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**// CED POSITION PAPER**

# **DRAFT DIRECTIVE ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE**

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## // SUMMARY

1. The Council of European Dentists (CED) is the representative organisation for the dental profession in the EU, representing over 300,000 practising dentists through 32 national dental associations. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED promotes high standards of oral healthcare and effective patient-safety centred professional practice across Europe.

2. In dentistry, although there has been much publicity given to dental patients travelling abroad, a relatively small number seek healthcare in another member state. Their decision is not normally based on medical necessity, lack of availability of treatment in their home state or the search for higher quality in another country. Rather the decision is made in relation to the extent of the patient's own financial contribution to the treatment, which may depend on the inclusion and availability of certain treatments within the patient's social security or insurance system. This makes patient mobility in the area of dental care somewhat different to mobility in other areas of healthcare.

3. The CED welcomes the European Commission's proposed directive. We support many of the measures designed to clarify patients' rights, protect patient safety and improve the quality of service and sharing information and good practice, whilst bearing in mind that the new article 152 of the Lisbon Treaty is not yet in force, and that the EU does not have any primary powers related to the structuring of health and social security systems of member states. However, a framework directive will necessarily leave many issues unresolved and we can see that there will be a great deal of debate, controversy and work to do in implementing the provisions in the member states, as there will be many challenges to decisions taken at all stages in the legislative process.

4. The CED emphasises the importance of continuity of care and of a strong dentist-patient relationship. Dental treatment often requires a series of visits to the dentist to properly plan and carry out the treatment, and to provide post-treatment care. Where patients spend only a short time in the vicinity of the dentist – as is often the case where patients receive care abroad – the overall quality of the health service is difficult to ensure. The CED therefore does not believe that patient mobility in the area of dental care should be actively promoted.

5. The quality and safety of healthcare services can best be ensured by having up-to-date minimum training requirements for health professionals; by promoting ethical codes developed by European health professionals' organisations in the context of cross-border care; through continuous professional development; and by a commitment to professional practice that is patient-safety-centred. The CED believes that professional and ethical standards can best be developed at national or regional level. We do not believe there is a role for the European Commission in the setting of such standards.

6. Patients must be informed that high-quality treatment depends on properly planned care with scope for post-treatment care. Patients should have access to clear information on the availability and procedure for receiving reimbursements for healthcare costs abroad. Information on access to health services in other EU countries should be objective and not involve any ranking. Whilst strongly supporting the establishment of national contact points we are not sure that the provisions in the draft directive on the availability of - valid - information are sufficiently robust.

7. The CED welcomes the provision that health services are to be provided according to the legislation of the member state of treatment. We believe that the draft directive should, in addition, clearly set out that regulatory responsibility in the context of patient mobility must reside with the member state of treatment.

8. The CED supports the provisions of the draft directive for extended cooperation between member states, including: the mutual recognition of prescriptions, the establishment of European reference networks, e-health, and the management of new health technologies. We believe these measures will contribute to enhancing quality and safety, improve patient care and increase cost-effectiveness in the long-term.

9. The role of the "Implementing Committee" proposed in the draft directive must be closely defined and limited to those issues that do not directly encroach on the role of member states in organising their healthcare systems.

## // CED POSITION ON THE DRAFT DIRECTIVE

10. The CED believes that most patients in the EU will continue to prefer to obtain healthcare close to home, but it is important that their rights and responsibilities are clear if they choose not to do so and that they are appropriately protected.

11. ECJ case law, while it might clarify the Community legal position and apply the principles of the Treaty, is an unsatisfactory way of protecting rights in a situation where an increasing, if relatively small, number of EU citizens wish to take advantage of freedom of movement and to exercise choice.

12. The draft Directive is therefore a significant step forward. As a framework directive, however, it leaves many areas still unclear and we can see there remains much to be resolved in the courts, whether nationally or at the level of the European Court of Justice (ECJ), and/or through subsequent legislation or regulation. These areas include how member states develop reimbursement tariffs and the decisions they take on the availability of care, what regional variations there may be, what bureaucratic and prior authorisation obstacles they may seek to impose on patients, and whether member states are required to provide care for nationals of other states.

Against the background of these introductory considerations, the CED comments the draft directive as follows:

### **Article 5 - Responsibilities of authorities of the member state of treatment**

13. According to Article 5 Para.1, the member states of treatment are responsible for ensuring compliance with common principles for the various types of healthcare. These include quality, safety, knowledge-based and ethically secure provision, patient-centred treatment, compensation, and respect for privacy and confidentiality of personal data. The CED expressly welcomes this approach.

