# This publication was withdrawn on 2 January 2024

The regulations were revoked on 31 December 2020 by The National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc.) (EU Exit) Regulations 2019.

S T A T U T O R Y  I N S T R U M E N T S

# 2013 No. 2269

# NATIONAL HEALTH SERVICE, ENGLAND AND WALES

## The National Health Service (Cross-Border Healthcare) Regulations 2013

| | |
|---|---|
| *Made - - - -* | *9th September 2013* |
| *Laid before Parliament* | *13th September 2013* |
| *Coming into force - -* | *25th October 2013* |

## CONTENTS

The Secretary of State, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**), 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(**b**).

# PART 1
## INTRODUCTORY

**Citation, commencement, extent and interpretation**

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

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

(3) In these Regulations—

"the Board" means the National Health Service Commissioning Board established under section 1H of the NHS Act(**c**) (the National Health Service Commissioning Board and its general functions);

"clinical commissioning group" means a body established under section 14D of the NHS Act(**d**)(effect of grant application);

"the Directive" means Directive 2011/24/EU of the European Parliament and of the Council of 9th March 2011 on the application of patients' rights in cross-border healthcare(**e**);

"healthcare" 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;

"healthcare provider" means a person providing healthcare on the territory of a member State;

"health professional" means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service

(**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**) S.I.2001/3495.
(**c**) Section 1H was inserted by the Health and Social Care Act 2012 (c.7), section 9(1).
(**d**) Section 14D was inserted by the Health and Social Care Act 2012, section 25(1).
(**e**) OJ No. L88, 4.4.2011, p.45.

Reform and Health Care Professions Act 2002(**a**) (the Professional Standards Authority for Health and Social Care);

"Local Health Board" means a body established under section 11 of the NHS (Wales) Act(**b**) (Local Health Boards);

"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; or

(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—

(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or

(b) any substance or combination of substances that may be used by or administered to human beings with a view to—

(i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or

(ii) making a medical diagnosis;

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

"the NHS Act" means the National Health Service Act 2006(**c**);

"the NHS (Wales) Act" means the National Health Service (Wales) Act 2006;

"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 of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications(**d**) who is legally entitled to do so in the member State in which the prescription is issued;

"resident patient" means an individual for whom the United Kingdom is the member State of affiliation within the meaning of Article 3(c) of the Directive (definitions);

"visiting patient" means an individual for whom a member State other than the United Kingdom is the member State of affiliation within the meaning of Article 3(c) of the Directive.

---

(**a**) 2002 c.17. Section 25 has been amended by the Health and Social Care Act 2008 (c.14), section 113, Schedule 10, paragraph 17 and Schedule 15, Part 2; and by S.I. 2010/231 and the Health and Social Care Act 2012 (c.7), sections 220 and 224.

(**b**) 2006 c.42.

(**c**) 2006 c.41.

(**d**) OJ No. L255, 30.9.2005, p.22; corrigenda to the Directive published in OJ No.L271, 16.10.2007, p18; and in OJ No. L 93, 4.4.2008, p.28.

# 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) The NCP must, in so far as it considers it is necessary or desirable for the purposes of enabling visiting patients to exercise their rights in relation to access to healthcare, ensure that information about each of the following is available to or accessible by visiting patients—

(a) healthcare providers;

(b) patients' rights;

(c) complaints procedures and methods of seeking remedies; and

(d) legal and administrative options available to settle disputes, including in the event of harm arising from the provision of healthcare.

(2) The NCP must also, in so far as it considers it is necessary or desirable for the purposes of enabling visiting patients to exercise their rights in relation to access to healthcare, ensure that information about each of the following is made available to a visiting patient, on request—

(a) a specific healthcare provider's right to provide services;

(b) any restrictions on a specific healthcare provider's right to provide services;

(c) standards and guidelines on quality and safety;

(d) provisions on the supervision and assessment of healthcare providers;

(e) healthcare providers who are subject to the standards mentioned in sub-paragraph (c); and

(f) accessibility of hospitals for persons with disabilities.

(3) Information provided under this regulation may be provided by whatever means the NCP thinks appropriate but must be—

(a) easily accessible, and

(b) available by electronic means.

