

07.11.2008

Decision
of the Bundesrat

Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare**COM (2008) 414 final.; Council Document 11307/08**

In its 850th meeting on 7th November 2008, pursuant to §§ 3 and 5 EUZBLG (Act on Cooperation between the Federation and the Federal States in European Union Affairs), the Bundesrat adopted the following Opinion:

1. The Bundesrat is pleased to note that the Commission is seeking to ensure legal security for patients, doctors and health insurance schemes on provision of health care by proposing a separate directive on this issue and has decided not to continue leaving decisions in this area solely to the European Court of Justice (ECJ). The Bundesrat supports the idea of ensuring enforcement of ECJ rulings on patient mobility in all Member States. Germany has already transposed this case law into national legislation (cf. § 13 German Social Law Code V). The Bundesrat also agrees that as a general rule the relevant conditions pertaining to provision of treatment that are valid in the Member State of affiliation should be applicable.

In addition, the Commission proposal aims to create a Community framework for cross-border provision of health care and to improve European cooperation in the sphere of health care. However, the Bundesrat takes the view that certain provisions in the draft directive do not entirely do justice either to this objective or to provisions found in primary law currently in force.

2. The Bundesrat draws attention to the need to clarify the scope of application of the directive, particularly with reference to Regulation (EEC) No. 1408/71 and Regulation (EC) No. 883/2004.

Article 3 Sub-section 2 provides that both systems shall exist in parallel. In this context however the Bundesrat is of the opinion that there are grounds to fear that it may prove impossible in practice to subsume particular cases absolutely clearly under just one of the schemes, and that differing legal consequences mean there could be a risk of misunderstandings and inequitable treatment (e.g. waiting lists, treatment methods in the catalogue of care provided in each system).

In particular in cases where Member States reserve the right to require prior authorization for in-patient treatment in another Member State, there would be no difference between this approach and Regulation (EEC) No. 1408/71 or Regulation (EC) No. 883/2004, whilst the legal consequences would differ considerably, because as a general rule pursuant to Regulation (EEC) No. 1408/71 the benefit-in-kind would constitute the legal consequence and not reimbursement of the costs.

The Bundesrat is therefore concerned that the practice observed in some instances of circumventing the guarantee to provide the benefit-in-kind as per Regulation (EEC) Nr. 1408/71, an approach that is to the detriment of patients, might possibly become more pronounced as a consequence of this draft directive. The Bundesrat therefore calls for greater legal security concerning the co-existence of the Directive and the Regulation envisaged in this draft directive.

3. The Bundesrat would like to see benefits from the social welfare scheme and the victims of war welfare scheme excluded from the draft direction. Furthermore, the Bundesrat points out that the definition of provision of health care in Article 4 Point a picks up on the existence of various health care professions pursuant to Directive 2005/36/EG and that this definition also encompasses fields of work that fall within the scope of long-term-care insurance in Germany, such as for example carers for the elderly.

The Bundesrat reserves the right to comment in future on whether nursing care, rehabilitation services, pensions insurance and benefits provided under accident insurance schemes should also fall within the scope of the draft directive. The same applies to special systems such as, for example, private health insurance schemes and the separate system providing benefits for civil servants.

4. The Bundesrat is of the opinion that Article 95 TEC cannot be taken as the legal basis for all the provisions comprised in the draft directive. In particular it is not apparent how provisions on establishing a network of European Reference Centres (c.f. Article 15) or on cooperation on telematics in health care (c.f. Article 16) might secure fundamental freedoms or overcome distortions of competition. In addition, the Bundesrat emphasizes that the choice of this legal basis should not signify that constraints on Community activities in the health sphere stipulated in Article 152 TEC are circumvented.

5. The Bundesrat welcomes the clarification in the introduction to Article 5 concerning Member States' responsibility for organizing and providing health care and calls for this approach to be reflected more consistently in the drafting of the other provisions in Article 5 than is currently the case. In the Bundesrat's view the provisions in Article 5 Sub-section 1 Sentence 2 and the aim of European guidelines referred to in Sub-section 3 constitute an inadmissible step towards Community intervention in national health care systems. In particular, requirements formulated in guidelines might have indirect financial implications. In the long term, guidelines might lead to health care systems becoming more uniform, with a general tendency to reduce the quality of provision of care to a low level. The Bundesrat is opposed to this scenario and therefore calls for the provisions of Article 5 Sub-section 3 to be dropped.

