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*Committee on the Environment, Public Health and Food Safety*

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**2008/0142(COD)**

20.10.2010

# **CONSOLIDATED AMENDMENTS**

## **1 - 6**

**Draft recommendation for second reading**  
**Françoise Grossetête**  
(PE433.081v02-00)

Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare

Council common position  
(11038/2010 – C6-0266/2010 – 2008/0142(COD))

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PE450.960v01-00

**EN**

*United in diversity*

**EN**



**Consolidated Amendment 1**  
**EPP, S&D, ALDE, Greens, ECR, EFD**

Compromise amendment replacing Amendments 96, 100, 133, 134 and 135

**Recital 3 a (new)**

*Council common position*

*Amendment*

***(3a). Within this general framework Member States themselves retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. On no account may Member States dismantle their own health care due to its also being available in other Member States. Moreover, this Directive shall leave the choice of where to obtain healthcare to the patients and shall not have the result of creating policies that encourage patients in any way whatsoever to go to another Member State to obtain healthcare.***

Or. en

**Article 1 – paragraph 1**

*Council common position*

*Amendment*

1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.

1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare ***and aims at complementing the existing framework on the coordination of social security systems, Regulation EC (No) 883/2004, with a view to application of patients' rights. This Directive establishes a general framework for patients' rights regarding cross-border mobility. In the application of this Directive, Member States shall take into account the principle of equity.***

*Justification*

*In order to strengthen patients' rights in cross-border mobility, the already existing framework of the coordination of social security systems - Regulation 883/2004 - should be used and complemented.*

**Consolidated Amendment 2**  
**EPP, S&D, ALDE, Greens, ECR, EFD**

Compromise amendment replacing Amendments 34, 35, 37, 143, 144, 145, 146, 147, 148, 149, 150, 151, 153, 154

**Article 4 – paragraph 2 – points a - f**

*Council common position*

(a) patients receive upon request relevant information on the standards and guidelines referred to in paragraph 1, including provisions on supervision and assessment of healthcare providers, and information on which healthcare providers are subject to these standards and guidelines;

(b) healthcare providers provide *individual patients with* relevant information *on* the availability, *quality and safety of the healthcare they provide in the Member State of treatment*, clear invoices and clear information on prices, as well as on the healthcare providers' *authorisation or registration status, their* insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident

*Amendment*

(a) patients receive *from the national contact point* upon request relevant information on the standards and guidelines referred to in paragraph 1 *point (b)*, including provisions on supervision and assessment of healthcare providers, and information on which healthcare providers are subject to these standards and guidelines *and clear information on costs in accordance with article 7 paragraph 6, on accessibility for persons with disabilities as well as on the healthcare provider's authorisation or registration status and number, and any restrictions on their practice;*

(b) healthcare providers provide *all* relevant information *to enable patients to make an informed choice, including on treatment option*, on the availability, clear invoices and clear information on prices, as well as on the healthcare providers' insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on

in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;

(c) there are complaints procedures and mechanisms for patients to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

(d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;

(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

(f) patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;

***(ba) the information referred to in points (a) and (b) is inter alia remotely accessible by electronic means and that such information is also made available in formats accessible to persons with disabilities.***

(c) there are ***transparent*** complaints procedures and mechanisms ***in place*** for patients, ***in order to seek remedies and compensation*** in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

(d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;

(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

(f) patients who have received treatment are entitled to a written or electronic medical record of such treatment, ***and of any medical advice for the continuity of their care***, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, ***without prejudice to the exceptions applicable in the Member States.***

**Article 4 – paragraph 4***Council common position*

4. Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable situation, **or that they charge a price calculated according to objective, non discriminatory criteria if there is no comparable price for domestic patients.**

This paragraph shall be without prejudice to national legislation which allows healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.

*Amendment*

4. **The Member State of treatment** shall ensure that the healthcare providers on **its** territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable situation, **whatever the socio-economic position of the patient.**

This paragraph shall be without prejudice to national legislation which allows healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.

Or. en

**Consolidated Amendment 3**  
**EPP, S&D, ALDE, Greens, ECR, EFD**

Compromise amendment replacing Amendments 40, 41, 155, 156, 157, 158

**Article 5 – point b- c***Council common position*

(b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards procedures for accessing and determining those entitlements, conditions for reimbursement of costs and systems of appeal and redress if the patients considers that their rights have not been respected;

*Amendment*

(b) there are **easily accessible** mechanisms in place to provide patients on request with information, **inter alia remotely accessible by electronic means**, on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards procedures for accessing and determining those entitlements, conditions for reimbursement of costs and systems of appeal and redress if the patients considers that their rights have not been respected **and the terms and conditions that would apply, inter alia**

*whenever harm is caused as a result of healthcare received in another Member State.*

*This information shall be published in formats accessible to persons with disabilities. Member States shall consult stakeholders, including patients' organisations, to ensure information is clear and accessible. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004.*

*(ba) in the event of complications resulting from healthcare provided abroad or if a particular medical follow-up proves necessary, it guarantees to provide healthcare equivalent to that received on its territory;*

(c) patients who seek to receive or do receive cross-border healthcare have access to at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

(c) patients who seek to receive or do receive cross-border healthcare have access to at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC. *If the medical records are held in electronic form, patients shall have a guaranteed right to obtain a copy of, or a right of remote access to, those records. Data shall be transmitted only with the express written consent of the patient or the patient's relatives.*

Or. en

**Article 6 – paragraph 2**

*Council common position*

2. National contact points shall cooperate with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.

*Amendment*

2. National contact points shall **facilitate the exchange of information referred to in paragraph 3 and** cooperate **closely** with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.

