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Committee on Employment and Social Affairs

2008/0142(COD)

4.3.2009

OPINION

of the Committee on Employment and Social Affairs

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

on the proposal for a directive of the European Parliament and of the Council
on the application of patients' rights in cross-border healthcare
(COM(2008)0414 – C6-0257/2008 – 2008/0142(COD))

Rapporteur (*): Iles Braghetto

(*) Associated committee – Rule 47 of the Rules of Procedure

PA_Legam

SHORT JUSTIFICATION

Based on Article 95 of the Treaty the directive proposes to establish a Community framework for cross-border healthcare, including legal definitions and general provisions. The directive also describes the coherence with other Community policies. The proposed directive applies to the provision of healthcare, regardless of how it is organised, delivered or financed.

Generally the EMPL Committee supports the aim of the proposed directive. It stresses that, for citizens to be able to make a deliberate choice, it is of the utmost importance to ensure clear information and a transparent framework for the provision of cross-border healthcare within the EU. Furthermore, the provided care should be safe and of good quality. Given that patients have to pay themselves for the treatment upfront, the procedures for reimbursement of costs should be clear and transparent.

The EMPL Committee has, given its tasks, paid specific attention to the following points:

Regulations for coordination of social security schemes

The aim of the directive is not to modify the existing framework for coordination of social security schemes and this framework will remain in place with all the general principles on which the regulations on coordination of social security schemes are based. The EMPL Committee supports this, but finds it strange that for the reimbursement of the costs, compared to the rules in the regulation on the coordination, separate rules are proposed. The main cause of concern is that a new administrative system will be needed, thus leading to an unnecessary and unwanted raise in 'red tape' and unclear rules. Therefore the EMPL Committee proposes to apply the same rules for the reimbursement of the cost as put down in the regulation.

Framework for mutual recognition of professional qualifications

The proposal would also apply without prejudice to the existing framework for mutual recognition of professional qualifications established by the Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. This fully supported by the EMPL Committee.

Racial equality

The EMPL Committee stresses that equal access for all should be one of the main targets of this directive.

Information

The opinion stresses the general importance of giving useful and clear information to the patients with regard to the quality of the care (including information regarding the hospitals). The importance of knowing what are the specialisations and results of the healthcare providers is also stressed; this in order to be able to make a deliberate choice on which hospital would be the best for a specific patient and to be able to establish a list of centres of excellence within Europe.

Evaluation

With regard to the data collection, monitoring (article 18) it stresses that the collection of the data should help in assessing if the Directive accomplishes the aim of improving the quality of the healthcare in general and more specific if it supports the principle of access for all. Within the reports mentioned in (article 20) this should be one of the focus points.

Definitions

Both definition of 'healthcare' and 'health care professional' are not clear and lead to contradictions and/or ambiguity. Therefore the definition of 'benefits in kind' has been introduced, in conformity with Regulation 883/04.

With respect to the definitions the EMPL Committee calls, in the recitals, on the Commission and Member States to consider the recognition of the positive impact of thermal cures on the convalescence and on preserving people's health.

Also in the recitals attention has been paid to the equal access to 'European Centres of Reference'.

General remarks

- The fundamental role played by health care services and general social services in the European social model. Therefore it calls on the Commission and Member States to recognise that role when applying internal market and competition law; emphasises the inadequate funding of those services, especially in certain eastern European Member States.
- The liberalisation of health services which could lead to greater inequality of access to high-quality health care.
- The development of a high quality, community-based health care in cooperation with users and patients, which can play an important role in the fight against poverty and social exclusion;
- Inequalities in health outcomes, both between and within Member States, which remain wide and urges Member States to tackle them, notably by ensuring effective access to healthcare for all.

AMENDMENTS

The Committee on Employment and Social Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) The Commission's Communication of 26 February 2007 on Social Reality Stocktaking - Interim report to the 2007 Spring European Council¹ observed that although the Member States are among the wealthiest countries in the world, new patterns of poverty and inequality affecting people's health are emerging, such as the rise in obesity and mental health problems.

¹ COM(2007)0063.

Justification

Stresses that community-based health and social care can play an important role in the fight against poverty and social exclusion.

Amendment 2

Proposal for a directive Recital 3 b (new)

Text proposed by the Commission

Amendment

(3b) The existing disparities between health-policy objectives and objectives of the internal market in services makes it necessary, where a conflict arises, always to assign priority to health-policy objectives as overriding reasons relating to the public interest (i.e. public health, social-policy objectives, preservation of

the financial balance of the social security system, etc.).

Justification

This will ensure, inter alia, that health-policy objectives have priority and that the Commission's aim of improving health care can be achieved.

Amendment 3

Proposal for a directive

Recital 3 c (new)

Text proposed by the Commission

Amendment

(3c) The Commission White Paper of 23 October 2007, entitled Together for Health: A Strategic Approach for the EU 2008-2013¹ sets out a first EC Health Strategy for Community activities in health.

¹ COM(2007)0630.

Justification

The Communication is based on the commitment by the Member States and the Community to respect the common values and principles of health policies. The resolution of the Parliament stresses that health is one of the key social and political issues on which the future of the European Union depends.

Amendment 4

Proposal for a directive

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) Healthcare services and general social services play a fundamental role in the European social model but receive inadequate funding in certain Member States. The Commission and Member States should recognise that fundamental role when applying internal market and competition law.

Justification

Reaffirms the general starting points when discussing the healthcare system.

Amendment 5

Proposal for a directive

Recital 4 b (new)

Text proposed by the Commission

Amendment

(4b) Healthcare services and general social services play a fundamental role in the European social model but receive inadequate funding in certain Member States. The Member States and the Commission should take better account of this fundamental role of healthcare services in all law-making.

Amendment 6

Proposal for a directive

Recital 4 c (new)

Text proposed by the Commission

Amendment

(4c) The liberalisation of health services could lead to greater inequality of access to high-quality health care and is therefore not the aim of this Directive.

Amendment 7

Proposal for a directive

Recital 4 d (new)

Text proposed by the Commission

Amendment

(4d) High-quality, community-based health care, developed, where possible, in cooperation with users and patients, could play an important role in the fight against poverty and social exclusion.

Justification

This is one of the central elements of the resolution mentioned in recital 1.