6. The Bundesrat welcomes the Commission's efforts to provide greater transparency for patients in respects of the costs of treatment abroad by introducing a mechanism for calculation of the costs (Article 6 Sub-section 4). However, there is a need to clarify that Article 6 Sub-section 4 only requires that Member States shall establish a mechanism to calculate the costs reimbursed within the system of the respective Member State of affiliation.

7. The federal states have a particular responsibility, in financial terms too, for ensuring provision of high-quality hospital care within easy reach of citizens' homes. Unregulated patient mobility could lead to patients moving away from certain regions and might undermine the structures that need to be maintained. The Bundesrat therefore welcomes the possibility of requiring prior authorization as a management instrument and indeed considers this to be

indispensable. The Bundesrat is of the opinion that the conditions that apply when requiring prior authorization are not appropriate if the very narrow definition of these conditions goes beyond the framework established by the ECJ. The Bundesrat is concerned that this management instrument may not be sufficiently powerful. Requiring prior authorization can also help patients to take an informed decision that takes financial aspects into account too.

8. The Bundesrat is of the opinion that the definition of hospital treatment in Article 8 of the draft guideline is too narrow. The Bundesrat draws attention to the fact that treatments that are partially in-patient and out-patient hospital treatments would not be covered by this definition, nor would treatment in day centres of patients suffering from psychological problems be included. Drawing up a definition of this notion must fall within the sphere of competence of the Member States. The planned list of highly specialized and cost-intensive treatments that may also be made subject to prior authorization must be drawn up by the Member States under their own responsibility. In the Bundesrat's view if the Commission were to draw up this list it would constitute an infringement of the Member States' responsibility for their national health systems as provided in Article 152 Sub-section 5 TEC.
9. The Bundesrat considers that statutory regulation of the European Reference Networks is not covered by Article 95 TEC. However the Bundesrat does welcome the principle of further development of a network of European Reference Centres, which promises to provide European added value through exchanges of high-quality expert know-how, which will be beneficial to Europe as a knowledge and health location in the spirit of the Lisbon Strategy, as well as to individual patients' specific health care needs. However, in this context the Commission must respect the limits of Article 152 TEC and may act solely to provide support and foster the establishment of a network.
10. The Bundesrat considers that there is no need to stipulate such far-reaching obligations for providers of health services, the Member States of affiliation and the Member States of treatment to make information available (Article 5 Sub-section 1 Point c, Article 8 Sub-section 5, Article 9 Sub-section 1 Sentence 1, Sub-section 2 and 3, Article 10, Article 12 Sub-section 2 Points a, b and c, as

well as Sub-section 3 Point c). Stipulating that those responsible should provide insured persons in their country with information on their rights and duties (Article 10) is an appropriate approach. The Bundesrat advocates deletion in particular of Article 10 Sub-section 3, as Member States alone bear responsibility for stipulating the precise details of the right to information.

11. The Bundesrat also recognizes the fundamental need to designate national contact points (Article 12) to prepare basic information on their own national system and – as far as possible – on the costs of treatment likely to be incurred (Article 6 Sub-section 4), as well as serving as a partner that can be contacted by individuals from other Member States seeking advice. The extent to which detailed provisions on the right to advice are stipulated should be decided nationally. The Bundesrat is thus in favour of amending Article 12 Sub-section 2 and 3.
12. The Bundesrat is opposed to the collection of data on the scale stipulated in Article 18, as a specific, concrete indication of the data to be collected is not provided. Information systems for statistical purposes must be limited to what is necessary and include data collected on a routine basis.
13. The Bundesrat is opposed to the introduction of a new bureaucratic procedure and the creation of a new committee chaired by the Commission (Article 19), as that would mean that legislative powers and responsibilities would be shifted to a forum comprised of experts rather than legislators.
14. Due to the complexity of the matters dealt with in the draft directive, the Bundesrat is of the opinion that a three-year time-frame for transposition is crucial.
15. The Bundesrat requests the federal government to take its opinion into account in deliberations in the Council and reserves the right to submit a Supplementary Opinion as deliberations proceed.

16. The Bundesrat shall transmit this Opinion directly to the Commission.