



31.3.2017

NOTICE TO MEMBERS

Subject: Petition No 0974/2016 by A. P. (German) on extending the scope of EU legislation in the area of patient law, to guarantee physical integrity through advanced patient data recording

1. Summary of petition

The petitioner calls for the drafting of a law on the protection of patients in the context of a European social security agreement, or for the extension of the scope of the regulation on the coordination of social security. The petitioner calls for an obligation to provide after-care and a new form of patient protection law, including stricter controls and legal standards, e.g. criminal law standards for doctors, as well as advanced patient data recording in a uniform data structure, through which doctors could have a comprehensive insight in the health condition of the patients and possibly improve health care.

2. Admissibility

Declared admissible on 10 January 2017. Information requested from Commission under Rule 216(6).

3. Commission reply, received on 31 March 2017

The petitioner proposes the introduction of European standards for the protection of patients. The EU's competences in this area are laid down in Article 168 of the Treaty on the Functioning of the European Union (TFEU) which calls for a high level of human health protection in the definition and implementation of all Union policies and activities.

It provides in this context that Union action shall complement national policies and shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission, their prevention, as well as health information and education on monitoring,

early warning of and combating serious cross-border threats to health.

Concrete legal measures for this purpose have not been included in Regulation (EC) No 883/2004 on the coordination of social security systems. In contrast, Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare provides an obligation on Member States to provide the same follow-up for cross-border treatment as if the healthcare had been provided on their territory. The Directive obliges Member States to have and provide information about liability insurance for healthcare providers and professionals, dispute settlement possibilities, complaints procedures and mechanisms for seeking remedies. The Member States are also obliged to provide information on the quality and safety of the healthcare they provide.

Through the eHealth Network supported by the European Commission, the Member States are working towards a system that would allow for the cross-border exchange of electronic patient summaries in a safe and standardised way. The plan is that such a system should be operational in 2018 for the first Member States participating, and that it will be expanded to all Member States step by step.

The various provisions of the Directive make it possible for patients to make informed choices in cross-border situations and establish a high level of trust between the patient and the healthcare provider. The rules regulating the healthcare provided, however, are those set out in the legislation of the Member State of treatment.

Conclusion

The Commission considers that the petitioner is in part requesting regulation that is already in place, in part regulation on areas of Member State competence according to the TFEU. Issues that are being addressed through voluntary cooperation between Member States are also touched upon. Therefore, even though supporting the aim of patient safety and patient rights, the Commission has limited competences to regulate certain aspects and can not support the petition.