STATUTORY RULES OF NORTHERN IRELAND

2013 No. 299

HEALTH AND PERSONAL SOCIAL SERVICES

The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013

Made - - - -	*19th December 2013*
Coming into operation-	*27th December 2013*

The Department of Health, Social Services and Public Safety [M1], makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 [M2].

The Department of Health, Social Services and Public Safety is a Department designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to cross-border health care [M3].

Marginal Citations

M1 Formerly the Department of Health and Social Services; See S.I. 1999/283 (N.I. 1) Article 3(6)

M2 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. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), **section 27(1)** and by the European Union (Amendment) Act 2008 (c.7), **section 3(3)** and Part 1 of the Schedule

M3 S.I. 2009/2743

PART 1

INTRODUCTORY

Citation and commencement

1.—(1) These Regulations may be cited as The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013 and come into operation on 27th December 2013.

Interpretation

2.—(1) In these Regulations—

"the Order of 1972" means the Health and Personal Social Services (Northern Ireland) Order 1972 [M4];

"the 2009 Act" means the Health and Social Care (Reform) Act (Northern Ireland) 2009 [M5];

"the Board" means the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

"the Department" means the Department of Health, Social Services and Public Safety;

"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 [M6];

"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 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 Reform and Health Care Professions Act 2002 [M7], (the Professional Standards Authority for Health and Social Care);

"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 any substance or combination of substances—

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

(b) which may be used by or administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action;

"NCP" means the National Contact Point designated under regulation 3(1);

"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 [M8] 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.

(2) The Interpretation Act (Northern Ireland) 1954 [M9] applies to these Regulations as it applies to an Act of the Assembly.

Marginal Citations

M4 S.I. 1972/1265 (N.I. 14)

M5 2009 c.1 (N.I.)

M6 OJ No. L88, 4.4.2011, p45.

M7 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.

M8 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.

M9 1954 c. 33 (N.I.)

PART 2

NATIONAL CONTACT POINT

National Contact Point: designation

3.—(1) The Department must, in relation to Northern Ireland, designate a suitable person or body to be the National Contact Point for the purposes of the Directive.

(2) The Department must, in relation to Northern Ireland, publish the identity and contact details of the NCP.

National Contact Point: information about treatment in Northern Ireland

4.—(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 health care in Northern Ireland, ensure that information about each of the following is available to or accessible by visiting patients—

(a) health care 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 health care.

(2) The NCP must also, in so far as it considers it necessary or desirable for the purposes mentioned in paragraph (1), ensure that information about each of the following is made available to a visiting patient, on request—

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

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

(c) standards and guidelines on quality and safety;

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

(e) health care 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.

National Contact Point: information about treatment in another member State

5.—(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 health care in other member States, ensure that information about each of the following is available to or accessible by resident patients and health 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 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 NCPs in other member States (designated as such for the purposes of the Directive).

(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.

[F1National Contact Point: information about prescriptions intended to be used in another member State

5A.—(1) The NCP must make available to patients information about the elements, specified in the Schedule, to be included in a prescription which is—

(a) issued in one member State, and

(b) intended to be used in another member State.**]**

F1 Reg. 5A inserted (27.3.2015) by The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015 (S.R. 2015/130), regs. 1, **2(2)**

National Contact Point: cross-border co-operation

6.—(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 NCPs in other member States;

(b) the NCPs established for the purposes of the Directive in England, Wales and Scotland; and

(c) 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 4(1) and (2); and

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

National Contact Point: duty to consult

7. 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 health care providers or organisations representing health care providers as it considers appropriate; and

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

PART 3

TREATMENT IN ANOTHER MEMBER STATE

Reimbursement of the cost of health care services

8.—(1) In Article 14B of the Order of 1972 (reimbursement of the cost of health care services secured in another EEA state) [M10],—

(a) in the title, at the end, add " where expenditure was incurred on or after 10th May 2012 but before 27th December 2013 ".

(b) after paragraph (1) insert—

"(1A) But the duty in paragraph (1) does not apply where Article 14D applies (qualifying EEA expenditure incurred on or after 27th December 2013).".

(2) After Article 14C of that Order (prior authorisation for the purposes of Article 14B(3)(b) or (c) [M11], insert—

"**Reimbursement of the cost of health services secured in another EEA state where expenditure occurred on or after 27th December 2013**

14D.—(1) This Article applies where qualifying EEA expenditure is incurred by or on behalf of an eligible person on or after 27th December 2013 (but see paragraphs (9) and (14)).

(2) The Department must, on an application being made by or on behalf of an eligible person, reimburse the amount of the qualifying EEA expenditure incurred by or on behalf of the person.

