STATUTORY RULES OF NORTHERN IRELAND

2013 No. 299

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

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(1);
 - "the 2009 Act" means the Health and Social Care (Reform) Act (Northern Ireland) 2009(2);
 - "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(3);
 - "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(4), (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;

⁽¹⁾ S.I. 1972/1265 (N.I. 14)

^{(2) 2009} c.1 (N.I.)

⁽³⁾ OJNo. L88, 4.4.2011, p45.

^{(4) 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) 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(5) 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(6) applies to these Regulations as it applies to an Act of the Assembly.

⁽⁵⁾ 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.

^{(6) 1954} c. 33 (N.I.)