Patients' rights in cross-border healthcare

2008/0142(COD) - 20/09/2010 - Commission communication on Council's position

The Commission accepted in full, in part or in principle 92 out of 120 amendments adopted at the first reading as it considered that these amendments clarified or improved the Commission proposal and were consistent with the general aim of the proposal.

Major problems when adopting the position of the Council at first reading were as follows:

Scope of prior authorisation: the Commission proposal foresees that the Member State of affiliation may not impose a system of prior authorisation for non-hospital care. However, as regards on one hand hospital care and on the other specialised care included in list established at Union level through a regulatory procedure, the proposal foresees that the Member State of affiliation may provide for a system of prior authorisation "to address the consequent outflow of patients due to the implementation" of the Directive and to prevent the financial balance of the Member State's social security system and/or the planning and rationalisation carried out in the hospital sector from being seriously undermined or being likely to be seriously undermined.

The position of the Council at first reading introduces the possibility for the Member State of affiliation to make the reimbursement of costs of certain types of cross-border healthcare (hospital, specialised care and healthcare which could raise serious and concrete concerns related to the quality or safety of the care) subject to prior authorisation without any explicit request to demonstrate an outflow of patients resulting from the freedom of mobility or any risk to the system. The text simply foresees that the system of prior authorisation shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.

The introduction of a system of prior authorisation as proposed by the Presidency text is based on a very restrictive interpretation of the jurisprudence.

Furthermore, the position of the Council at first reading refuses the adoption of a list at EU level of specialised healthcare subject to prior authorisation. It only provides that the Member State of affiliation shall make publicly available which healthcare is actually subject to prior authorisation. The Parliament took the same approach. The Commission considers that a list at EU level would have provided better transparency and more legal certainty.

The Commission is convinced of the need to ensure that patients seeking healthcare in another Member State can exercise their rights as confirmed by the Court in its settled case-law and without undermining the rights granted under Regulation 883/2004.

Conditions for refusal of a prior authorisation: the Council introduces a non-exhaustive list of criteria for refusing individual prior authorisation, which may, in the Commission's view, create legal uncertainty for the patients. Firstly, the mere fact that the position of the Council at first reading provides for a non-exhaustive list of criteria creates legal uncertainty. Secondly, without a clearer delineation of their scope and modalities of application, the criteria introduced by the Council do not provide enough legal certainty.

This list also includes a criterion based on patient safety risk: it would be extremely useful to clarify that this criterion cannot be interpreted as allowing such ground for refusal, if the same assessment is not carried out for care received domestically.

eHealth: in its initial proposal the Commission had included an article on "eHealth" whose aim was to establish the framework for the adoption, through a comitology procedure, of measures to achieve the interoperability (standards and terminologies) of information and communication technology systems in the field of healthcare.

After some discussions, Member States have eventually agreed to initiate a formal cooperation on eHealth at EU level and have identified three concrete priority areas for patient safety and the continuity of cross-border healthcare: (i) identification and authentication of health professionals; (ii) list of essential data to include in patient summaries; (iii) and use of medical information for public health and medical research.

The Commission believes that the Council text is more precise than the Commission's initial proposal, but lacks working methods, such as provisions giving the Commission the power to adopt measures to implement the work at EU level.

In conclusion, the Commission takes the view that the position of the Council at first reading contains elements departing from the Commission's proposal which may create **risks of legal uncertainty**. In order to allow the legislative process to move forward, the Commission did not stand against the position adopted by the Council by qualified majority in order to allow the legislative process to move forward. **The Commission indicated to the Council in the attached declaration that it reserves the right to support European Parliament amendments during second reading on eHealth**, the scope of the prior authorisation, increasing legal certainty for patients, and assuring that the proposed Directive does not undermine the rights granted under Regulation 883/2004.