STATUTORY INSTRUMENTS.

S.I. No. 203 of 2014

EUROPEAN UNION (APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE) REGULATIONS 2014

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I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011[1], hereby make the following regulations:

Citation

1. These Regulations may be cited as the European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014.

Commencement

2. These Regulations come into operation on 1st June 2014.

Interpretation

3. In these Regulations—

"cross-border healthcare" means healthcare provided to a person in a Member State other than the Member State of affiliation of that person within the meaning of the Directive;

"Directive" means Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011[1];

"health professional" means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of the Professional Qualifications Directive, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(*a*) of the Professional Qualifications Directive, or a person considered to be a health professional according to the legislation of the Member State of treatment;

"healthcare" means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;

"healthcare provider" means any natural or legal person or any other entity legally providing healthcare in a Member State;

"medical device" means a medical device which falls within any of the definitions of "medical device" in—

[1]OJ No. L 88, 4.4.2011, p. 45.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 16*th May*, 2014.

(*a*) Article 1 of Council Directive 90/385/EEC of 20 June 1990[2],

(*b*) Article 1 of Council Directive 93/42/EEC of 14 June 1993[3], or

(*c*) Article 1 of Directive 98/79/EC of 27 October 1998[4];

"medicinal product" has the meaning assigned to it in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[5];

"Member State" means a State which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992;

"Minister" means the Minister for Health;

"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 the Professional Qualifications Directive who is legally entitled to do so;

"Professional Qualifications Directive" means Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005[6];

"Patient resident in the State" means an individual for whom the State is the Member State of affiliation within the meaning of Article 3(*c*) of the Directive;

"Regulation 883/2004" means Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004[7].

National contact point

4. The Health Service Executive shall carry out the functions of the national contact point for cross-border healthcare in the State for the purposes of these Regulations and the Directive.

Information on cross-border healthcare in State

5. (1) The Health Service Executive shall, in so far as it considers it is necessary or desirable for the purposes of enabling patients resident in another Member State to exercise their rights in relation to access to cross-border healthcare provided in the State, ensure that information about each of the following is available or accessible:

(*a*) healthcare providers;

(*b*) patients' rights;

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

[2]OJ No. L 189, 20.07.1990, p. 17.
[3]OJ No. L 169, 12.07.1993, p. 1.
[4]OJ No. L 331, 07.12.1998, p. 1.
[5]OJ No. L 311, 28.11.2004, p. 67.
[6]OJ No. L 255, 30.9.2005, p. 22.
[7]OJ No. L 166, 30.4.2004, p. 1.

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

(2) The Health Service Executive shall, in so far as it considers it is necessary or desirable for the purposes of enabling patients resident in another Member State to exercise their rights in relation to access to cross-border healthcare in the State, ensure that, on request, information about each of the following is made available:

(*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 shall be provided by whatever means the Health Service Executive considers appropriate provided that it is—

(*a*) easily accessible, and

(*b*) available by electronic means.

Information on cross-border healthcare in other Member States

6. (1) The Health Service Executive shall, in so far as it considers it is necessary or desirable for the purposes of enabling patients resident in the State to exercise their rights in relation to access to cross-border healthcare in other Member States, ensure that information about each of the following is available to, or accessible by, patients resident in the State and health professionals:

(*a*) the rights and entitlements of patients resident in the State 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 shall be provided by whatever means the Health Service Executive considers appropriate provided that it is—

(*a*) easily accessible, and

(*b*) available by electronic means.

Co-operation with other national contact points

7. (1) In so far as it considers it is appropriate for the purposes of giving effect to the Directive, the Health Service Executive shall co-operate with—

(*a*) the national contact points in other Member States, and

(*b*) the European Commission.

(2) The co-operation referred to in paragraph (1) shall include—

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

(*b*) facilitating the exchange of information mentioned in Regulation 6(1), and

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

Consultation

8. 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 Health Service Executive shall 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.

