



STATUTORY INSTRUMENTS.

**S.I. No. 65 of 2015**

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EUROPEAN UNION (APPLICATION OF PATIENTS' RIGHTS IN  
CROSS-BORDER HEALTHCARE) (AMENDMENT) REGULATIONS  
2015

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CROSS-BORDER HEALTHCARE) (AMENDMENT) REGULATIONS  
2015

I, LEO VARADKAR, 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 further effect to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011<sup>1</sup> and Commission Implementing Directive 2012/52/EU of 20 December 2012<sup>2</sup>, hereby make the following regulations:

*Citation*

1. (1) These Regulations may be cited as the European Union (Application of Patients' Rights in Cross-Border Healthcare) (Amendment) Regulations 2015.

(2) The Principal Regulations and these Regulations may be cited together as the European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014 and 2015 and shall be construed together as one.

*Commencement*

2. Regulation 7, in so far as that Regulation inserts Regulation 15 in the Principal Regulations, shall come into operation on 31 March 2015.

*Interpretation*

3. In these Regulations "Principal Regulations" means the European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014.

*Amendment of Regulation 3 of Principal Regulations*

4. Regulation 3 of the Principal Regulations is amended—

(a) by inserting before the definition of "cross-border healthcare" the following definition:

“‘authorised officer’ means a person appointed under Regulation 16;”, and

(b) by inserting after the definition of "prescription" the following definition:

“‘professional liability insurance’ includes a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose to professional liability insurance;”.

<sup>1</sup>OJ No. L 88, 4.4.2011, p. 45.

<sup>2</sup>OJ No. L 356, 22.12.2012, p. 68.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 27th February, 2015.*

*Amendment of Regulation 4 of Principal Regulations*

5. The Principal Regulations are amended by substituting for Regulation 4 the following:

*“National contact point*

4. (1) 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.

(2) In providing information about cross-border healthcare under these Regulations, the Health Service Executive shall make a clear distinction between the rights which patients have by virtue of the Directive and rights arising from Regulation 883/2004.

(3) The Health Service Executive shall set out reasonable periods of time within which requests to it for cross-border healthcare under these Regulations must be dealt with and make them public in advance.

(4) When considering a request for cross-border healthcare, the Health Service Executive shall take into account—

(a) the specific medical condition, and

(b) the urgency and individual circumstances.”.

*Amendment of Regulation 10 of Principal Regulations*

6. Regulation 10 of the Principal Regulations is amended by inserting after paragraph (9) the following paragraphs:

“(10) For the purposes of this Regulation, in the case of telemedicine, healthcare is considered to be provided in the Member State in which the healthcare provider is established.

(11) The Health Service Executive shall ensure that eligible persons receive reimbursement under this Regulation without undue delay.”.

*Insertion of new Regulations in Principal Regulations*

7. The Principal Regulations are amended by inserting after Regulation 12 the following Regulations:

*“Duties of healthcare providers*

13. (1) Subject to paragraph (3), healthcare providers shall, where requested, provide relevant information to help individual patients to make an informed choice as to whether or not to avail of cross-border treatment in the State, including information on—

(a) treatment options, and

(b) the availability, quality and safety of the healthcare they provide.

(2) Subject to paragraph (3), healthcare providers shall provide to patients availing of, or seeking to avail of, cross-border healthcare in the State clear invoices and clear information on—

(a) prices,

(b) their authorisation or registration status, and

(c) their professional liability insurance, as required under Regulation 15.

(3) Paragraphs (1) and (2) shall not oblige healthcare providers to provide more extensive information to patients resident in other Member States than they provide to patients resident in the State.

(4) Healthcare providers shall apply the same scale of fees for healthcare for cross-border patients as for patients resident in the State in a comparable medical situation, or shall charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for patients resident in the State.

(5) Healthcare providers shall apply the principle of non-discrimination with regard to nationality to patients from other Member States.

#### *Information on cross-border prescriptions*

14. The Health Service Executive shall provide patients, for the purposes of exercising their rights in relation to cross-border healthcare, with information about the elements to be included in—

(a) a prescription issued in a Member State other than the State, for dispensing in the State, and

(b) a prescription issued in the State, for dispensing in a Member State other than the State.

#### *Professional liability insurance*

15. (1) A health professional who is providing cross-border healthcare in the State must have professional liability insurance which is appropriate to the nature and the extent of the risk, for treatment provided in the State.

(2) A health professional who is providing cross-border healthcare in the State must provide evidence of professional liability insurance which is appropriate to the nature and the extent of the risk, for the particular treatment being provided, if requested to do so by an authorised officer.

(3) The evidence requested under paragraph (2) must be provided within 15 working days of the date that the request is issued.

*Appointment of authorised officers*

16. (1) The Health Service Executive may appoint in writing such and so many persons, including members of the staff of the Health Service Executive, to be authorised officers for the purposes of these Regulations and such appointment may be specified to be for a fixed period.

