Patients' rights in cross-border healthcare

2008/0142(COD) - 23/04/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 297 votes to 120, with 152 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

The main amendments are as follows:

Aim: Parliament states that this Directive lays down rules for access to safe and high-quality healthcare in another Member State and establishes cooperation mechanisms on healthcare between Member States, whilst fully respecting national competencies in the organisation and delivery of healthcare. In the application of the Directive, Member States shall take into account the principles of good quality care and equity.

Scope: the Directive will apply to provision of cross-border healthcare regardless of how it is organised, delivered and financed or whether it is public or private. It shall be without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EEC) No 1408/71 and its successor Regulation (EC) No 883/2004. The Directive shall not apply to health services whose main focus is in the field of long-term care, including services provided over an extended period of time whose purpose is to support people in need of assistance in carrying out routine, everyday tasks.

This Directive shall also not apply to **organ transplantation**. Due to their specific nature, they will be regulated by a separate directive.

Relationship with other Community provisions: Parliament added certain pieces of legislation to the list of this which apply without prejudice to this directive. It deleted the Commission’s text regarding Community legislation which takes precedence over this directive, including Directive 2005/36/EC on the recognition of professional qualifications;

In addition, it clarified that the Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State . Nor does the Directive affect patients' rights to be granted an authorisation for treatment in another Member State where the conditions provided for by the regulations on coordination of social security schemes, in particular Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004, are met.

Definitions: Members amended definitions for "healthcare", "cross-border healthcare" "health professional" "healthcare provider" "patient" "insured person" and "Member State of affiliation". It inserted some new terms, including “health data.”

Responsibilities of Member State of treatment: Parliament specified that patients and healthcare providers from other Member States must be provided with information by the national contact point of the Member State of treatment, inter alia by electronic means, on quality standards and guidelines, including provisions on supervision, and on availability, quality and safety, treatment options, prices, outcomes of the healthcare provided, accessibility for persons with disabilities and details of the healthcare provider's registration status and insurance cover or other means of personal or collective protection with regard to their professional liability.

It also stated that this Directive shall not oblige healthcare providers in a Member State either to provide healthcare to an insured person from another Member State or to prioritise the provision of healthcare to

an insured person from another Member State to the detriment of a person who has similar health needs and is an insured person of the Member State of treatment.

Parliament inserted a list of standards that the Member State of treatment and affiliation must meet in order to **maximise patient safety**. This includes patients' means of making a complaint, language requirements and the right to continuity of care. The Commission shall adopt measures necessary for achieving a common security level of health data at national level, taking into account existing technical standards in this field.

Member States shall have a transparent mechanism for the calculation of costs that are to be charged for the healthcare provided. This calculation mechanism shall be based on objective, non-discriminatory criteria known in advance and it shall be applied at the relevant administrative level in cases where the Member State of treatment has a decentralised healthcare system.

Responsibilities of Member State of affiliation: the Member State of affiliation shall reimburse the costs to the Member State of treatment or the insured person, which would have been paid for by its statutory social security system had equally effective healthcare been provided in its territory. If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision.. Parliament added that Patients affected by rare diseases should have the right to access healthcare in another Member State and to get reimbursement even if the treatment in question is not among the benefits provided for by the legislation of the Member State of affiliation.

Definition of hospital care: in order to correspond to the real nature of the services provided in practice, the definition of hospital care should refer to the definition in force in the patient's Member State of affiliation. Members deleted references to a specific list.

Prior authorisation: the prior authorisation system shall be based on clear and transparent criteria, and shall not constitute an obstacle to freedom of movement of patients. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that patients are expected only to pay upfront any costs that they would be expected to pay in this manner had their care been provided in the health system of their Member State of affiliation. Member States shall seek to transfer funds directly between the funders and the providers of care for any other costs. Prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way. Patients seeking to receive healthcare provided in another Member State shall be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

Parliament specified that there must be **appeal procedures** in the event of a refusal to give authorisation Patients with **rare diseases** shall not be subject to prior authorisation.

Procedural guarantees regarding the use of healthcare in another Member State: a new clause stipulates that Member States of affiliation shall ensure that patients who have received prior authorisation for the use of healthcare abroad will only be required to make upfront or top-up payments to the healthcare systems and/or providers in the Member State of treatment, to the extent that such payments would be required in the Member State of affiliation itself.

The Commission shall conduct a feasibility study into the **establishment of a clearing house** to facilitate the reimbursement of costs under this Directive across borders, healthcare systems and currency zones within two years of the entry into force of this Directive and if appropriate, present a legislative proposal.

Prior notification: Parliament inserted a new clause stating that Member States may offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a

written confirmation of the maximum amount that will be paid. That written confirmation can then be taken to the hospital of treatment and reimbursement would then be made directly to that hospital by the Member State of affiliation.

European Patients Ombudsman: a further new clause makes provision for the Commission to present a legislative proposal to establish a European Patients Ombudsman within 18 months after the entry into force of the Directive. The European Patients Ombudsman shall consider, and if appropriate, mediate on patient complaints with regard to prior authorisation, reimbursement of costs or harm. He shall only be engaged once all the complaint options within the relevant Member State have been exhausted.

Duty of cooperation: Parliament inserted new clauses stating that Member States, particularly neighbouring countries, may conclude agreements with one another concerning the continuation or potential further development of cooperation arrangements. They shall guarantee that registers in which health professionals are listed can be consulted by relevant authorities of other Member States. They shall immediately and proactively exchange information about disciplinary and criminal findings against health professionals where they impact upon their registration or their right to provide services .

Recognition of prescriptions issued in another Member State: Members consider that the recognition of such prescription shall not affect: (i) national rules governing prescribing and dispensing, including generic substitution; ii) national rules governing the reimbursement of Community cross-border prescriptions; (iii) any professional or ethical duty that would require the pharmacist to refuse to dispense had the prescription been issued in the Member State of affiliation.

In addition, where a prescription is issued in the Member State of treatment for medicinal products which are not normally available on prescription in the Member State of affiliation, it shall be for the latter to decide whether to authorise exceptionally or to provide an alternative medicinal product deemed to be as effective.

Trial areas: a new clause states that the Commission, in cooperation with the Member States, may designate border regions as trial areas in which innovative cross-border healthcare initiatives can be tested, analysed and evaluated.

E-health: the use of e-Health and other telemedicine services: must (a) adhere to the same professional medical quality and safety standards as those in use for non-electronic healthcare provision; (b) offer adequate protection to patients, notably through the introduction of appropriate regulatory requirements for practitioners similar to those in use for non-electronic healthcare provision.

Cooperation on management of health technologies: the European Commission (rather than Member States) shall, in consultation with the European Parliament, facilitate the establishment of a network connecting the national authorities or bodies responsible for health technology assessment.