Patients' rights in cross-border healthcare

2008/0142(COD) - 09/03/2011 - Final act

PURPOSE: the establishment of a Community framework facilitating access to safe and high-quality cross-border healthcare.

LEGISLATIVE ACT: Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

CONTENT: The new directive **provides clarity about the rights of patients who seek healthcare in another Member State** and supplements the rights that patients already have at EU level through the legislation on the coordination of social security schemes (regulation 883/04). It meets the Council's wish to fully respect the case law of the European Court of Justice on patients' rights in cross-border healthcare while preserving member states' rights to organise their own healthcare systems.

Sales of medicinal products and medical devices via internet, long-term care services provided in residential homes and the access and allocation of organs for the purpose of transplantation fall outside the scope of the Directive.

The new directive contains the following provisions:

- cross-border healthcare shall be provided in accordance with standards and guidelines on quality and safety laid down by the Member State of treatment, the Union's legislation on safety standards and taking into account the **principles of universality, access to good quality care, equity and solidarity**;
- healthcare providers must provide relevant information to help individual patients to make an **informed choice**, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability;
- the Member State of affiliation shall ensure that where a patient has received cross-border healthcare and where medical follow-up proves necessary, the **same medical follow-up** is available as would have been if that healthcare had been provided on its territory;
- as a general rule, the costs of cross-border healthcare shall be reimbursed to the patient or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory;
- the Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare **based on overriding reasons of general interest,** such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources;
- Member States may introduce a **system of prior authorisation** to manage eventual outflows of patients. This system would, however, be limited to healthcare that needs to meets planning requirements, such as: i) overnight hospital accommodation; ii) care that requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment; iii) treatments that present a particular risk for the patient or the population; or iv) treatment dispensed by a healthcare provider that could give rise to serious and specific concerns relating to the quality or safety of the care;
- the Member State of affiliation may **refuse to grant prior authorisation** for the following reasons: i) the patient will be exposed with reasonable certainty to a patient-safety risk that cannot be

regarded as acceptable; ii) the general public will be exposed with reasonable certainty to a substantial safety hazard; iii) this 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; or iv) this healthcare can be provided on its territory within a time limit which is medically justifiable;

- to **manage inflows of patients**, and to ensure sufficient and permanent access to treatment on its territory, a Member State of treatment may adopt measures regarding access to treatment, where it is justified by overriding reasons of general interest (such as planning requirements to ensure permanent access to a balanced range of high-quality treatment or the wish to control costs and avoid the wastage of resources);
- Member States shall establish **national contact points** responsible to provide patients with information on their entitlement to benefit from cross-border healthcare and on the practical aspects, such as, for example, information regarding healthcare providers, the quality and safety of treatments and the accessibility of hospitals for **persons with disabilities**, to allow patients to make informed choices. The Commission will also help the Member States to create European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases;
- Member States shall set out **reasonable periods of time** within which requests for cross-border healthcare. When considering a request for cross-border healthcare, Member States shall take into account i) the specific medical condition; and ii) the urgency and individual circumstances. Individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are **properly reasoned** and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings. A Member State of affiliation must ensure that patients receive r**eimbursement without undue delay**;
- cooperation in healthcare between Member States was strengthened, for example, in the area of **eHealth** and thanks to the creation of a European network that will bring together, on a voluntary basis, the national authorities responsible for eHealth; rare diseases are another field of cooperation in which the Commission will assist the Member States to work together on diagnosis and treatment capacities;
- the **recognition of prescriptions** in another Member State has been improved. Generally speaking, if a medicinal product is authorised to be marketed on their territory, the Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force. A pharmacist retains the right when, by virtue of national rules, he can refuse, for ethical reasons, to dispense a product that was prescribed in another Member State where he would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

No later than 25 October 2015 and thereafter every three years, the Commission must provide a **report** on the application of the Directive.

ENTRY INTO FORCE: 24/04/2011.

TRANSPOSITION: 25/10/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts in respect of measures that would exclude specific categories of medicinal products or medical devices from the recognition of prescriptions. The powers to adopt delegated acts shall be conferred on the Commission for a period of five years from 24 April 2011.The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it. The European Parliament or the Council may object to the delegated act within a period of two months from the date of notification (this period may be extended by a further two months). If the European Parliament or the Council objects to a delegated act, it shall not enter into force.