Patients' rights in cross-border healthcare

2008/0142(COD) - 27/10/2010

The Committee on Environment, Public Health and Food Safety adopted the recommendation for second reading in the report by Françoise GROSSETÊTE (EPP, FR), 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' right in cross-border healthcare.

The committee recommends that the European Parliament's position adopted in second reading in accordance with the ordinary legislative procedure (codecision), should amend the Council's position in first reading as follows:

Scope and application: Members consider that the Directive should apply to all types of cross-border healthcare, independent of the way in which it is organised, delivered or financed. The already existing framework of the coordination of social security systems, Regulation, 883/2004, should be complemented. It should also establish a general framework for patients rights in relation to cross-border mobility. In the application of this Directive, Member States should take into account the principle of equity.

This Directive should not apply to i) organ transplants, ii) the sale of pharmaceuticals and medical devices by mail order or via the internet.

Responsibility of the Member State of treatment: the amended text stipulates that the Member States of treatment have to take responsibility for the organisation and the delivery of cross-border healthcare, taking into account the principles of universality, access to good quality care, equity and solidarity. They shall define clear quality standards for healthcare provided on their territory, and ensure compliance with existing Union legislation on safety standards.

They must, in addition, ensure that cross-border healthcare shall not lead to patients being encouraged against their will to receive treatment outside of their Member State of affiliation.

Patients should receive from the national contact point clear information on the prices and the accessibility for persons with disabilities, as well as on the healthcare provider's authorisation or registration status and number and any restrictions on their practice. Healthcare providers should provide patients with all relevant information to enable them to make an informed choice, including on treatment options. This information must be remotely accessible by electronic means and made available in formats accessible to persons with disabilities.

Members consider that the Directive should not oblige healthcare providers in a Member States 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 of the Member State of treatment.

Healthcare providers in the Member State of treatment shall apply the same scale of fees for healthcare of patients from other Member States, as for domestic patients in a comparable situation, whatever the socio-economic position of the patient.

Responsibility of Member States of affiliation: the Member State of affiliation must ensure that easily accessible mechanisms are in place to provide patients, on demand, including by electronic means, with

information concerning their rights in that Member State and concerning the conditions that would apply whenever harm is caused as a result of healthcare received in another Member State. This information must be published in a format accessible to disabled persons.

In the event of complications resulting from healthcare provided abroad or if a particular medical follow-up proves necessary, the Member State of affiliation must guarantee to provide healthcare equivalent to that received on its territory.

In addition, patients who benefit from cross-border healthcare must be guaranteed the right to receive a copy of their medical records or to access them remotely, if the medical records are held in electronic form. Data shall be transmitted only with the express written consent of the patients or the patient's relatives.

National contact points: Member States shall ensure that independent patients organisations, sickness funds and healthcare providers are encompassed by national contact points. The national contact points shall be established in an independent, efficient and transparent way. Members call for information about the existence of these contact points to be disseminated across Member States, so that patients have easy access to the information.

National contact points shall also support patients in protecting their rights by providing with the information, inter alia remotely, accessible by electronic means, concerning healthcare providers, including on request, information on the protection of personal data, the level of accessibility to healthcare facilities for people with disabilities.

General principles applicable to reimbursement: the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits provided for by legislation, administrative regulations nor guidelines or codes of conduct of the medical professions, to which the insured person is entitled in the Member State of affiliation or is equally effective to healthcare that is among those benefits. Member States may choose to only reimburse such methods of treatment that are sufficiently tried and tested by international medical science.

In addition, the Member State of affiliation must reimburse to the Member State of treatment or the insured person the costs which would have been paid for by it§s statutory social security system had equally effective healthcare been provided on its territory. If the Member State of affiliation refuses to reimburse this treatment, that Member State shall give a medical justification for its decision. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

On the basis of a prior objective clinical examination, patients affected or suspected to be affected by rare diseases shall have the right to access healthcare in another Member State and to receive reimbursement even if the diagnosis or treatment in question is not among the benefits provided for by legislation, administrative guidelines or codes of conduct of the medical professions, of the Member State of affiliation. Such treatment shall be subject to prior authorisation.

Any costs incurred by the insured person over and above the level reimbursed by the Member State of affiliation shall be borne solely by the insured person, unless the Member State of affiliation decides also to reimburse the insured person for the costs incurred in excess of that level.

Members do not agree that the Member State of affiliation should limit the application of the rules on reimbursement for cross-border healthcare a) based on overriding reasons of general interest such as the

risk of seriously undermining the financial balance of a social security system or the objective of maintaining a balanced hospital service open to all ; b) to providers that are affiliated to a system of professional liability insurance.

Prior notification: a new article stipulates that the 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. On presentation of that written confirmation by the patient at the hospital of treatment, reimbursement shall be made directly to that hospital by that Member State of affiliation.

Prior authorisation: Members ask that the Member State of affiliation should prepare a list of treatments likely to require prior authorisation and transmit this to the Commission. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of cross-border healthcare where the following conditions are met:

i) had the treatment been provided on its territory, it would have been assumed by the Member State' s social security system and

ii) the absence of prior authorisation could seriously undermine or be likely to undermine i) the financial balance of the Member State's social security system and/or the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, iii) the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Members consider that prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent for patients. The rules for application and refusal of prior authorisation must be public and 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, inter alia by electronic means, where appropriate.

Procedure guarantees: Member States shall organise, in all cases where and when appropriate, transfer of funds of corresponding costs of cross-border healthcare directly between the competent institutions. This procedure would avoid patients paying up front and waiting to be reimbursed. In other cases, the Member State of affiliation shall ensure that patients will receive reimbursement without undue delay.

When setting out the time limits within which requests for cross-border healthcare must be dealt with and when considering these requests, Member States shall take into account a) the specific medical condition, b) the patient's degree of pain, c) the nature of the patient's disability, d) the patient's ability to carry out a professional activity.

Recognition of prescriptions: Members consider that the recognition of prescriptions should not affect 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. They recommend the drawing up of a single European cross-border prescription template which would support interoperability of prescriptions.

When a prescription is issued in the Member State of treatment for medicinal products or medical devices which are not normally available on prescription ion 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 have the same therapeutic effect.

On-line medicine: Members suggest that the Commission, by means of the committee procedure, draws up the specific measures necessary for the interoperability of information technology and communication systems in the healthcare field that are applicable whenever Member States decide to introduce them. Those measures should respect applicable data protection legislation applicable in each Member State, reflect the technological developments in health and medical science, in particular telemedicine and telepsychiatry and respect the fundamental right to the protection of personal data.

Members believe that Member States should ensure that the use of online healthcare services and other telemedicine services should 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 health professionals similar to those in use for non-electronic healthcare provision.

Network: the European Commission should facilitate, in consultation with the European Parliament, facilitate the establishment of a network connecting national authorities or bodies responsible for health technology assessment.