Amendment 8

Proposal for a directive

Recital 4 e (new)

Text proposed by the Commission

Amendment

(4e) Inequalities in healthcare outcomes, both between and within Member States, remain wide. Member States should tackle those inequalities, in particular by ensuring effective access to healthcare for all.

Justification

Cornerstone of all policies that involve healthcare should have the aim of ensuring access for all.

Amendment 9

Proposal for a directive

Recital 5

Text proposed by the Commission

Amendment

(5) As confirmed by the Court of Justice on several occasions, while recognizing their specific nature, ***all types of medical care fall within the scope of the Treaty.***

(5) As confirmed by the Court of Justice on several occasions, while recognizing their specific nature, ***medical services provided for consideration fall within the scope of the EC Treaty's provisions on the freedom to provide services.***

Justification

Given the fact that the Directive specifically deals with free movement of services, it is important to refer to the relevant EC Treaty provisions. The amendment also specifies - in accordance with settled ECJ case-law - that medical services fall within the ambit of these EC Treaty provisions if they are provided for consideration (see e.g. C-372/04, Watts, par 86).

Amendment 10

Proposal for a directive
Recital 8

Text proposed by the Commission

(8) This directive aims to ***establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting*** the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Amendment

(8) This directive aims to ***provide rules for the access to safe and high-quality healthcare in another Member State and establish cooperation mechanisms on healthcare between Member States, in full respect of national competence in organising and delivering healthcare, in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control. It fully respects*** the responsibilities of the Member States for ***healthcare according to the Treaty, including for*** the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Amendment 11

Proposal for a directive
Recital 8

Text proposed by the Commission

(8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Amendment

(8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility, ***a better balance between patients' individual rights in relation to mobility and the maintenance of national regulatory capabilities, for the benefit of all***, and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Amendment 12

Proposal for a directive Recital 9 a (new)

Text proposed by the Commission

Amendment

(9a) In defining healthcare, the Commission and Member States should consider recognising the positive impact of thermal cures on convalescence and health maintenance.

Justification

This amendment is linked to amendment 2. Thermal cures can play an important role in preventing health problems but also in solving them. Member States, Commission and healthcare insurance companies should investigate the values added by these kinds of provisions.

Amendment 13

Proposal for a directive Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) Member States should, when implementing this Directive, take into account the European Parliament resolution of 29 May 1997 on the status of non-conventional medicine¹.

¹ OJ C 182, 16.6.1997, p. 67.

Justification

Given that a number of people in the Member States are making use of these kind of medicines and therapies the resolution calls on the Commission to launch a process of recognising non-conventional medicine.

Amendment 14

Proposal for a directive
Recital 14 b (new)

Text proposed by the Commission

Amendment

(14b) In order to ensure that new barriers to the free movement of healthcare workers are not created and to ensure patient safety, equal standards of occupational safety for healthcare workers must be provided, in particular with a view to avoiding risks from infections resulting from accidents at the workplace such as needlestick injuries that can lead to potentially fatal infections, including Hepatitis B, Hepatitis C and HIV, as referred to in the European Parliament's resolution with recommendations to the Commission of 6 July 2006 on the protection of healthcare workers from blood-borne infections due to needlestick injuries¹.

¹ OJ C 303 E, 13.12.2006, p. 754.

Justification

The varying standards of occupational safety for healthcare staff can pose a significant barrier to the free movement of healthcare workers. The protection of healthcare workers from needlestick injuries needs to be particularly addressed as it represents a major and important difference in the standard of occupational safety across the European Union.

Amendment 15

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) Member States should in particular ensure that a high level of protection is ensured to protect patients, staff and all other persons who have cause to enter healthcare establishments from healthcare-associated infections, as these constitute a major threat to public health especially considering cross-border healthcare. All appropriate preventive measures, including hygiene standards

***and diagnostic screening procedures,
should be employed in order to avoid or
minimise the risks of healthcare-
associated infections.***

Justification

The European Commission is expected to release its Communication on Patient Safety and Healthcare Associated Infections during 2008. The Council is also committed to a common text on this matter in the near future. The European Parliament should therefore ensure the inclusion of this subject given that healthcare associated infections do not respect geographical borders and hence should be reflected in a legislative text governing cross-border aspects of healthcare.

Amendment 16

**Proposal for a directive
Recital 21**

Text proposed by the Commission

(21) It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulation (EC) No. 1408/71 should be able to benefit from the principles of free movement of services in accordance with the Treaty and the provisions of this Directive. Patients should be guaranteed assumption of the costs of that healthcare at least at the level provided for the same or ***similar healthcare*** had they been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. Member States may nevertheless provide in their national legislation for reimbursement of the costs of the treatment at the tariffs in force in the Member State of treatment if this is more beneficial for the patient. This may be the case in particular for any treatment provided through European reference networks as

Amendment

(21) It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulation (*EEC*) No. 1408/71 should be able to benefit from the principles of free movement of services in accordance with the Treaty and the provisions of this Directive. Patients should be guaranteed assumption of the costs of that healthcare at least at the level provided for ***treatment which is*** the same or ***equally effective***, had they been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. Member States may nevertheless provide in their national legislation for reimbursement of the costs of the treatment at the tariffs in force in the Member State of treatment if this is more beneficial. This may be the case in particular for any treatment provided through European reference

mentioned in Article 15 of this Directive.

networks as mentioned in Article 15 of this Directive.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on the coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 17

Proposal for a directive Recital 24 a (new)

Text proposed by the Commission

Amendment

(24a) This Directive recognises that entitlement to treatment is not always determined by Member States at national level and that not all Member States have a defined list of the services they do or do not provide. Member States must retain the right to organise their own healthcare and social security systems in such a way that availability of treatments and entitlement to them, can be determined at a regional or local level.

Justification

A number of healthcare systems do not have national level eligibility criteria for determining access to particular treatments or a defined "basket of care" which all people they cover are automatically entitled to receive. The Directive should fully recognise that some Member States rely on sub-national decision-making arrangements for planning and financing their healthcare systems.

