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

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1 This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare. This Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.

2 This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

3 This Directive shall not apply to:

- a services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;
- b allocation of and access to organs for the purpose of organ transplants;
- c with the exception of Chapter IV, public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.

4 This Directive shall not affect laws and regulations in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. In particular, nothing in this Directive obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.

Article 2

Relationship with other Union provisions

This Directive shall apply without prejudice to:

(a) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems[(1)];

(b) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[(2)], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(3)] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(4)];

(c) Directive 95/46/EC and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector[(5)];

(d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services[(6)];

(e) Directive 2000/31/EC;

(f) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin[(7)];

(g) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[(8)];

(h) 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[(9)];

(i) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[(10)];

(j) Regulation (EC) No 859/2003;

(k) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[(11)];

(l) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[(12)];

(m) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems[(13)];

(n) Directive 2005/36/EC;

(o) Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC)[(14)];

(p) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work[(15)];

(q) Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)[(16)], Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)[(17)] and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law;

(r) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation[(18)];

(s) Regulation (EU) No 1231/2010.

Article 3

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) '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;

(b) 'insured person' means:

(i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and

(ii) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits;

(c) 'Member State of affiliation' means:

(i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;

(ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State;

(d) 'Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established;

(e) 'cross-border healthcare' means healthcare provided or prescribed in a Member State other than the Member State of affiliation;

(f) '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 Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment;

(g) 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State;

(h) ‘patient’ means any natural person who seeks to receive or receives healthcare in a Member State;

(i) ‘medicinal product’ means a medicinal product as defined by Directive 2001/83/EC;

(j) ‘medical device’ means a medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;

(k) ‘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 who is legally entitled to do so in the Member State in which the prescription is issued;

(l) ‘health technology’ means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare;

(m) ‘medical records’ means all the documents containing data, assessments and information of any kind on a patient’s situation and clinical development throughout the care process.

(**1**) OJ L 40, 11.2.1989, p. 8.
(**2**) OJ L 189, 20.7.1990, p. 17.
(**3**) OJ L 169, 12.7.1993, p. 1.
(**4**) OJ L 331, 7.12.1998, p. 1.
(**5**) OJ L 201, 31.7.2002, p. 37.
(**6**) OJ L 18, 21.1.1997, p. 1.
(**7**) OJ L 180, 19.7.2000, p. 22.
(**8**) OJ L 121, 1.5.2001, p. 34.
(**9**) OJ L 311, 28.11.2001, p. 67.
(**10**) OJ L 33, 8.2.2003, p. 30.
(**11**) OJ L 102, 7.4.2004, p. 48.
(**12**) OJ L 136, 30.4.2004, p. 1.
(**13**) OJ L 284, 30.10.2009, p. 1.
(**14**) OJ L 210, 31.7.2006, p. 19.
(**15**) OJ L 354, 31.12.2008, p. 70.
(**16**) OJ L 177, 4.7.2008, p. 6.
(**17**) OJ L 199, 31.7.2007, p. 40.
(**18**) OJ L 207, 6.8.2010, p. 14.