

Patients' rights in cross-border healthcare

2008/0142(COD) - 13/09/2010 - Council position

The Council position at first reading was adopted by a qualified majority. The Polish and Slovak delegation voting against with the Romanian delegation abstaining.

The Council accepted 16 amendments in full and 15 in large part adopted by the European Parliament (EP) at first reading.

It should be noted that the Council included a double legal basis for the Directive (Article 114 and 168 of the Treaty), which was supported by the Commission.

Subject matter and scope: the Council takes the same line as the EP, that the Directive should on the one hand provide for rules to facilitate access to safe, high-quality cross-border healthcare and promote cooperation between the Member States, while on the other hand fully respecting national competence for organising and delivering healthcare. The Council is of the opinion that Article 1(2) covers all the different types of healthcare systems in the Member States and therefore that the wording "whether it is public or private" is unnecessary and misleading.

Like the EP, the Council recognised the need to exclude long-term care from the scope of the Directive, thus following the EP, and limited the exclusion of organ transplantation to access to and allocation of organs. The Council added the exclusion of public vaccination programmes against infectious diseases.

The definition of "healthcare" is consistent with the EP's amendments and covers healthcare that is provided (treatments) or prescribed (medicinal products and/or medical devices) while dropping the reference to professional mobility.

Relationship with Regulation (EC) No 883/2004 on the coordination of social security system: the Council agrees with the EP that the Directive should apply without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EC) No 883/2004. This framework allows the Member States to refer patients abroad for treatment that is not available at home. The Council's position is that when the conditions of the Regulation are met, prior authorisation must be given pursuant to that Regulation, since in the majority of cases this will be more advantageous to the patient. Nevertheless, the patient can always request to receive healthcare under the Directive.

Member State of treatment (MST): the Council groups together all the responsibilities of the MST in one article. The main responsibilities of the MST are those that the EP asked for. Furthermore, while recognising the principle of non-discrimination with regard to nationality against patients from other Member States, the Council introduced the possibility for the MST, where justified by overriding reasons of general interest, to adopt measures regarding access to treatment aimed at fulfilling its responsibility to ensure sufficient and permanent access to healthcare within its territory to its insured persons.

The Council followed the thrust of the EP's amendment on the necessity for systems to be in place for making complaints, and mechanisms for patients to seek remedies in accordance with the legislation of the MST if they suffer harm arising from the healthcare they have received. In addition, the Council included additional guarantees for patients (e.g. application of the same scale of fees by healthcare providers to cross-border patients).

Member State of affiliation (MSA): as a general principle for reimbursement of the costs of cross-border healthcare, the MSA would have to have a mechanism for calculation of such costs. It can also introduce a

system for prior authorisation based on non-discriminatory criteria, limited to what it is necessary and proportionate and applied at the appropriate administrative level. This goes along with what the EP proposed in amendments.

Prior authorisation: the Council agreed to the general principle that reimbursement of the costs of cross-border healthcare must not be subject to prior authorisation in line with the EP's amendment. The prior authorisation system that the MSA may introduce pursuant to the Directive, and as an exception to the above-mentioned principle, has to be based on clear and transparent criteria, should avoid unjustified obstacles to the freedom of movement of persons and thus reflects the thrust of the EP's amendments. The MSA may limit the application of the rules on reimbursement for cross-border healthcare by overriding reasons of general interest or to providers that are affiliated to a system of professional insurance in the MST. In this respect, the Council opted for a different approach than proposed by the EP.

The basic principles for the procedure for granting the prior authorisation are detailed in the Council's position, and include the obligation to give the reasons for refusal, e.g. the healthcare is provided by providers that raise serious and concrete concerns related to compliance with the applicable quality and safety standards and guidelines. The Council limited the healthcare that may be subject to prior authorisation to healthcare that the EP defined as "Hospital care" and took the approach of focusing on the factors justifying it. The Council agrees with the EP that there should not be a common EU-wide list of healthcare, but that it is for the Member States to define it.

Pensioners living abroad: when pensioners and members of their families whose MSA is listed in Annex IV to the Regulation reside in a different Member State, this MSA has to provide them with healthcare at its own expense when they stay on its territory. If the healthcare provided in accordance with the Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation, and is provided in the territory of the Member State that, according to the Regulation, is, in the end, responsible for reimbursement of the costs, the costs should be assumed by that Member State.

Direct payment and the concepts of prior notification and of vouchers: the Council rejects the EP's amendments as it considers them contrary to the competence of the Member States to organise their health systems, in particular when it comes to the regulation of upfront payments.

Equal treatment of patients and extension of entitlements to reimbursement: the Council has not incorporated the amendments on this issue in order to respect the principle of equal treatment for all insured persons from the same MSA regardless of the MST. The explicit reference to particular pieces of legislation on equal treatment is unnecessary as the principle is embodied in the Council's text. The Council's position states that the Member States have to ensure that all patients are treated equitably on the basis of their healthcare needs, which reflects the EP amendment.

Goods used in connection with healthcare: the Council has not included the definition of "goods used in connection with healthcare" proposed by the EP and prefers to use the definitions of "medical device" and "medicinal product" that already exist in EU legislation and would not pose transposition and implementation problems.

Continuity of care: the Council considered that ensuring continuity of care is an important aspect of the provision of cross-border healthcare and that it should be achieved through practical mechanisms, the transfer of personal data, e-health and sharing of information between health professionals. In agreeing on these aspects, the Council drew on the relevant parts of the EP's amendments.

Information for patients and the National Contact Points (NCPs): in conformity with the EP's amendments, the Member States must provide patients on request with relevant information on the safety and quality of the healthcare provided as well as on their entitlements and rights. The NCPs have to cooperate with each other and with the Commission. In addition, the NCPs have to provide patients with

information concerning healthcare providers, and, on request, on any restrictions on their practice. They should also provide information to patients on procedures for complaints and for seeking remedies and on provisions on supervision and assessment of healthcare providers. All this information should be easily accessible, including by electronic means.

Data collection and protection: the Council's text includes several provisions creating obligations in relation to the protection of personal data on the MST and MSA and in relation to e-Health reflecting the existing EU legislation on protection of personal data.