COUNCIL OF EUROPEAN DENTISTS

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// CED POSITION PAPER

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

2008/0142 (COD)

COUNCIL OF EUROPEAN DENTISTS (formerly EU Dental Liaison Committee)
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// SUMMARY

The Council of European Dentists (CED) is the representative organisation of the dental profession in the European Union, representing over 327,000 practicing dentists from 32 national dental associations in 30 European Countries. 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. The CED welcomes the opportunity to present the comments on the draft Directive on the application of patients' rights in cross-border healthcare prepared by the CED Board Task Force Internal Market.

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.

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.

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.

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. The CED strongly supports the establishment of national contact points.

The CED welcomes the provision that health services are to be provided according to the legislation of the Member State of treatment.

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 on the implementation of the health technology assessment network. We believe these measures will contribute to enhancing quality and safety, improve patient care and increase cost-effectiveness in the long-term.

// CED POSITION ON THE COUNCIL POSITION/ENVI DRAFT RECOMMENDATION FOR SECOND READING

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.

While the European Court of Justice (ECJ) case law may clarify the Union's legal framework and apply the principles of the Treaties, it 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.

The draft Directive is therefore a significant step forward. As a framework directive, however, it leaves many areas still unclear and we can see that much remains to be resolved by case law, whether in national courts or at the level of the ECJ, and/or through subsequent legislation or regulation.

Against the background of these introductory considerations, the CED would like to put forward the following comments:

1. **Council position Recital 18 (Amendment 7 in Draft recommendation for second reading)**

The CED is concerned about the reference in the proposed amendment to the information "on the characteristics of healthcare provided by a specific healthcare provider." We believe that this phrase should be more precisely defined to avoid it being understood as a basis for ranking of individual healthcare providers, which we strongly oppose. We would like to recall that no commonly agreed systems for ranking exist. The emergence of unauthorized and unreliable ranking systems would likely lead to increasing misinformation for patients. (See also our comments on Amendment 33.)

2. **Council position Recital 19 point a(new) (Amendment 9 in Draft recommendation for second reading)**

The CED strongly supports the proposed amendment. We agree that while the patients should have the opportunity to make an informed decision to seek treatment abroad, they should not be encouraged (against their will) to do so.

3. **Council position Recital 44 (Amendment 27 in Draft recommendation for second reading)**

The CED strongly supports the proposed amendment. We agree that stakeholders, including healthcare providers, should be encompassed by national contact points. (See also our comments on Amendment 42 and Amendment 44.)

4. **Council position Recital 50 (Amendment 31 in Draft recommendation for second reading)**

The CED strongly supports the proposed amendment. We agree that stakeholders, including healthcare providers, should be included in assessment of healthcare technologies. (See also our comment on Amendment 87.)

5. **Council position Recital 53**

The CED would like to see the health professional organisations represented at European level mentioned.

When empowered to adopt delegated acts in accordance with Article 290 of the Treaty, the European Commission should consult the health professional organisations represented at EU level in order to be fully transparent during the decision-making process and to ensure that the implementation measures are well understood by those who will be, directly or indirectly, affected by them. (See also our comments on Amendment 93.)

6. **Council position Article 3 point f – Definition of health professionals**

The CED is concerned with the proposed definition of *"health professionals"*, in particular when reference is made to *"(…) or a person considered to be a health professional according to the legislation of the Member State of treatment"*. This part of the definition should be eliminated since this would imply that national healthcare systems had to reimburse cross-border healthcare performed by health professionals that are not recognised as such in the Member State of affiliation and, even worse, under Directive 2005/36/EC on the recognition of professional qualifications.

In fact, for the dental profession, the consequences of establishing this definition, and the subsequent right to reimbursement of costs, would be the acceptance, by the European Union, that the professional activity of dental practitioner could be carried out by professionals that are not qualified as dentists under Directive 2005/36/EC.

Furthermore, this definition would open the door for an increase in less qualified health professionals, endangering patient safety and quality of care. This would be against Article 168, paragraph 1 of the

Treaty on the Functioning of the EU which establishes that "a *high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities"*.

7. Council position Article 3 point m – Definition of medical records

The CED is also concerned with the proposed definition of *"medical records"* when it is established that *"medical records means **all** the documents containing data, assessments and information of any kind on patient's situation and clinical development throughout the care process"*. It should be brought to the attention that personal medical notes written aside in the medical file (or other subjective elements) constitute an intellectual property right of the health professional that wrote them and not the patient. Therefore, they cannot be disclosed unless authorised by the owner of that right. In permitting to do so, this Article is in strict violation of the intellectual property and data protection rules.