**NCP: information about treatment in another member State**

**4.**—(1) The NCP must, in so far as it considers it is necessary or desirable for the purposes of enabling resident patients to exercise their rights in relation to access to healthcare in other member States, ensure that information about each of the following is available or accessible by resident patients and health professionals—

(a) the rights and entitlements of resident patients to receive healthcare in another member State;

(b) the procedures for accessing and determining those rights and 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; and

(e) the contact details of national contact points in other member States.

(2) Information provided under this regulation may be provided by whatever means the NCP thinks appropriate but must be—

(a) easily accessible, and

(b) available by electronic means.

**NCP: cross-border co-operation**

**5.**—(1) In so far as it considers it is appropriate for the purposes of giving effect to 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 for Northern Ireland and for Scotland established for the purposes of the Directive; and

(d) the Commission of the European Union.

(2) In particular, that co-operation must include —

(a) co-operating on standards and guidelines on quality and safety;

(b) facilitating the exchange of information mentioned in regulation 3(2); and

(c) co-operating on the clarification of the content of invoices.

**NCP: duty to consult**

**6.** In so far as it considers it is appropriate for the purposes of giving effect to the Directive (including giving effect to the measures implementing the Directive in these Regulations), the NCP must consult with—

(a) such organisations representing the interests of patients as it considers appropriate;

(b) such healthcare providers or organisations representing healthcare providers as it considers appropriate; and

(c) such persons providing insurance in relation to healthcare or organisations representing such persons as it considers appropriate.

# PART 3

## TREATMENT IN ANOTHER STATE (ENGLAND)

**Reimbursement of cost of treatment**

**7.**—(1) In section 6A of the NHS Act (reimbursement of the cost of services provided in another EEA state)**(a)** after subsection (1) insert—

"(1A) But the duty in subsection (1) does not apply where section 6BA applies."

(2) After section 6B of the NHS Act (prior authorisation for the purposes of section 6A) insert the following—

"**6BA Reimbursement of cost of services provided in another EEA state where expenditure incurred on or after 25 October 2013.**

(1) This section applies where expenditure is incurred by a person on or after 25 October 2013 (but see subsections (9) and (14)).

(**a**) Section 6A (reimbursement of the cost of services provided in another EEA state) was inserted by regulation 2 of the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 ( S.I. 2010/915) and amended by s.55(1) of and paragraph 3 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

(2) The Secretary of State must, on an application made by the person, reimburse to that person the amount of the qualifying EEA expenditure incurred by that person, but this is subject to subsections (8) and (9), to any limit applicable under subsection (11) and to any deduction applicable under subsection (12).

(3) 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.

(4) Condition A is that the service—

(a) was necessary to treat or diagnose a medical condition of the patient, and

(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.

(5) But in the case of a service which, although meeting the requirements in paragraphs (a) and (b) of subsection (4), falls within subsection (6), condition A is only met if, before the service was provided, the Secretary of State had given authorisation under section 6BB for the provision of the service to the patient.

(6) A service falls within this subsection if—

(a) it is subject to planning requirements relating to the objective of ensuring sufficient and permanent access to a balanced range of high quality treatment or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources, and—

(i) it involves a stay in hospital accommodation for at least one night, or

(ii) it requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(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, with the exception of a service which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.

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

(8) The duty in subsection (2) does not apply where the applicant incurred the qualifying EEA 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.

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

(10) Subsections (11) and (12) apply where the service is the same as or equivalent to a service that the Secretary of State, the Board or a responsible authority would have made available to the patient under this Act in the circumstances of the patient's case.

(11) The Secretary of State may limit the amount of any reimbursement under this section to the cost that the Secretary of State, the Board or a responsible authority would have incurred if the same or an equivalent service had been made available by any of them.

(12) 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, the Board 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.

(13) 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.

(14) This section does not apply where expenditure is incurred in Iceland, Liechtenstein or Norway before Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare applies to those states in accordance with the EEA Agreement.

(15) In this section and section 6BB, "authorised provider", "NHS charge", "responsible authority" and "service" each have the meaning given in section 6A.

**6BB Prior authorisation for the purposes of section 6BA**

(1) A person may apply to the Secretary of State under this section for prior authorisation for the purposes of section 6BA 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 service which falls within section 6BA(6) and meets the requirements in paragraphs (a) and (b) of section 6BA(4), or

(b) a service that is neither the same as nor equivalent to a service that the Secretary of State, the Board 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 service mentioned in subsection (2)(a) (but see subsection (5)), and

(b) may authorise the provision of the requested service in any case where—

(i) the requested service is necessary to treat or diagnose a medical condition of the patient, and

(ii) the duty in paragraph (a) does not apply.