Circumstances where provision of cross-border healthcare in State may be limited

9. (1) Where the Health Service Executive considers that it is justified by overriding reasons of general interest, such as—

(*a*) planning requirements related to the aim of ensuring sufficient and permanent access to a balanced range of high quality treatment in the State, or

(*b*) the wish to control costs or to avoid, as far as possible, any waste of financial, technical and human resources,

the Health Service Executive shall, subject to the approval of the Minister, prescribe the healthcare which healthcare providers in the State shall not provide

to patients resident in another Member State and shall publish a list of healthcare so prescribed.

Reimbursement of costs of treatment

10. (1) Subject to the provisions of this Regulation and Regulation 11, and without prejudice to Regulation 883/2004, the Health Service Executive shall, on application by the person concerned, reimburse a patient resident in the State, in an amount determined in accordance with paragraph (4), in respect of expenditure he or she has incurred in relation to the provision, by a healthcare provider in a Member State other than the State, of cross-border healthcare which qualifies in accordance with paragraph (2).

(2) Cross-border healthcare qualifies for the purpose of paragraph (1) where the Health Service Executive is satisfied that—

(*a*) the patient was entitled under the Health Acts 1970 to 2013 (as amended) to the healthcare in question,

(*b*) the healthcare was necessary to treat or diagnose a medical condition of the patient,

(*c*) the healthcare was the same as, or equivalent to, healthcare that would have been made available to the patient in the State, in the particular circumstances of the patient,

(*d*) the healthcare has not been excluded under Regulation 11, and

(*e*) where required, the Health Service executive granted prior authorisation in accordance with Regulation 12.

(3) A patient seeking reimbursement under paragraph (1) shall provide to the Health Service Executive such evidence as the Health Service Executive considers necessary for it to establish the entitlement of the patient to the reimbursement, prior to the Health Service Executive making a reimbursement for any expenditure.

(4) The level of expenditure that shall be reimbursed under paragraph (1), shall be the cost of treatment incurred by the patient in respect of qualifying cross-border healthcare or the cost of providing such healthcare in the State by the Health Service Executive, as determined by the Health Service Executive, whichever is the lesser.

(5) Paragraph (1) does not apply in circumstances where Article 20 or 27(3) of Regulation 883/2004 applies.

(6) The Health Service Executive may impose on patients seeking reimbursement of the costs of cross-border healthcare under this Regulation, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities as it would impose if the healthcare in respect of which reimbursement is sought was provided in the

State, including an assessment by a health professional or healthcare administrator providing services for the statutory health system of the State, such as a general practitioner or primary care practitioner, if this is necessary for determining the patient's entitlement to healthcare.

(7) Notwithstanding paragraph (6), the Health Service Executive shall not, unless it is objectively justified by planning requirements relating to—

(*a*) the object of ensuring sufficient and permanent access to a balanced range of high quality treatment in the State, or

(*b*) the wish to control costs or avoid, as far as possible, any waste of financial, technical and human resources,

impose other conditions, criteria of eligibility or regulatory and administrative formalities that are discriminatory or constitute an obstacle to the free movement of patients, services or goods.

(8) The Health Service Executive shall not make the reimbursement of the costs of cross-border healthcare under this Regulation subject to prior authorisation, except where it has been made subject to prior authorisation under Regulation 12.

(9) The Health Service Executive may deduct from any reimbursement made under this Regulation the amount of any charge which would have been payable by the patient resident in the State for the same or equivalent healthcare if that healthcare had been made available by, or on behalf of, the Health Service Executive in the State.

Exclusion of cross-border healthcare from reimbursement

11. (1) Subject to this Regulation, the Health Service Executive may exclude certain cross-border healthcare from reimbursement under Regulation 10 based on overriding reasons of general interest, such as such as—

(*a*) planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high quality treatment in the State, or

(*b*) the wish to control costs, or to avoid, as far as possible, any waste of financial, technical and human resources.

(2) Any decision by the Health Service Executive to exclude cross-border healthcare under paragraph (1) shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services.

(3) The Health Service Executive shall notify the Minister within 15 days of a decision under paragraph (1) to exclude cross-border healthcare from reimbursement, in order that the Minister may notify the European Commission of such decision in accordance with Article 11(7) of the Directive.