Amendment 18

Proposal for a directive Recital 30

Text proposed by the Commission

Amendment

(30) There is no definition of what constitutes hospital care throughout the

(30) There is no definition of what constitutes hospital care throughout the

different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be appropriate to submit to the same regime of hospital care also certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk for the patient or the population (e.g. treatment of serious infectious diseases). A regularly updated list of such treatments shall be specifically defined by the *Commission through the comitology procedure*.

different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be appropriate to submit to the same regime of hospital care also certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk for the patient or the population (e.g. treatment of serious infectious diseases) *and for which planning is necessary in order to maintain a balanced geographical distribution of health care services, to control costs and to prevent any significant wastage of financial, technical and human resources*. A regularly updated list of such treatments shall be specifically defined by the *competent authorities of the Member State of affiliation*.

Justification

In accordance with ECJ case-law, the amendment reflects the idea that hospital care is inextricably linked with the need for planning, which ensures that there is sufficient and permanent access to a balanced range of high-quality hospital treatment whilst controlling costs and safeguarding the sustainability of the social security system. Provided that the Member State of affiliation is responsible for the assumption of costs, it is up to that Member State to draw up the list of hospital care.

Amendment 19

Proposal for a directive Recital 31

Text proposed par la Commission

(31) *The evidence available indicates that the application of free movement*

Amendment

(31) *The* Court of Justice has recognised that *there is a* risk of seriously

*principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems. However, the Court of Justice has recognised that **it cannot be excluded that the possible** risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for **hospital** care received in another Member State, **where the following conditions are met: had the treatment been provided on its territory, it would have been assumed by its social security system and the consequent outflow of patients due to the implementation of the directive seriously undermines or is likely to seriously undermine the financial balance of the social security system and/or this outflow of patients seriously undermines, or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member. As the assessment of the precise impact of an expected***

undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for **healthcare** received in another Member State. **Prior authorisation is essential for all hospital and specialised care as it provides a guarantee for patients that they will be treated and that the treatment will be covered by their social security system.**

outflow of patients requires complex assumptions and calculations, the Directive allows for a system of prior authorisation if there is sufficient reason to expect that the social security system will be seriously undermined. This should also cover cases of already existing systems of prior authorisation which are in conformity with conditions laid down in Article 8.

Amendment 20

Proposal for a directive

Recital 32

Text proposed by the Commission

(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same or *similar healthcare* been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment

Amendment

(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had *treatment which is the same or equally effective for the patient* been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (*EEC*) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are

obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 21

Proposal for a directive Recital 33 a (new)

Text proposed by the Commission

Amendment

(33a) Refusals to grant prior authorisation cannot be based merely on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in each individual case an objective medical assessment of the patient's medical condition, the history and probable course of the illness, the degree of pain the patient is in and/or the nature of the disability at the time when the request for authorisation was made or renewed.

Justification

The amendment clarifies the conditions under which prior authorization can be refused (see C-372/04, Watts case).

Amendment 22

Proposal for a directive
Recital 34

Text proposed by the Commission

(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These contact points should cooperate with each other and should enable patients to make informed choices about cross-border healthcare. They should also provide information about options available in case of problems with cross-border healthcare, in particular about out-of-court schemes for settling cross-border disputes.

Amendment

(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These contact points should cooperate with each other and should enable patients to make informed choices about cross border healthcare. They should also provide information about options available in case of problems with cross-border healthcare, in particular about out of court schemes for settling cross border disputes. ***In developing arrangements for provision of information on cross-border healthcare, the Member States should give consideration to the need to provide information in accessible formats and to potential sources of additional assistance for vulnerable patients, disabled people and people with complex needs.***

Justification

It is vital that information about cross border healthcare is available in accessible formats.

Amendment 23

Proposal for a directive
Recital 45

Text proposed by the Commission

(45) In particular, power should be conferred on the **Commission** to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; ***a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.***

Amendment 24

Proposal for a directive
Recital 45

Text proposed by the Commission

(45) In particular, power should be conferred on the Commission to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference

Amendment

(45) In particular, power should be conferred on the **Member States' competent authorities** to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive.

Amendment

(45) In particular, power should be conferred on the Commission to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; ***the list of services which fall under the headings of telemedicine services, laboratory services and remote diagnosis and prescription;*** accompanying measures to exclude specific categories of medicinal products or substances from the recognition of

networks must fulfil; the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Council Decision 1999/468/EC.

Justification

It is important also to make it clear what services qualify as telemedicine services, laboratory services and remote diagnosis and prescription. In this way the directive will become more clear and comprehensive and therefore more effective.

Amendment 25

Proposal for a directive Recital 46 a (new)

Text proposed by the Commission

Amendment

(46a) By facilitating the freedom of movement for patients within the European Union, this Directive is likely to lead to competition between healthcare providers. Such competition is likely to contribute to an increase in the quality of the healthcare, for all and to the establishment of centres of excellence.

Justification

When the Directive has this as an outcome it would have a positive contribution to the healthcare systems in the Member States, but careful monitoring is needed to check the results of the Directive.

Amendment 26

Proposal for a directive

Recital 46 b (new)

Text proposed by the Commission

Amendment

(46b) Everyone should have access to a European Centre of Reference (ECR).

Justification

The discussion on the ECRs is still going on. It is important to stress that this discussion needs to come to a conclusion and that the aim of the Centres is equal access for all. The reimbursement should therefore be part of the regulation on coordination of social security schemes.

Amendment 27

Proposal for a directive

Article 1

Text proposed by the Commission

Amendment

This Directive establishes a general framework for the provision of safe, *high quality* and efficient cross-border healthcare.

This Directive establishes ***common rules to ensure patient mobility and access to safe, high-quality, sustainable, effective and efficient cross-border healthcare, whilst fully respecting the Member States' responsibility for the definition of social security benefits related to health and the organisation and delivery of healthcare, medical care and social security benefits in accordance with the principles of universal access, solidarity, access to good quality care, equity, affordability, equal territorial accessibility and democratic control.***

Justification

In order to prevent citizens from having to move to another Member State for their healthcare it is important that the system is also effective.

Amendment 28

Proposal for a directive
Article 2

Text proposed by the Commission

This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.