(5) The duty in subsection (4)(a) does not apply if at least one 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 healthcare 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 or regulations or through accreditation systems established by the state in which the service will be provided;

(d) the Secretary of State, the Board or a responsible authority can provide to the patient a service that is the same as or equivalent to the requested service within a period of time that is medically justifiable, 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)(d) whether the length of any delay is medically justifiable 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**

**8.** In section 183 (payment of travelling expenses) of the NHS Act(**a**), in paragraph (a)(ii), after the words "under section 6A" insert "or 6BA".

**Information on rights and entitlements**

**9.**—(1) The Board or a clinical commissioning group must ensure that information on the rights and entitlements mentioned in Article 5(b) of the Directive is provided to resident patients for whom the Board or the clinical commissioning group is responsible for making services available under the NHS Act.

(2) The information referred to in paragraph (1) must be made available in a manner that is compatible with the performance by the NCP of its functions under regulation 4.

# PART 4

## TREATMENT IN ANOTHER STATE (WALES)

**Reimbursement of cost of treatment**

**10.**—(1) In section 6A of the NHS (Wales) Act (reimbursement of the cost of services provided in another EEA state)(**b**) after subsection (1) insert—

"(1A) But the duty in subsection (1) does not apply where section 6BA applies.".

(2) After section 6B of the NHS (Wales) Act (prior authorisation for the purposes of section 6A) insert the following—

"**6BA Reimbursement of cost of services provided in another EEA state where expenditure incurred on or after 25 October 2013**

(1) This section applies where expenditure is incurred by a person on or after 25 October 2013 (but see subsections (9) and (14)).

(2) The Welsh Ministers must, on an application made by the person, reimburse to that person the amount of the qualifying EEA expenditure incurred by that person, but this is subject to subsections (8) and (9), to any limit applicable under subsection (11) and to any deduction applicable under subsection (12).

---

(**a**) Section 183 was amended by S.I. 2010/915 and by s.55 of and Schedule 4 Part 8 to the Health and Social Care Act 2012.

(**b**) Section 6A (reimbursement of the cost of services provided in another EEA state) was inserted by regulation 5 of the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 (S.I. 2010/915).

(3) 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.

(4) Condition A is that the service—

(a) was necessary to treat or diagnose a medical condition of the patient, and

(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.

(5) But in the case of a service which, although meeting the requirements in paragraphs (a) and (b) of subsection (4), falls within subsection (6), condition A is only met if, before the service was provided, the Welsh Ministers had given authorisation under section 6BB for the provision of the service to the patient.

(6) A service falls within this subsection if—

(a) it is subject to planning requirements relating to the objective of ensuring sufficient and permanent access to a balanced range of high quality treatment or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources, and—

(i) it involves a stay in hospital accommodation for at least one night, or

(ii) it requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(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, with the exception of a service which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.

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

(8) The duty in subsection (2) does not apply where the applicant incurred the qualifying EEA 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.

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

(10) Subsections (11) and (12) 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.

(11) The Welsh Ministers may limit the amount of any reimbursement under this section 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.

(12) 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.

(13) 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.

(14) This section does not apply where expenditure is incurred in Iceland, Liechtenstein or Norway before Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare applies to those states in accordance with the EEA Agreement.

(15) In this section and section 6BB, "authorised provider", "NHS charge" and "service" each have the meaning given in section 6A.

**6BB Prior authorisation for the purposes of section 6BA**

(1) A person may apply to the Welsh Ministers under this section for prior authorisation for the purposes of section 6BA 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 service which falls within section 6BA(6) and meets the requirements in paragraphs (a) and (b) of section 6BA(4), 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 service mentioned in subsection (2)(a) (but see subsection (5)), and

(b) may authorise the provision of the requested service in any case where—

(i) the requested service is necessary to treat or diagnose a medical condition of the patient, and

(ii) the duty in paragraph (a) does not apply.