(3) The duty under paragraph (2) is subject to—

(a) the exceptions in paragraphs (8) and (9);

(b) any limit applicable under paragraph (11);

(c) any deduction applicable under paragraph (12).

(4) For the purpose of this Article, "qualifying EEA expenditure" is expenditure incurred on the provision, by an authorised provider, in an EEA state other than the United Kingdom, of a service as respects which Condition A or B is met.

(5) Condition A is that—

(a) the service was necessary to treat or diagnose a medical condition of the eligible person;

(b) the service is the same as or equivalent to a service that the Department would make or have made available to the eligible person under this Order or the 2009 Act in the circumstances of the person's case; and

(c) where it falls within paragraph (6), the Department had given authorisation under Article 14E(4)(a) for the provision of the service to the eligible person before the service was provided.

(6) A service falls within this paragraph 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 eligible person or the population; or

(c) it is provided by a health care 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 Department had given authorisation under Article 14E(4)(b) for its provision to the eligible person.

(8) The duty in paragraph (2) does not apply where the qualifying EEA expenditure was incurred in connection with an arrangement which was entered into by or on behalf of the eligible person in the course of business and under which the applicant for reimbursement has gained or might be expected to gain any financial benefit.

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

(10) Paragraphs (11) and (12) apply where the service is the same as or equivalent to a service that the Department would have made available to the eligible person under this Order or the 2009 Act in the circumstances of the person's case.

(11) The Department may limit the amount of any reimbursement under this Article to the cost that it would have incurred if the same or an equivalent service had been made available by it.

(12) The Department may deduct from the amount of any reimbursement under paragraph (2) the amount of any health care charge which would have been payable for the same service or an equivalent service if the service had been available by the Department; and in determining for this purpose the amount of any health care charge regard shall be had to any entitlement the eligible person would have had—

(a) to any payment or contribution by virtue of regulations made under paragraph 2A(1) or (4) of Schedule 15; or

(b) to any remission or repayment by virtue of regulations made under paragraphs 1(b) and 1B of that Schedule.

(13) The Department may determine—

(a) the form in which an application under this Article must be made; and

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

(14) This Article 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 Article and Article 14E, "authorised provider", "eligible person", "health care charge" and "service" each have the meaning given in Article 14B.

Prior authorisation for the purposes of Article 14D(5)(c) and (7)

14E.—(1) A person may apply to the Department under this Article for prior authorisation for the purposes of Article 14D(or (7) in relation to the provision of a service ("the requested service") to an eligible person.

(2) The requested service must be—

(a) a service as respects which Condition A, mentioned in paragraph (5) of Article 14D, is satisfied and which falls within paragraph (6) of that Article; or

(b) a service that is neither the same as nor equivalent to a service that the Department would make available to the eligible person under this Order or the 2009 Act in the circumstances of the person's case.

(3) The Department may determine—

(a) the form in which an application under this Article must be made; and

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

(4) The Department—

(a) must authorise the provision of the requested service if it is a service mentioned in paragraph (2)(a) (but see paragraph (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 eligible person; and

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

(5) The duty in paragraph (4)(a) does not apply if at least one of the following conditions is met—

(a) the eligible person 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 person 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 or regulations or through accreditation systems established by the member State in which the service will be provided;

(d) the Department can provide to the eligible person 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 paragraph (4)(a) is made and the probable course of the medical condition to which the service relates.

(6) The matters to which the Department is to have regard in determining for the purpose of paragraph (5)(d) whether the length of any delay is medically justifiable include—

(a) the eligible person'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 eligible person to carry out ordinary daily tasks; and

(d) the extent to which the provision of the service would be likely to alleviate, or to enable the alleviation of the pain, disability, discomfort or suffering.

(7) Any authorisation under paragraph (4) must be in writing.".

Marginal Citations

M10 Article 14B (Reimbursement of the cost of health care services secured in another EEA state) was inserted into the Order of 1972 by regulation 4(2) of The Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012 (S.R. 2012 No. 167)

M11 Article 14C (Prior authorisation for the purpose of Article 14B(3)(b) or (c)) was inserted into the Order of 1972 by regulation 4(2) of The Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012 (S.R. 2012 No. 167)

Payment of travelling expenses

9. In Article 45 (travelling expenses of patients, etc) of the Order of 1972 [M12], in paragraph (1)(a)(ii), after the words "Article 14B", insert " or 14D ".

Marginal Citations

M12 Article 45 (Travelling expenses of patients, etc) was amended by regulation 5 of The Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012 (S.R. 2012 No. 167)

Information on rights and entitlements

10.—(1) The 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 the Board is responsible for making services available under the Order of 1972 or the 2009 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 5.