Amendment

This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private. ***This Directive shall apply to statutory, private and combined sickness insurance schemes.***

Amendment 29

Proposal for a directive
Article 3 – paragraph 1 – point f

Text proposed by the Commission

(f) Regulations on coordination of social security schemes, in particular **Article 22** of Regulation (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

Amendment

(f) Regulations on coordination of social security schemes, in particular **Articles 19, 20, 22 and 25** of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and **Articles 17, 18, 19, 20, 27 and 28** of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

Amendment 30

Proposal for a directive
Article 3 – paragraph 1 – point ga (new)

Text proposed by the Commission

Amendment

(ga) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-

Amendment 31

Proposal for a directive

Article 3 – paragraph 2

Text proposed by the Commission

2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Amendment

2. *Until the date of application of Regulation (EC) No 883/2004, the rule shall apply that* when the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EEC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Regulation (EEC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EEC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Amendment 32

Proposal for a directive

Article 3 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. *From the date of application of Regulation (EC) No 883/2004, the rule shall apply that when the circumstances, under which an authorisation to go to another Member State in order to receive*

appropriate treatment under Article 20 of Regulation (EC) No 883/2004 must be granted, are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 20 of Council Regulation (EC) No 883/2004 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 20(2) of Regulation (EC) No 883/2004 are fulfilled, the authorisation shall always be accorded, and the benefits provided, in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Amendment 33

Proposal for a directive Article 4 – point a

Text proposed by the Commission

(a) "healthcare" means a health service provided *by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private;*

Amendment

(a) "healthcare" means a health service provided *to patients in order to assess, maintain or restore their state of health. For the purpose of Articles 6, 7, 8, 9, 10 and 11 of this Directive, healthcare means treatments that are among the healthcare benefits provided for by the legislation of the Member State of affiliation;*

Amendment 34

Proposal for a directive Article 4 – point b

Text proposed by the Commission

(b) "cross-border healthcare" means healthcare *provided in a* Member State

Amendment

(b) "cross-border healthcare" means healthcare *received by a patient in another*

other than that where the patient is an insured person *or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established*;

Member State than that where the patient is an insured person;

Amendment 35

Proposal for a directive Article 4 – point c

Text proposed by the Commission

(c) "use of healthcare in another Member State" means healthcare *provided* in the Member State other than that where the patient is an insured person.

Amendment

(c) "use of healthcare in another Member State" means healthcare *received* in a Member State other than that where the patient is an insured person.

Amendment 36

Proposal for a directive Article 4 – point g – subpoint ii a (new)

Text proposed by the Commission

Amendment

(iia) an insured person as defined in the policy conditions of private sickness insurance schemes;

Amendment 37

Proposition de directive Article 4 – point h a (new)

Text proposed by the Commission

Amendment

(ha) where, due to the application of Regulation (EEC) 1408/71 and Regulation (EC) 883/04 respectively, the health insurance body in the Member State of residence of the patient is responsible for the provision of benefits according to the legislation of that state, then that Member State is regarded as the Member State of affiliation for the

Amendment 38

Proposal for a directive Article 4 – point 1

Text proposed by the Commission

(1) **"harm"** means **adverse outcomes or injuries stemming from** the provision of healthcare.

Amendment

(1) **"adverse event"** means **an unintended injury or complication, which would not ordinarily be an outcome of the condition treated or** the provision of healthcare **required**.

Justification

The definition of "harm" as "adverse outcomes or injuries stemming from the provision of healthcare" in the Commission's proposal is far too broad as all surgery carries some risk of harm (no matter how small) even if it is performed to the highest standard. A reasonable element of risk of harm must be recognised by the Directive as a natural aspect of the treatment process. The wording in this section of the text should only address exceptional adverse events where serious injury or complication occurs far beyond any minor ailments which may ordinarily result from treatment. It seems therefore more appropriate to replace the word "harm" with "adverse event".

Amendment 39

Proposal for a directive Article 5 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and **ensure** that:

Amendment

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and **take into account** that:

Justification

Requiring Member States to "ensure" specific points cuts across their responsibility for determining their own quality and safety standards. In light of article 152 of the Treaty, which

states that Member States are responsible for the organisation, funding and delivery of healthcare to their citizens, it seems more appropriate to say that Member States should “take into account” rather than “ensure”.

Amendment 40

Proposal for a directive

Article 5 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In ***such a context and taking into account*** principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:

Amendment

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In ***compliance with*** principles of ***general interest***, universality, access to good quality care, equity and solidarity, ***and the public-service missions that derive therefrom, as conferred upon health service providers***, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:

Justification

It should be specified that health services are services of general interest and cannot be equated with ordinary services subject to the general provisions regulating the internal market, in compliance with Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market.

Amendment 41

Proposal for a directive

Article 5 – paragraph 1 - point a a (new)

Text proposed by the Commission

Amendment

(aa) such quality and safety standards are made publicly available in a clear and accessible format for citizens;

Amendment 42

Proposal for a directive

Article 5 -paragraph 1 - point b

Text proposed by the Commission

(b) the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;

Amendment

(b) the application of such standards by healthcare providers in practice is regularly monitored **and assessed** and corrective action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;

Justification

The assessment of the results of the monitoring is important in order to show on what the corrective action are constructed. Furthermore, the results of the assessment can be used to create, in the coming years, a network of accredited and recognised healthcare providers.

Amendment 43

Proposal for a directive

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate standards are **not** met, taking into account progress in medical science and health technology;

Amendment

(b) the application of such standards by healthcare providers **and the competence of health professionals** in practice is regularly monitored and corrective action taken when appropriate **to promote excellence and to ensure** appropriate standards are met, taking into account progress in medical science and health technology;

Justification

It is vital for patient safety that health professionals are competent to practice.

Amendment 44

Proposal for a directive

Article 5 – paragraph 1 – point c

Text proposed by the Commission

(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;

Amendment

(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on **quality**, availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability, **and with regard to the reimbursement of other expenses for which the patient is liable, such as travel and accommodation costs for parents accompanying their children;**

Justification

This is to make sure that the patients are informed about the reimbursement rules that apply to them.

Amendment 45

Proposal for a directive

Article 5 – paragraph 1 – point c

Text proposed by the Commission

(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;

Amendment

(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, **quality, safety**, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;

Amendment 46

Proposal for a directive
Article 5 – paragraph 1 – point d

Text proposed by the Commission

(d) patients have a means of making complaints and are guaranteed remedies and compensation when they suffer harm arising from **the** healthcare **they receive**.

