Patients' rights in cross-border healthcare

2008/0142(COD) - 19/01/2011 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

It adopted its position at second reading in accordance with the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise reached between the European Parliament and the Council.

They amend the Council's position at first reading as follows:

Scope and application: it is stipulated that this Directive also aims at clarifying the relation with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.

Responsibility of the Member State of treatment: the amended text stipulates that cross-border healthcare shall be provided in accordance with the standards and guidelines on quality and safety laid down by the Member State of treatment and with Union legislation on safety standards, taking into account the **principles of universality, access to good quality care, equity and solidarity**.

Patients should receive from the national contact point upon request relevant **information** on the standards and guidelines, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities.

Healthcare providers provide relevant information to help individual patients to make an **informed choice** , including on treatment options.

There are **transparent complaints procedures** and mechanisms in place for patients, in order to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive.

The principle of non-discrimination with regard to nationality shall be applied to patients from other Member States. This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by overriding reasons of general interest, such as planning requirements to the object 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, so far as possible, any waste of financial, technical and human resources. Such measures shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination and shall be made publicly available in advance.

Responsibility of the Member States of affiliation: 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. In addition, patients who seek to receive or do receive cross-border healthcare should have remote access to or have at least a copy of their medical records.

National contact points for cross-border healthcare: the Commission and the Member States shall make the **information as regards the national contact points publicly available**. Member States shall

ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers. They shall facilitate the exchange of information and cooperate closely with each other and with the Commission.

In order to enable patients to make use of their rights, national contact points in the Member State of treatment shall provide them with the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

The information shall be easily accessible and be made available by electronic means and in formats accessible, as appropriate, **to people with disabilities**.

General principles for reimbursement of costs: the amended text stipulates that the Member States of affiliation may decide to reimburse the full cost of cross-border healthcare **even if this exceeds the level of costs that would have been assumed had the healthcare been provided in its territory**.

Member States of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that sufficient documentation setting out these costs exists.

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 object 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, so far as possible, any waste of financial, technical and human resources.

Member States shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed as authorised.

Healthcare that may be subject to prior authorisation: the Member State of affiliation may provide for a system of **prior authorisation** for reimbursement of costs of cross-border healthcare. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and **may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients**.

Healthcare that may be subject to prior authorisation shall be limited to healthcare which: (i) is made subject to planning requirements relating to the object 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, so far as possible, any waste of financial, technical and human resources and (ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment. Member States shall notify the categories of healthcare to the Commission.

When a patient affected or suspected of being affected by a **rare disease** applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice.

The text stipulates that the Member State of affiliation **may not refuse to grant prior authorisation** when the patient is entitled to the healthcare in question, and when this healthcare cannot be provided on its territory within a time-limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.

Administrative procedures regarding cross-border healthcare: Member states shall set out **reasonable time limits** within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member states shall take into account: (a) the specific medical condition, (b) urgency and individual circumstances.

Member States shall ensure that 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, which include provision for interim measures.

It is stated that this Directive is without prejudice to Member States' right to offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply. In other cases Member States of affiliation shall ensure that patients receive reimbursement without undue delay.

Recognition of prescriptions issued in another Member State: the amended text stipulates the recognition of prescription **shall not affect any national rules** recognising for ethical reasons the right of 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 or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation, that Member State shall take all necessary measures, in addition to the recognition of prescription, in order to ensure continuity of treatment.

Rare diseases: the Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

- make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;

- make patients, health professionals and payers of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases.

eHealth: the Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States. Amongst the objectives of the eHealth network, the text highlights the need to work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and quality healthcare.

The objectives shall be pursued in due observance of the principles of data protection.