(5) The duty in subsection (4)(a) does not apply if at least one 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 healthcare 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 or regulations or through accreditation systems established by the state in which the service will be provided;

(d) The Welsh Ministers or the Local Health Board can provide to the patient a service that is the same as or equivalent to the requested service within a period of time that is medically justifiable, 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)(d) whether the length of any delay is medically justifiable 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**

**11.** In section 131 (payment of travelling expenses) of the NHS (Wales) Act(**a**), in paragraph (a)(ii), after the words "under section 6A" insert the words "or 6BA".

**Information on rights and entitlements**

**12.**—(1) A Local Health Board must ensure that information on the rights and entitlements mentioned in Article 5(b) of the Directive is provided to resident patients for whom it is responsible for making services available under the NHS (Wales) Act.

(2) The information in paragraph (1) must be made available in a manner that is compatible with the performance by the NCP of its functions under regulation 4.

# PART 5

## VISITING PATIENTS

**NHS charges**

**13.**—(1) Where a visiting patient is provided with a cross-border healthcare service in England or in Wales (as the case may be) which is a service prescribed by—

(a) the Secretary of State pursuant to section 175 of the NHS Act (charges in respect of non-residents) as a service for which a charge may be made; or

(b) the Welsh Ministers pursuant to section 124 of the NHS (Wales) Act (charges in respect of non-residents) as a service for which a charge may be made,

the amount of the charge to the visiting patient for that service must not exceed the amount that the person or body responsible for providing the service, as mentioned in paragraph (2)(b), would assess as the cost of that service if it had been provided to a resident patient.

(2) In this regulation and regulation 14—

"cross-border healthcare service" means healthcare—

(a) provided to or prescribed for a visiting patient as a consequence of that patient exercising their rights in relation to access to healthcare under the Directive; and

(b) provided by the Secretary of State, the Board or a responsible authority under the NHS Act in the case of England or by the Welsh Ministers or a Local Health Board under the NHS (Wales) Act in the case of Wales;

"responsible authority" has the meaning given by section 6A(11) of the NHS Act(**b**).

---

(**a**) Section 131 was amended by S.I. 2010/915 and by s.297 of and Sch.21 to the Health and Social Care Act 2012.
(**b**) Section 6A(11) was amended by s.55(1) of and Schedule 4 Part 1 to the Health and Social Care Act 2012.

**Exemption from NHS charges for certain persons who reside in another member State**

**14.**—(1) Where a person (P) is provided with a cross-border healthcare service which is a service prescribed by—

(a) the Secretary of State pursuant to section 175 of the NHS Act (charges in respect of non-residents) as a service for which a charge must be made; or

(b) the Welsh Ministers pursuant to section 124 of the NHS (Wales) Act (charges in respect of non-residents) as a service for which a charge must be made,

P is exempt from a charge if P falls within paragraph (2) and the cross-border healthcare service falls within paragraph (3).

(2) P falls within this paragraph if P is an insured person or a member of the family of an insured person—

(a) who is resident in a member State other than the United Kingdom; and

(b) for whom the United Kingdom is the competent member State under Regulation (EC) No. 883/2004.

(3) The cross-border healthcare service falls within this paragraph if—

(a) it is not a service that falls within section 6BA(6) of the NHS Act 2006 or the NHS (Wales) Act 2006 as a service subject to prior authorisation; and

(b) it is not provided in accordance with Chapter 1 of Title III of Regulation (EC) No 883/2004 (sickness, maternity and equivalent paternity benefits).

(4) In this regulation—

(a) the expressions "competent member State", "insured person" and "member of the family" have the same meaning as they have for the purposes of Regulation (EC) No 883/2004;

(b) "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(**a**).

# PART 6

## AMENDMENTS TO REGULATIONS AND REVIEW

**Amendment to the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013**

**15.** Part 2 (exercise of EU functions by the Board) of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013(**b**) is amended as follows—

(a) in regulation 3(a)(exercise of functions) after the words "sections 6A and 6B of the 2006 Act (prior authorisation of and reimbursement of costs of services provided in another EEA state)" insert the words "or sections 6BA and 6BB of the 2006 Act (reimbursement of the cost of services provided in another EEA state where expenditure incurred on or after 25 October 2013 and prior authorisation for the purposes of section 6BA)";

(b) in regulation 4 (procedure for applications)—

(i) in paragraph (1)(a) after the words "section 6A" insert "or 6BA",

(ii) in paragraph (1)(b) after the words "section 6B" insert "or 6BB", and

(iii) in paragraph (3)(a), for the words "reimbursement under section 6A of the 2006 Act and prior authorisation under section 6B of the 2006 Act" substitute "reimbursement

