 6B of the NHS (Wales) Act which—

- (a) relates to expenditure incurred on or after 9 March 2011 but before 25 October 2013, and
- (b) is not determined before 25 October 2013.

(2) The application must be treated as if—

- (a) it relates to expenditure incurred on or after 25 October 2013, and
- (b) it is made on or after that date.

Signed by authority of the Secretary of State for Health

Date

Name
[Minster for Health]
Department of Health

EXPLANATORY NOTE

(This note is not part of the Order)