Amendment

(d) patients, **health providers and the public** have a means of making complaints and are **given** guaranteed **recourse to appropriate** remedies and compensation when they suffer harm **or become aware of harm caused** arising from **cross-border** healthcare. **This is set in the context of an effective health system and professional regulation.**

Amendment 47

Proposal for a directive
Article 5 – paragraph 1 – point g

Text proposed by the Commission

(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment.

Amendment

(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment. **However, nothing in this Directive requires healthcare providers to accept for planned treatment, or to prioritise, patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment.**

Justification

For the sake of clarity and consistency, it would seem useful to include a statement in main body of the Directive confirming, as set out in Recital 12, that healthcare providers are not required to accept for planned treatment or prioritise patients from other Member States to the detriment of patients from the Member State of treatment.

Amendment 48

Proposal for a directive
Article 5 – paragraph 1 - point g b (new)

Text proposed by the Commission

Amendment

(gb) Member States shall define clearly patients' rights and people's rights in relation to healthcare, in accordance with the European Charter of Fundamental Rights.

Amendment 49

Proposal for a directive
Article 5 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In view of the major importance, particularly to patients, of safeguarding the quality and safety of cross-border care, the organisations involved in drawing up norms and guidelines as referred to in paragraphs 1 and 3 shall at the minimum include patients' organisations (particularly those of a cross-border nature).

Amendment 50

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission

Amendment

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons ***deliberately*** travelling to another Member State with the purpose of receiving healthcare ***(planned care)*** there or seeking to receive healthcare ***(planned care)*** provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in

by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs ***to the insured person***, which would have been paid for by its statutory social security system had the same or ***similar healthcare*** been provided in its territory. 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.

question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The ***competent institutions of the Member State of affiliation (without prejudice to Regulation (EEC) No 1408/71 and, as of its date of application, Regulation No 883/2004)*** shall reimburse the costs which would have been paid for by its statutory social security system had the same ***treatment or treatment which is equally effective*** been provided in its territory. 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.

Justification

It is desirable to state specifically that this article refers to planned care which is the reason for travelling abroad.

Amendment 51

Proposal for a directive Article 6 – paragraph 2

Text proposed by the Commission

2. The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.

Amendment

2. The costs of healthcare provided in another Member State shall be reimbursed ***or paid for by the social security system or competent institution of the Member State of affiliation (without prejudice to Regulation No 1408/71 and as of its date of application, Regulation No 883/2004)*** in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same ***treatment or treatment which is equally effective*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. ***Member States may decide to cover other related costs, such as accommodation and travel costs.***

Justification

Clarification that it is not the Member State but the social insurance institution(s) concerned that should reimburse the costs.

Amendment 52

Proposal for a directive

Article 6 - paragraph 3

Text proposed by the Commission

3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same or **similar healthcare** was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons

Amendment

3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same **treatment** or **treatment which is equally effective** was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 53

Proposal for a directive

Article 6 - paragraph 4

Text proposed by the Commission

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed

Amendment

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed

had the same or ***similar healthcare*** been provided in the territory of the Member State of affiliation.

had the same ***treatment*** or ***treatment which is equally effective*** been provided in the territory of the Member State of affiliation.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 54

Proposal for a directive Article 6 – paragraph 4

Text proposed by the Commission

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed ***to*** the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.

Amendment

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed ***for*** the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.

Justification

Equal access to care abroad can be compromised by the need for a patient to pay for the care first from his own pocket before being able to seek reimbursement. Member States of affiliation and treatment could set up swift reimbursement schemes between them (at least for economically disadvantaged patients, if not for all). By specifying that the costs will be reimbursed to the insured person, this possibility is excluded.

Amendment 55

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Amendment

5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community 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 these records or a right of remote access to these records.***

Amendment 56

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

5. Patients ***travelling to another Member State with the purpose of*** receiving healthcare ***there*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Amendment

5. Patients receiving healthcare ***in a Member State other than their Member State of affiliation*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Justification

The Commission proposal on the reimbursement of health care costs might discriminate in practice against the principle of ‘equal access for all’ to cross-border health services and the principles of equity and equal treatment regardless of patients’ income and treatment costs. People with lower incomes would be unlikely to be able to take advantage of the Commission’s much-vaunted ‘internal market freedom’ in view of upfront payments to be made, the costs of travel and accommodation, and because language barriers and uncertainty over the legal situation in other EU countries would make the risks of seeking treatment in another Member States too daunting. And for insured persons from poorer Member States such as e.g. Romania or Bulgaria it is hardly likely that they can obtain treatment in richer

Member States such as e.g. Sweden or France on this basis, as their own health insurance scheme would pay only a small fraction of the costs of any such treatment. In order to strengthen patients' rights in cross-border health care, therefore, the already existing framework of the coordination of social protection schemes exclusively should be used.

Amendment 57

Proposal for a directive

Article 7

Text proposed by the Commission

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system.

Amendment

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its **statutory** social security system.

Justification

The principles on the assumption of healthcare costs apply in so far it concerns costs of that care which, if it had been provided in its territory, would have been paid under the statutory social security system of the Member State of affiliation. It corresponds to the term used in Article 6 of the Directive.

Amendment 58

Proposal for a directive

Article 8 – paragraph 1 – introductory part

Text proposed by the Commission

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital **care** shall mean:

Amendment

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital **and specialised care** shall mean **healthcare defined as such by the Member State of affiliation and which requires:**

Amendment 59

Proposal for a directive
Article 8 – paragraph 1 – point a

Text proposed by the Commission

(a) **healthcare which** requires overnight accommodation of the patient in question for at least one night.

Amendment

(a) **it** requires overnight accommodation of the patient in question for at least one night; **or**

Justification

The definition provided by the Commission does not correspond to the real nature of the services provided in the Member States. It does not, for example, take account of outpatient surgery.

In order to correspond to the real nature of the services provided in practice, the definition of hospital care should refer to the definition in force in the patient's Member State of affiliation.

Amendment 60

Proposal for a directive
Article 8 – paragraph 1 – point b

Text proposed by the Commission

(b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:

- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
- healthcare involving treatments presenting a particular risk for the patient or the population.

Amendment

(b) it requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
(c) it involves treatments presenting a particular risk for the patient or the population.