(**a**) OJ No. L166, 30.4.2004 p. 1-123; corrigenda to the Regulation published in OJ No. L 200,7.6.2004 p. 1-49 and OJ No. L 204, 4.8.2007, p 30.
(**b**) S.I. 2013/261.

under section 6A or 6BA of the 2006 Act and prior authorisation under section 6B or 6BB of the 2006 Act";

(c) in regulation 6 (form and content of determination)—

(i) in paragraph (2)(a), after the words "section 6A" insert "or 6BA", and

(ii) in paragraph (2)(b), after the words "section 6B" insert "or 6BB"; and

(d) in regulation 7 (CCGs), in paragraph (3)(b), after the words "section 6A" insert "or 6BA".

**Review**

**16.**—(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive that is implemented in England and Wales by means of these Regulations is implemented in other member States.

(3) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, the NHS Act 2006 and the NHS (Wales) Act 2006 (as amended by these Regulations) and by Part 2 of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013 (as amended by these Regulations);

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) 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.

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

Signed by authority of the Secretary of State for Health.

*Anna Soubry*
Parliamentary Under-Secretary of State,
Department of Health

9th September 2013

## EXPLANATORY NOTE

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

These Regulations implement in England and Wales provisions of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare ("the Directive").

Regulation 2 requires the Secretary of State in respect of England and Welsh Ministers in respect of Wales to designate a suitable person or body as the national contact point.

Regulation 3 requires the national contact point to make specified information available or accessible to patients from other member States seeking to access healthcare in England or Wales ("visiting patients"). Regulation 4 requires the national contact point to make specified information about rights and entitlements to obtain a healthcare service in another member State available or accessible to NHS patients ("resident patients").

Regulation 5 requires the national contact point to cooperate with other national contact points and the Commission of the European Union. Regulation 6 requires the national contact points to consult organisations representing patients, health providers and insurers.

Regulation 7 amends section 6A of the National Health Service Act 2006 ("the NHS Act") by inserting new sections 6BA and 6BB. Regulation 10 makes the equivalent amendments to the National Health Service (Wales) Act 2006 ("the NHS (Wales) Act").

The new sections 6BA of the NHS Act and the NHS (Wales) Act set out the conditions for reimbursement for qualifying EEA expenditure (defined in subsection (3)) incurred on or after 25th October 2013, the services subject to the condition of prior authorisation, the limitations that may be imposed on the reimbursement and the NHS charges that may be deducted. Subsection (14) provides that section 6BA does not apply where expenditure is incurred on the provision of a service provided by an authorised provider in Iceland, Liechtenstein or Norway before the Directive applies to those states in accordance with the EEA Agreement. The new sections 6BB of the NHS Act and the NHS (Wales) Act provide for an application for prior authorisation and set out when authorisation must be granted and when it may be refused.

Regulation 9 requires the National Health Service Commissioning Board or a clinical commissioning group to ensure that information about their rights and entitlements is available to patients. Regulation 12 makes corresponding provisions in relation to Local Health Boards in Wales.

Regulation 13 makes provision relating to the amount of charges where certain NHS services are provided to a visiting patient.

Regulation 14 implements Article 7(2)(b) of the Directive by providing an exemption from charges for NHS healthcare provided to a person who is an insured person or a family member of an insured person for whom the UK is the competent member State under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, and who is resident in another member State. The exemption does not apply to healthcare service that falls within section 6BA(6) of the NHS Act or the NHS (Wales) Act (as the case may be) as a service that is subject to the condition of prior authorisation.

Regulation 16 requires the Secretary of State to review the operation and effects of these Regulations and to publish a report within five years and within every five years after that. Following a review, it will fall to the Secretary of State to consider whether these Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke these Regulations or to amend them.

An Impact Assessment and Transposition Notes have been prepared for these Regulations. Copies of the Impact Assessment and the Transposition Notes can be obtained from the Department of Health Richmond House, 79 Whitehall London SW1A 2NS and are published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

---



Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£5.75

UK2013090917 09/2013 19585

http://www.legislation.gov.uk/id/uksi/2013/2269

ISBN 978-0-11-110382-1

9 780111 103821