Furthermore, in some Member States the patient does not have direct access to his medical file. In line with national legislation, the access is guaranteed through a doctor. These situations should be taken in consideration in the draft Directive.

8. Council position Article 4 paragraph 2 points a and b – Responsibilities of the Member State of treatment (Amendment 33 in Draft recommendation for second reading)

The CED supports the amendment in principle.

The CED welcomes the fact that cross-border health services are to be provided according to the legislation of the Member State of treatment and according to standards and guidelines on quality and safety defined by that Member State.

The CED also welcomes the fact that the Member State of treatment must ensure that patients are informed about those specific standards and guidelines. However, it is not clear what exactly the *"(…) assessment of healthcare providers (…)"* means and involves, under Article 4 paragraph 2 point (a) of the draft Directive. Again, the CED strongly opposes any kind of ranking of health professionals, as it is not clear what kind of criteria might be used and who would perform the ranking to ensure its accuracy. Further clarification is necessary in this respect.

9. Council position Article 6 paragraph 1 – National contact points for cross-border healthcare (Amendment 42 in Draft recommendation for second reading)

The CED strongly supports the proposed amendment. The CED is of the opinion that organisations of health professionals at national and regional level should be involved in the process of setting up any information systems (also in national contact points) and that this should be provided for in the draft Directive. The CED would however like to propose replacing the words "healthcare providers" with "organizations of healthcare professionals" to clarify that it would not be individuals but rather organizations who would be included in national contact points. (See also our comments on Amendment 27 and Amendment 44.)

10. Council position Article 6 paragraph 3 – National contact points for cross-border healthcare (Amendment 44 in Draft recommendation for second reading)

The CED would like to stress that close cooperation with health professional organisations at national and regional level, as well as competent authorities, is needed in order to provide accurate and updated information to patients on healthcare providers. National contact points are not able to give correct information on the *"provider's right to provide services or any restrictions on its practice"* if such information is not provided or at least confirmed by national competent authorities and/or professional organisations. Therefore, the draft Directive should establish that these entities should exchange information before the national contact point is able to provide information to patients on healthcare providers.

Furthermore, it is necessary to clarify what is meant by the *"right to provide services"* as well as *"any restrictions"*, namely;

a) does it imply restrictions on a whole category of healthcare services, and if so how is the category going to be defined?;

b) does it imply disciplinary restrictions or only restrictions sentenced by a Court (i.e., judgement which has obtained the force of *res judicata*)?;
c) does it imply restrictions only on individual practitioners or also on legal persons (for instance dental clinics)?

Again, the CED strongly rejects any ranking of the possibilities of treatment, as there are no reliable criteria for this.

11. Council position Article 6 paragraph 4 – National contact points for cross-border healthcare (Amendment 45 in Draft recommendation for second reading)

The CED strongly supports the proposed amendment. We agree that national contact points should provide information also to healthcare professionals.

12. Council position Article 10 paragraphs 2b(new) and 2c(new)–Mutual assistance and cooperation (Amendments 72 and 73 in Draft recommendation for second reading)

The CED would like to see some clarification on the type of information about healthcare providers that would be exchanged. (See also our comments on Amendment 44.)

The CED would also like to stress that we support the use of the IMI System and increasing administrative cooperation between (dental) competent authorities from all Member States. Mechanisms such as the one used in dentistry by the UK General Dental Council (i.e. distribution of a list of dental practitioners under disciplinary sanctions) could be taken in consideration also for other kinds of healthcare.

13. Council position Article 13 paragraph 2 - E-health

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.

Furthermore, the CED draws the attention to the risks of the so-called “patients summaries”. Healthcare providers need to have as much information as possible on the state of health of the patient in order to provide a conscientious cross-border healthcare service. Therefore, health professionals must be involved in the definition of the non-exhaustive list of data to be included in the patient summaries, cooperating in the elaboration of the guidelines referred to under Article 13 paragraph 2 point a of the Council position.

14. Council position Article 14 paragraph 1 – Cooperation on health technology assessment (Amendment 87 in Draft recommendation for second reading)

The CED strongly supports the proposed amendment. 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. (See also our position on Amendment 31.)

15. Council position Article 15 paragraph 1 – Committee (Amendment 93 in Draft recommendation for second reading)

The CED strongly supports the proposed amendment. We agree that the Commission should consult the relevant professional groups in the implementation of the Directive. (See also our comments on Recital 53.)

16. Council position Article 19 – Reports

The CED would like to stress its willingness to assist and provide available information for preparing the reports on the operation of the Directive, referred to under Article 19.

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