Amendment 61

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission

2. This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in

Amendment

deleted

accordance with the regulatory procedure with scrutiny referred to in Article 19(3).

Justification

This amendment recognises that prior authorisation systems can be valuable to patients in terms providing them with clarity on matters such as what reimbursement they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong. These considerations apply equally to care provided in hospitals and in other settings, as do issues about the need to plan services and manage financial resources for those who run health systems.

Amendment 62

Proposal for a directive

Article 8 – paragraph 3

Text proposed by the Commission

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where *the following conditions are met:*

(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and

(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:

(i) the financial balance of the Member State's social security system; and/or

(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of

Amendment

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where *it could affect important aspects of its healthcare system, including its scope, cost or financial structure. Such a system shall be without prejudice to Regulation (EEC) No 1408/71 as of its date of application, (EC) No 883/2004.*

***treatment capacity or medical competence
on the territory of the concerned Member
State.***

Justification

This amendment recognises that prior authorisation systems are valuable to patients in terms of providing them with clarity on matters such as what reimbursement they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong. Member States should be able to decide the circumstances in which prior authorisation systems are mandatory for patients seeking healthcare abroad, provided these systems meet criteria such as transparency and proportionality, are simple and straightforward, and provide timely responses to requests.

Amendment 63

**Proposal for a directive
Article 8 – paragraph 4**

Text proposed by the Commission

4. The prior authorisation system shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.

Amendment

4. The prior authorisation system ***shall apply without prejudice to Article 3(2) and*** shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.

Amendment 64

**Proposal for a directive
Article 8 – paragraph 4 a (new)**

Text proposed by the Commission

Amendment

4a. Prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way.

Amendment 65

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that the patient is expected only to pay upfront any costs that they would be expected to pay in this manner had their care been provided in their home health system. Member States should seek to transfer funds directly between the funders and the providers of care for any other costs.

Amendment 66

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Patients seeking to receive healthcare provided in another Member State shall be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

Justification

With the purpose of making the right of cross boarder health care a right for everyone, and in order to give patients the possibility to know for sure whether they will be reimbursed or not, it is important to give patients the right to apply for a prior authorisation in the Member State of affiliation. A system without this right to apply for prior authorisation would lead to great economical uncertainty for the patients. This uncertainty would make the right to cross boarder health care less attractive for those with a low income and thus not equally available to all.

Amendment 67

Proposal for a directive Article 8 – paragraph 6 (new)

Text proposed by the Commission

Amendment

6. The Member State of treatment may take appropriate measures to address the inflow of patients and to prevent it from undermining the healthcare system. The Member State of treatment shall refrain from discriminating with regard to nationality and shall ensure that the measures restricting free movement shall be limited to what is necessary and proportionate.

Amendment 68

Proposal for a directive Article 9 – paragraph 1

Text proposed by the Commission

Amendment

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met.

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. ***Until the date of application of Regulation (EC) No 883/2004, the rule shall apply that,*** in any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation (EEC) No1408/71 are met. ***From the date of application of Regulation (EC) No***

883/2004, the rule shall apply that when the circumstances referred to in Article 20 of Regulation (EC) No 883/2004 are met, an insured person shall always be granted authorisation by virtue of the regulations concerning coordination of social security schemes as referred to in Article 3(1)(f).

Amendment 69

Proposal for a directive

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account:

Amendment

Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account ***and set out criteria by which they measure:***

Amendment 70

Proposal for a directive

Article 9 – paragraph 4 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the urgency of the treatment or of the medical procedure in question;

Justification

Although many medical conditions could not be painful, they might require urgent treatment or intervention though specific medical procedures.

Amendment 71

Proposal for a directive

Article 9 -paragraph 4 -point d a (new)

Text proposed by the Commission

Amendment

(da) accreditation of the healthcare providers in the Member State of

treatment.

Justification

Accreditation is an important element in order to assess the quality of the healthcare providers in other Member States.

Amendment 72

Proposal for a directive

Article 9 - paragraph 4 – point d a (new)

Text proposed by the Commission

Amendment

(da) the medical history of the patient.

Justification

The Court of Justice holds that, in order to determine whether a treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is also required to take due account of the medical history of the patient (see C-372/04, Watts, paragraph 62).

Amendment 73

Proposal for a directive

Article 10 – paragraph 1

Text proposed by the Commission

Amendment

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with ***impartial, comparative and complete*** information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

1a. The Member State of treatment shall ensure that there are mechanisms in place to make impartial, comparative and complete information publicly available including information on receiving healthcare and on registered health professionals and providers in that Member State, on the quality and safety

standards that apply, the regulatory system in place, and the process for making complaints where harm is caused as a result of healthcare received in that Member State.

1b. In information about cross-border care, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from regulations on the coordination of social security schemes as referred to in Article 3(1)(f).

Justification

In order to be able to make a well balanced choice for a hospital the information mentioned in the amendment is needed.

Amendment 74

**Proposal for a directive
Article 10 – paragraph 2**

Text proposed by the Commission

2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, and shall include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements.

Amendment

2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, ***in formats easily accessible to people with disabilities at no extra cost***, and shall include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements.

Amendment 75

**Proposal for a directive
Article 10 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. In addition to the information outlined in paragraph 1, information on health professionals and healthcare providers shall be made easily available via electronic means by the Member State in which the health professionals and

healthcare providers are registered, and shall include the name, registration number, practice address of the healthcare professional, and any restrictions on their practice;

Justification

In the interests of patients availing of cross-border services, there is also a need for greater transparency of health professional and health service regulation. Public registers of health professionals and health service providers should be available in Member states so that patients can easily identify prescribers, professionals and other treatment providers and if necessary to verify and validate the professional standing of the health professionals providing care. The international evidence illustrates that the most practical way for patients to have access to information on their current or prospective healthcare providers is via the publication of public registers of such practitioners. Such registers should now be available via the Internet and should allow the patient to access the relevant data by searching either via the name or via the registration number of the healthcare provider (or indeed by searching via geographical area). The relevant data that should be in the public domain should be, at a minimum, the name, registration number and practice address of the healthcare professional, the date of their first registration on that register, the expiry date of their current registration, and any conditions or restrictions on their practice or suspensions should this be the case. Healthcare professionals, who are not registered, be it for voluntary reasons or if struck off for whatever reason, should not appear on such register.