Prior authorisation of cross-border healthcare

12. (1) The Health Service Executive may specify particular cross-border healthcare to be subject to prior authorisation in order to be eligible for reimbursement under Regulation 10, where it considers that the healthcare—

(*a*) involves planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high quality treatment in the State, or the wish to control costs or avoid, as far as possible, any waste of financial, technical and human resources, and—

(i) involves overnight hospital accommodation of the insured person for at least one night, or

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

(*b*) involves treatments presenting a particular risk for a patient, or,

(*c*) 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 healthcare which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.

(2) Where a patient resident in the State is seeking to be provided with cross-border healthcare in another Member State which is specified under paragraph (1) as being subject to prior authorisation from the Health Service Executive, he or she shall not be entitled to reimbursement under Regulation 10 unless he or she applies for, and is granted, prior authorisation from the Health Service Executive under this Regulation.

(3) The Health Service Executive shall decide and make available the form in which an an application for prior authorisation must be made, and the information which must be provided in support of such an application.

(4) Subject to subsection (5), the Health Service Executive shall grant prior authorisation for reimbursement in respect of the costs of cross-border healthcare to be provided to a patient resident in the State where the healthcare is specified under paragraph (1) as being subject to prior authorisation and the Health Service Executive is satisfied that—

(*a*) the patient concerned is entitled under the Health Acts 1970 to 2013 (as amended) to the requested healthcare,

(*b*) the requested healthcare is necessary to treat or diagnose a medical condition of the patient resident in the State, and

(*c*) the requested healthcare is the same as, or equivalent to, healthcare that would have been made available to the patient in the State, in the particular circumstances of the patient.

(5) The Health Service Executive may refuse to grant prior authorisation under this Regulation where it considers that—

(*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 person of the sought cross-border healthcare,

(*b*) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question,

(*c*) the healthcare 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 and regulations or through accreditation systems established by the Member State of treatment, or

(*d*) the Health Service Executive can provide healthcare that is the same as, or equivalent to, the healthcare sought by the patient within a time limit which is medically justifiable, taking into account the patient's current state of health at the time the decision under this Regulation is taken and the probable course of the medical condition to which the healthcare relates.

(6) Without prejudice to paragraph (5)(*a*) to (*c*), the Health Service Executive may not refuse to grant prior authorisation under this Regulation when the patient would otherwise be entitled to reimbursement for the healthcare in question in accordance with Regulation 10, and when the healthcare cannot be provided in the State within a time limit which is medically justifiable, based on an objective medical assessment of any or all of the following:

(*a*) the insured person's medical condition;

(*b*) the history and probable course of the insured person's illness;

(*c*) the degree of the insured person's pain; and

(*d*) the nature of the insured person's disability at the time when the request for authorisation is made or renewed.

(7) When a patient affected, or suspected of being affected, by a rare disease, as referred to in the Directive, applies for prior authorisation under this Regulation, the Health Service Executive may require a clinical evaluation of the patient to be carried out by experts in that field in order to assist it in making a decision under this Regulation as to whether or not to grant prior authorisation.

(8) Where an expert referred to in paragraph (7) cannot be found in the State or the expert's opinion is inconclusive, the Health Service Executive may

request scientific advice in order to assist it in making a decision under this Regulation as to whether or not to grant prior authorisation.

L.S.

GIVEN under my Official Seal,
14 May 2014.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

The Directive on Patients' Rights in Cross-Border Healthcare (Directive 2011/24) seeks to ensure a clear and transparent framework for the provision of cross-border healthcare within the EU, for those occasions where the healthcare patients seek is provided in a Member State other than their home Member State. These Regulations will implement three key provisions of the Directive concerning the National Contact Point (NCP), the reimbursement process and the prior authorisation process. Following publication of this Regulation, patient's resident in Ireland will be able to seek reimbursement of the costs of treatment received in other EU Member States, subject to terms and conditions.

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nó trí aon díoltóir leabhar.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4468-1907-4

€3.05

9 781446 819074

Wt. (B30585). 285. 5/14. Clondalkin. Gr 30-15.