14. The requirement for cross-border health providers to demonstrate proof of professional liability insurance is also essential. However, the CED specifically warns against Europe-wide application of legal regulations for risk liability or the introduction of reversal of the burden of proof in the field of medical/dental treatment.

15. Article 5 Para. 3 gives the Commission the right to lay down guidelines and standards, for example regarding quality assurance, safety standards and patient information. The CED advocates a moderate approach. The powers of the Commission to set standards must by all means be restricted to those issues that do not directly encroach on the member states' role in national health policy. In particular, monitoring of quality assurance must remain in the hands of the member states and their professional organisations. Moreover, the Open

Method of Coordination for health policy questions at EU level already represents a procedure for coordination of the above issues between member states.

16. The CED's approach to quality is based on fostering professionalism. We believe that greater professionalism will drive up clinical standards and contribute to continuous improvement in patient safety. However, we do not believe that the setting of professional and ethical standards at EU level is of added value. It could result in greater risk to patients through the application of "lowest common denominator" standards. Standards for high quality healthcare must be developed at national and regional level, involving the professional organisations. We do not believe there is a role for the European Commission here.

#### **Articles 7 to 9 – Reimbursement of healthcare provided in another member state**

17. The CED welcomes the regulations regarding cost reimbursement, which reflect the latest judgments of the European Court of Justice (ECJ). With regard to prior authorisation requirements, we agree they are acceptable if they avoid a serious threat to the financial balance of a member states' social security system, capacity for planning treatment etc. However, we do not yet understand how these provisions will be interpreted in practice.

#### **Articles 10 and 12 – "Information for patients" and "national contact points"**

18. The CED welcomes the proposal that patients should be informed about the possibility of receiving treatment in other EU member states, and the terms and conditions that would apply if harm were caused as a result of such treatment. However, we would suggest that the tasks of the national contact points be reduced to realistic proportions. For example, they cannot provide reliable information about the legal systems in all the other 26 member states. Any ranking of the possibilities of treatment must also be strictly excluded, as there are no reliable criteria for this.

19. Organisations of health professionals at national and regional level should be involved in the process of setting up any information systems.

20. The draft directive should make it more explicit that in the context of patient mobility responsibility for the provision of information about the regulatory system should reside with the member state of treatment.

#### **Article 11 – Applicable rules for healthcare provided in another member state**

21. The CED expressly welcomes the fact that cross-border health services are to be provided according to the legislation of the member state of treatment.

22. As indicated above, the draft directive should state more clearly that it will be for the member state of treatment to regulate services provided for visitors and to ensure that they have all information they need, including how to get redress if necessary. Healthcare professionals and providers have to be aware of their responsibilities for obtaining valid consent. We know from experience that language and cultural differences can be significant barriers to effective healthcare and particularly patient understanding and expectations of care.

#### **Article 15 - European reference networks**

23. The CED supports the establishment of European reference networks to bring together resources and expertise in order to guarantee access and quality regarding highly specialised healthcare for patients from all member states. However, we do not believe that laying down the criteria for the reference networks can be the task of the Commission alone – it must be carried out in conjunction with the member states, professional organisations and academics. Care should also be taken to ensure that the setting up of reference networks does not result in any disadvantaging either of health locations and providers who already provide highly qualified and specialised treatment, or of medical researchers.

#### **Article 16 - E-health**

24. The CED supports measures ensuring interoperability of information and communication technology systems so as to foster safe, high-quality and efficient provision of cross-border health services. We suggest that existing measures in individual member states be taken into account, and where possible made use of.

#### **Article 17 – Cooperation on management of new health technologies**

25. The CED welcomes in principle the development and operation of a network connecting the national authorities or bodies responsible for health technology assessment. However, here too, care should be taken that representatives of the health professions are involved.

#### **Article 18 - Data collection for statistical and monitoring purposes**

26. According to this Article, member states should collect data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. A balance should be ensured between the costs and benefits of collecting such data. It must be clearly stated who is allowed to use this data and in what way.

#### **Article 19 – Implementing Committee**

27. The CED supports the tried-and-tested committee system for passing implementation provisions, provided the powers given to the Commission are closely defined and limited in law so as to avoid disproportionate, unanticipated and inappropriate spill-over into the role of member states and their bodies.

**Adopted unanimously by the CED General Meeting on 28 November 2008.**