(2) Every authorised officer appointed under this Regulation shall be furnished with a warrant of appointment.

(3) An appointment under this Regulation as an authorised officer shall cease—

- (a) if the Health Service Executive revokes the appointment,
- (b) if the appointment is for a fixed period, on the expiry of that period, or
- (c) in the case of a person who is member of staff of the Health Service Executive, if he or she ceases to be a member of staff.

*Powers of authorised officers*

17. (1) An authorised officer may, for the purpose of obtaining any information which may be required in relation to a matter under these Regulations—

- (a) subject to paragraph (2), at all reasonable times enter (if need be by reasonable force) or, where the premises is a vehicle, stop and enter (if need be by reasonable force), any premises on, at or in which there are reasonable grounds to believe that cross-border healthcare is, or has been, provided, or that records in relation to cross-border healthcare are kept, and search and inspect the premises and any records that are on, at or in that premises,
- (b) secure for later inspection any, or any part of any, premises on, at or in which such records are kept or there are reasonable grounds for believing that such records are kept,
- (c) require any person who provides cross-border healthcare, or any person employed in respect of same, to produce to the authorised officer such records and, where such records are kept in a non-legible form, to reproduce them in a legible form, or to give to him or her any information, as the authorised officer may reasonably require in relation to such records,
- (d) inspect and take copies of or extracts from any such records on, at or in the premises, including in the case of information in a non-legible form, copies of or extracts from such information in a permanent legible form,
- (e) make a record whether in writing, by photography or otherwise of any record or thing on, at or in the premises,

- (f) remove and retain such records for such periods as may be reasonable for further examination,
- (g) require any person to give to the authorised officer any information which the authorised officer may reasonably require regarding the provision of cross-border healthcare, or in respect of the persons providing same or employed in connection with same, including evidence of professional liability insurance,
- (h) require any person to give to the authorised officer any other assistance or information which the authorised officer may reasonably require in respect of the provision of cross-border healthcare,
- (i) require any person by or on whose behalf data equipment is or has been used or any person having charge of, or otherwise concerned with the operation of, the data equipment or any associated apparatus or material, to afford the authorised officer all reasonable assistance in relation to it and assist in the retrieval of information connected with the operation of such data equipment, apparatus or material, and
- (j) summon, at any reasonable time, any other person employed in connection with the provision of cross-border healthcare to give to the authorised officer any information which the authorised officer may reasonably require in relation to same and to produce to the authorised officer any records which are in the control of that other person.

(2) An authorised officer shall not, other than with the consent of the occupier, enter a dwelling unless he or she has obtained a warrant from the District Court under paragraph (5) authorising such entry.

(3) Where an authorised officer in the exercise of his or her powers under this Regulation is prevented from entering any premises an application may be made under paragraph (5) authorising such entry.

(4) An authorised officer, when exercising any powers conferred on an authorised officer by this Regulation, may, subject to any warrant issued under paragraph (5), be accompanied by such other authorised officers or members of the Garda Síochána, or both, as he or she considers necessary.

(5) Without prejudice to the powers conferred on an authorised officer under this Regulation, where a judge of the District Court is satisfied on the sworn information of an authorised officer that there are reasonable grounds for suspecting that there is information required by an authorised officer under this Regulation held on or at any, or any part of any, premises, the judge may issue a warrant authorising an authorised officer (accompanied, where appropriate, by such other authorised officers or members of the Garda Síochána, or both) at any time or times within one month from the date of issue of the warrant, on production if so requested

of the warrant, to enter the premises, using reasonable force where necessary, and exercise all or any of the powers conferred on an authorised officer under this Regulation.

*Offences and related matters*

18. (1) A health professional who contravenes Regulation 13(1), (2), (4) or (5) or Regulation 15(1) or (2) is guilty of an offence.

(2) A person who—

- (a) falsely represents himself or herself as an authorised officer,
- (b) obstructs or impedes an authorised officer,
- (c) without reasonable excuse, does not comply with a request or requirement of an authorised officer, or
- (d) gives information or documentation to an authorised officer that is false or misleading in a material respect,

is guilty of an offence.

(3) A person guilty of an offence under these Regulations is liable—

- (a) on summary conviction to a Class A fine or to imprisonment for a term not exceeding 3 months or both or,
- (b) on conviction on indictment to a fine not exceeding €300,000 or to imprisonment for a term not exceeding one year or both.

(4) A prosecution for a summary offence under these Regulations may be taken by the Health Service Executive.”.



GIVEN under my Official Seal,  
23 February 2015.

LEO VARADKAR,  
Minister for Health.

EXPLANATORY NOTE

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

These Regulations give further effect to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 and Commission Implementing Directive 2012/52/EU of 20 December 2012.

These Regulations amend the European Union (Cross-Border Healthcare) Regulations 2014.

These Regulations may be cited as the European Union (Cross-Border Healthcare) (Amendment) Regulations 2015.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ó  
FOILSEACHÁIN RIALTAIS,  
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2  
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)  
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