Or. en

**Article 6 – paragraph 3**

*Council common position*

3. National contact points in the Member State of treatment shall provide patients with information concerning healthcare providers, including on request information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State.

*Amendment*

3. National contact points in the Member State of treatment shall **support patients to protect their rights by providing them** with information, **inter alia remotely accessible by electronic means**, concerning healthcare providers, including on request information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), **and on the protection of personal data, the level of accessibility to healthcare facilities for people with disabilities**, as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State, **as well as the options available to settle any dispute, and to identify the appropriate out-of-court settlement scheme for the specific case, including in the event of harm arising from cross-border healthcare.**

Or. en

**Consolidated Amendment 5**  
**EPP, S&D, ALDE, Greens, ECR, EFD**

Compromise amendment replacing Amendments 53, 62, 67, 68, 175, 192, 194, 195, 196  
**Article 7 a (new)**

*Council common position*

*Amendment*

**Article 7a**

**Prior notification**

***Member States may offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a written confirmation of the maximum amount that will be paid. On presentation of that written confirmation by the patient at the hospital of treatment, reimbursement shall be made directly to that hospital by the Member State of affiliation.***

Or. en

*Justification*

*When this voluntary system is applied, the reimbursement shall then be done directly by the competent authority of the Member State of affiliation to the hospital of treatment.*

**Article 9 – paragraph 1 a (new)**

*Council common position*

*Amendment*

***1a. Member States shall organise, in all cases where and when appropriate, transfer of funds of corresponding costs of cross border healthcare directly between the competent institutions.***

Or. en

*Justification*

*This would enable patients receiving cross border healthcare under the provisions of this directive to benefit, when and where possible, of the same system than the one set in the regulation 2004/883/2004. When and where it is concretely feasible, depending on national*

*healthcare invoice system ('forfait' or not, ...etc), this will avoid to patients to pay up front and to wait for being reimbursed. This will not create an extra charge for MS because it will be based on the same practices that the ones already set and used in the regulation.*

## **Article 9 – paragraph 1 b (new)**

*Council common position*

*Amendment*

***(1b). In the other cases, the Member State of affiliation shall ensure that patients will receive reimbursement without undue delay.***

Or. en

### *Justification*

*When and where not possible to organise the direct transfer of funds corresponding to the costs of cross border healthcare between the competent Institutions, and when prior authorisation has been granted, Member State of affiliation shall guarantee patients to receive reimbursement without undue delay. Taking into account that care submitted to prior authorisation are in general the more expensive ones, this is a crucial provision for patients especially for ones who have less financial means.*

## **Consolidated Amendment 6 EPP, S&D, ALDE, Greens, ECR, EFD**

Compromise amendment replacing Amendments 47, 64, 164, 165, 166, 167, 186, 189, 193, 209, 66

## **Article 7 – paragraph 1**

*Council common position*

*Amendment*

1. Subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

1. Subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits ***provided for by the legislation, or administrative regulations, or guidelines or codes of conduct of the medical professions***, to which the insured person is entitled in the Member State of affiliation.

***Without prejudice to Regulation (EC) No 883/2004, the Member State of affiliation***

*shall reimburse the costs to the Member State of treatment or the insured person which would have been paid for by its statutory social security system had equally effective healthcare been provided in its territory. If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.*

*Without prejudice to Regulation (EC) No 883/2004, on the basis of a prior objective clinical examination subject to article 9 paragraph 3, patients affected or suspected to be affected by rare diseases shall have the right to access healthcare in another Member State and to receive reimbursement even if the diagnosis and/or treatment in question is not among the benefits provided for by the legislation, or administrative regulations, or guidelines or codes of conduct of the medical professions, of the Member State of affiliation. Such treatment shall be subject to prior authorisation.*

Or. en

#### *Justification*

*As diagnosis of rare diseases is the first difficulty met by patients, a clinical examination would enable to determine also the suspicion of rare diseases and then should open the possibility for such cases to have access to cross border healthcare and reimbursement even if the treatment methods are not among the benefits provided by the Member State of affiliation.*

#### **Article 9 – paragraph 3**

##### *Council common position*

3. Member States shall ensure that administrative decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare

##### *Amendment*

3. Member States shall ensure that **any** administrative **or medical** decisions regarding the use of cross-border healthcare and reimbursement of costs of

incurred in another Member State are subject to administrative review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

healthcare incurred in another Member State are subject, ***on a case-by-case basis, to an appeal procedure, to an additional medical opinion or an*** administrative review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

Or. en

## Article 12 – paragraph 2 – point e

### *Council common position*

(e) facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice within and outside the networks;

### *Amendment*

(e) facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice ***and to foster developments of the diagnosis and treatment of rare diseases,*** within and outside the networks;

Or. en