Amendment 76

Proposal for a directive Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10a

The Member State of treatment shall ensure that:

(a) patients receive upon their request information on guarantees of quality and safety of healthcare provided.

(b) healthcare providers in the Member State of treatment provide information on availability, prices and outcomes of healthcare provided, including procedures for complaints and means of redress available for healthcare provided.

Justification

Patients must be supplied with the most relevant and most useful information. To this end, it is for the Member State to provide the information on its own healthcare system. If the Member States were required individually to provide information on the other 26 Member States, there would be a risk that the information is not relevant and the information system could be unreliable.

Amendment 77

Proposal for a directive

Article 12 – paragraph 1

Text proposed by the Commission

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.

Amendment

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States shall ensure that patients' organisations, health insurance funds and care providers are involved in these national contact points.***

Amendment 78

Proposal for a directive

Article 12 – paragraph 1

Text proposed by the Commission

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.

Amendment

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***They may also draw up national lists of centres for hospital and specialised care, for the benefit of stakeholders.***

Amendment 79

Proposal for a directive

Article 12 -paragraph 2 -point a

Text proposed by the Commission

(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, *and* on the terms and conditions applicable;

Amendment

(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, on the terms and conditions applicable, ***and on centres of excellence or healthcare centres specialised in certain diseases;***

Justification

The patient right on information must be completed with information on centres of excellence and specialised healthcare centres to be able to make a well balance choice.

Amendment 80

Proposal for a directive

Article 12 – paragraph 2 – point a

Text proposed by the Commission

(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and ***the guarantees of*** quality and safety, protection of personal data, procedures for complaints ***and*** means of redress available for healthcare provided in ***another*** Member State, and on the terms and conditions applicable;

Amendment

(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and quality and safety ***standards***, protection of personal data, procedures for complaints, ***the means by which professionals and providers are regulated and the means by which regulatory action can be taken, the*** means of redress available for healthcare provided in ***that*** Member State, and the terms and conditions applicable;

Amendment 81

Proposal for a directive
Article 12 – paragraph 2 – point a

Text proposed by the Commission

(a) provide and disseminate information to patients in particular on ***their*** rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

Amendment

(a) provide and disseminate information to patients ***and healthcare professionals*** in particular on ***patients'*** rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

Justification

Health professionals are the patients' first point of contact and need information about patient's rights in order both to observe all the rights and to guide the patients to get the help they need.

Amendment 82

Proposal for a directive
Article 12 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The national contact point in the Member State of treatment shall register all activities in the Member State of treatment pursuant to Articles 6, 7, 8, 9 and 15 and notify the competent authorities of the Member State of treatment and the national contact point of the Member State of affiliation thereof. Health service providers shall supply the necessary information to the national contact point of their Member State as soon as they receive it.

Justification

To ensure that the procedure runs as smoothly as possible.

Amendment 83

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.

Amendment

1. Member States shall render such mutual assistance ***for the promotion of the quality and safety of healthcare*** as is necessary for the implementation of this Directive.

Amendment 84

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.

Amendment

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive ***and shall conclude agreements on this subject.***

Amendment 85

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission

Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Amendment

Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation, ***and shall conclude agreements on this subject.***

Amendment 86

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and, as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Amendment

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and ***communication between healthcare providers in the Member States of treatment and affiliation respectively in order to better ensure continuity of care***, as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Justification

Continuity of care is vital to patient safety. Medical teams from the patients' country of origin should cooperate closely with the medical and specialists teams of the country of treatment to ensure continuity of care.

Amendment 87

Proposal for a directive
Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Member States, particularly neighbouring countries, may conclude agreements among themselves as referred to in paragraphs 1 and 2 concerning, inter alia, worthwhile cooperative frameworks which should remain in existence or be allowed more scope for development, concerning the inflow and outflow of patients between these Member States, and concerning planning systems and certain intramural forms of care.

Justification

De verplichting tot samenwerking van artikel 13 is niet voldoende uitgewerkt, waardoor instellingen in grensgebieden in hun plannen te zeer afhankelijk blijven van de toevallige

patiëntenbewegingen en de willekeur van verzekeraars/lidstaten om e.e.a. toe te laten. Voor structurele samenwerking en investeringen daarin hebben instellingen nu eenmaal enige zekerheid nodig, dat het ook zal gaan lopen en ook gefinancierd gaat worden. Door deze toevoeging kunnen instellingen, verzekeraars en patiënten terugvallen op afspraken die zijn toegesneden op bestaande problematiek en mogelijkheden in de grensregio's. Deze samenwerkingsovereenkomsten kunnen per lidstaat meer of minder vergaand zijn.

Amendment 88

Proposal for a directive

Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Member states shall immediately and proactively inform each other about health providers or health professionals when regulatory action is taken against their registration or their right to provide services.

Amendment 89

Proposal for a directive

Article 14 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) are limited to what is necessary ***and*** proportionate to safeguard human health and are ***non-discriminatory*** or

(a) are ***not*** limited to what is necessary, ***are not*** proportionate to safeguard human health and are ***discriminatory*** or

Justification

The sentence is wrong in the Commission's version. Point (a) enumerates the exceptions which permit Member States not to abide by the general rule: bans on any limit on recognition of individual prescriptions are accepted in cases where prescriptions are not limited to what is necessary and proportionate with the aim of safeguarding human health, or are discriminatory.

Amendment 90

Proposal for a directive
Article 14 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The recognition of prescriptions issued in another Member State shall not imply a modification to the right of Member States to determine the benefits which the Member States themselves decide to grant.

Justification

The directive is not intended to invalidate the subsidiarity principle, which allows the Member States to determine which benefits they wish to grant.

Amendment 91

Proposal for a directive
Article 14 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. Reimbursements regarding individual prescriptions shall be based only on the relevant provisions of the Member State of affiliation..

Justification

The issue of mutual recognition of prescriptions has to be clarified in conjunction with the question of reimbursement. It is important that reimbursement is only possible for medicinal products that are part of the basket of benefits in the Member State of affiliation of the patient.