PART 4

VISITING PATIENTS

Health care charges

11.—(1) Where a visiting patient is provided with a cross-border health care service in Northern Ireland in respect of which a charge may be recovered pursuant to Article 42 of the Order of 1972 (provision of services to persons not ordinarily resident in Northern Ireland), 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 12 "a cross-border health care service" means health care—

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

(b) provided by the Department under the Order of 1972 or the 2009 Act.

Exemption from Health care charges for certain persons who reside in another member State

12.—(1) Where a person (P) is provided with a cross-border health care service in respect of which a charge may be recovered pursuant to Article 42 of the Order of 1972, P is exempt from a charge if P falls within paragraph (2) and the cross-border health care service falls within paragraph (3).

(2) P falls within this paragraph if P is an insured person or a member of a 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 health care service falls within this paragraph if—

(a) it is not a service that falls within Article 14D(6) of the Order of 1972 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 29th April 2004 on the coordination of social security systems [M13].

Marginal Citations

M13 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.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 19th December 2013

L.S.

Heather Stevens
A senior officer of the
Department of Health, Social Services and
Public Safety

[F2SCHEDULE

Regulation 5A

Elements that must be included in prescriptions intended to be used in another member State

F2 Sch. added (27.3.2015) by The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015 (S.R. 2015/130), regs. 1, **2(3)**

1. The patient's—
   (a) surname,
   (b) first names, and
   (c) date of birth.
2. The issue date of the prescription.
3. The prescribing professional's—
   (a) surname,
   (b) first names,
   (c) professional qualification,
   (d) direct contact details including—
      (i) email address, and
      (ii) telephone or fax number with the appropriate international prefix,
   (e) work address,
   (f) member State in which the professional works,
   (g) signature (either written in ink or electronic depending on the medium chosen for issuing the prescription).
4. The details of the prescribed product, including where applicable the—
   (a) common name as defined by Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ("Directive 2001/83/EC"),
   (b) brand name if—
      (i) the prescribed product is a biological medicinal product, as defined in point 3.2.1.1(b) of Annex 1 (Part 1) to Directive 2001/83/EC, or
      (ii) the prescribing professional deems it medically necessary for that product to be dispensed and, in that case, the prescribing professional's reasons justifying the use of the brand name,
   (c) pharmaceutical formulation (such as tablet, solution etc),
   (d) quantity,
   (e) strength, as defined in Article 1 of Directive 2001/83/EC, and
   (f) dosage regimen.]

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement in Northern Ireland provisions of 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 ("the Directive").

Regulation 3 requires the Department to designate a suitable person or body as the National Contact Point.

Regulation 4 requires the national contact point to make specified information available or accessible to patients from other member States seeking to access health care in Northern Ireland ("visiting patients").

Regulation 5 requires the national contact point to make specified information about rights and entitlements to obtain a health care service in another member State available or accessible to patients in Northern Ireland ("resident patients").

Regulation 6 requires the national contact point to cooperate with other national contact points and the Commission of the European Union. Regulation 7 requires the national contact points to consult organisations representing patients, health providers and insurers.

Regulation 8 amends the Health and Personal Social Services (Northern Ireland) Order 1972, ("the Order of 1972") by inserting new Articles 14D and 14E.

The new Article 14D sets out the conditions for reimbursement for qualifying EEA expenditure (defined in paragraph (4)) incurred on or after 27th December 2013, the services subject to the condition of prior authorisation, the limitations that may be imposed on the reimbursement and the health care charges that may be deducted if the same service had been made available by the Department. Paragraph (14) provides that Article 14D 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 2011/24 EU applies to those States in accordance with the EEA Agreement. The new Article 14E provides for an application for prior authorisation and sets out when authorisation must be granted and when it may be refused.

Regulation 9 amends the regulation making power in Article 45(1)(a) of the Order of 1972 in respect of travelling expenses for patients.

Regulation 10 requires the Board to ensure that information about their rights and entitlements is available to resident patients.

Regulation 11 makes provision that the amount of the charge for certain health care services provided to a visiting patient must not exceed the amount of the cost of providing the service to a resident patient.

Regulations 12 implements Article 7(2)(b) of the Directive by providing an exemption from charges for health care 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 a health care service that falls within Article 14D (6) of the Order of 1972 as a service that is subject to the condition of prior authorisation.

A Transposition Note has been prepared for these Regulations and is published with the Explanatory Memorandum alongside the Statutory Rule on the Departmental website.

Status:
Point in time view as at 27/03/2015.

Changes to legislation:
There are currently no known outstanding effects for the The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013.