Amendment 92

Proposal for a directive
Article 14 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1c. The Member State of affiliation shall be obliged to reimburse the costs of a medical prescription from another Member State only if these costs would

also be borne in the Member State of affiliation (e.g. in accordance with a reimbursement code or a positive list).

Justification

Otherwise there would be a contradiction with Article 11.

Amendment 93

Proposal for a directive

Article 14 – paragraph 2 – point a

Text proposed by the Commission

(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions;

Amendment

(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a ***standardised*** Community prescription template, and supporting interoperability of ePrescriptions;

Justification

The monitoring of trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care will enable Member States and the Commission to identify some of the problems that will arise following the implementation of this Directive.

Amendment 94

Proposal for a directive

Article 14 – paragraph 2 – point b

Text proposed by the Commission

(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible;

Amendment

(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible; ***prescriptions issued using this Community form must be formulated in accordance with the international non-proprietary name (INN) system;***

Justification

In order to be readable anywhere in Europe, prescriptions made out on the basis of a Community form should use a common language, the International Non-proprietary Name (INN) system, which identifies medicinal products by their molecules and not by their commercial names, which may vary from one country to another.

Amendment 95

Proposal for a directive

Article 14 – paragraph 2 – point c

Text proposed by the Commission

(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.

Amendment

(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article ***where the conditions referred to in paragraph 1 above apply or*** where necessary in order to safeguard public health.

Justification

In the interests of greater clarity, it is desirable to recall the conditions which enable Member States not to prohibit any limit on the recognition of individual prescriptions.

Amendment 96

Proposal for a directive

Article 14 – paragraph 2 - point c a (new)

Text proposed by the Commission

Amendment

(ca) measures to ensure that prescriptions issued and information given about medicinal products prescribed are accessible to people with disabilities.

Amendment 97

Proposal for a directive

Article 15 a (new)

Text proposed by the Commission

Amendment

Article 15a

Trial areas

In order, in future, to establish as effective a care policy as possible, the Commission shall designate border regions as trial areas where innovative initiatives relating to cross-border care can be thoroughly tested, analysed and assessed.

Amendment 98

**Proposal for a directive
Article 15 - paragraph 1**

Text proposed by the Commission

1. Member States shall facilitate the development of the European reference networks of healthcare providers. Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria

Amendment

1. Member States shall facilitate the development of the European reference networks of healthcare providers ***and enhance the experience of cooperation as regards healthcare within the European cross-border cooperation groupings.*** Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria

Justification

The EGCC is, on the level of cross-border health cooperation, an important and already existing instrument. Best practices from the EGCC could be used for further developments in the field of this directive.

Amendment 99

**Proposal for a directive
Article 15 – paragraph 2 – point f a (new)**

Text proposed by the Commission

Amendment

(fa) to help ensure effective access to healthcare for all, in particular with a view to combating inequalities in healthcare outcomes, both between and within Member States;

Justification

This is one of the central elements of the healthcare policies.

Amendment 100

Proposal for a directive

Article 15 – paragraph 2 – point f b (new)

Text proposed by the Commission

Amendment

(fb) to establish a database of all healthcare providers and information on the specific specialisations, in order to establish a list of centres of excellence;

Justification

This can help patients to make the right choice for a specific hospital.

Amendment 101

Proposal for a directive

Article 16 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Member States purchasing e-health services from providers and professionals in other Member States shall ensure that such providers and professionals are appropriately regulated and qualified and that they have demonstrated, via the relevant competent authority, that they are fit to practise and to provide e-health services.

Amendment 102

Proposal for a directive

Article 18 – paragraph 1

Text proposed by the Commission

Amendment

1. Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided,

1. Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided,

its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.

its providers and patients, the cost and the outcomes. ***They shall also monitor trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care.*** They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.

Justification

The monitoring of trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care will enable Member States and the Commission to identify some of the problems that may arise following the implementation of this Directive.

Amendment 103

Proposal for a directive

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The aim of that data collection is to assess whether this Directive contributes to the mobility of patients, the quality of the healthcare in general, and the principle of access for all.

Justification

It needs to be stressed that, given the aim of the Directive, the collected data should help assessing if the Directive accomplishes this aim. Also in the report (Article 20) this should be one of the main elements.

Amendment 104

Proposal for a directive

Article 18 - paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The collection of data in the context of this Article shall be done in close cooperation with the collection of data provided for by the Administrative

***Commission on Social Security for
Migrant Workers.***

Justification

Close cooperation on the collection of data under this Directive and the collection of data under the rules on the coordination of social security schemes will allow drawing a more comprehensive image of cross-border flows of people in the field of healthcare.

Amendment 105

Proposal for a directive

Article 20 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Commission shall ensure that the requisite information is gathered to chart cross-border flows of patients and practitioners so as to be able to remedy any adverse effects promptly and to further encourage positive effects. The Commission shall include this information in the report referred to in paragraph 1.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	EMPL 2.9.2008
Associated committee(s) - date announced in plenary	23.9.2008
Rapporteur Date appointed	Iles Braghetto 9.9.2008
Discussed in committee	26.1.2009 10.2.2009
Date adopted	2.3.2009
Result of final vote	+: 35 -: 2 0: 4
Members present for the final vote	Jan Andersson, Edit Bauer, Iles Braghetto, Philip Bushill-Matthews, Milan Cabrnoch, Alejandro Cercas, Luigi Cocilovo, Jean Louis Cottigny, Jan Cremers, Richard Falbr, Joel Hasse Ferreira, Roger Helmer, Karin Jöns, Jean Lambert, Bernard Lehideux, Elizabeth Lynne, Thomas Mann, Siiri Oviir, Marie Panayotopoulos-Cassiotou, Rovana Plumb, Bilyana Ilieva Raeva, Elisabeth Schroedter, Gabriele Stauner, Ewa Tomaszewska, Anne Van Lancker, Gabriele Zimmer
Substitute(s) present for the final vote	Françoise Castex, Gabriela Crețu, Donata Gottardi, Anna Ibrisagic, Rumiana Jeleva, Sepp Kusstatscher, Jamila Madeira, Viktória Mohácsi, Georgios Toussas
Substitute(s) under Rule 178(2) present for the final vote	Glenn Bedingfield, Herbert Bösch, Maddalena Calia, Ljudmila Novak, Gianluca Susta, Silvia-Adriana Țicău