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**NOTE**

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from : General Secretariat of the Council

to : Working Party on Public Health

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No. Cion prop. : 11307/08 SAN 136 SOC 389 MI 234 CODEC 904

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Subject : **Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare**

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Following several discussions in the Working Party on Public Health, delegations will find in the Annex Presidency suggestions for wording of Articles 1 to 9, 11 and 14a (new) and corresponding recitals of the above proposal. The explanations of these suggestions are indicated in respective footnotes.

Additions to the text in the Commission's proposal (doc. 5431/08) are indicated in **bold underlined**, while deletions are indicated in ~~strikethrough~~.

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the application of patients' rights in cross-border healthcare**

...

- (10) For the purpose of this Directive, the concept of "cross-border healthcare" covers **only** ~~following modes of supply of healthcare:~~ use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility'<sup>1</sup>;

~~— Cross border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;~~

~~— Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,~~

~~— Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).~~

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<sup>1</sup> The concept of cross-border healthcare is limited to patients' mobility in so far as the Directive only marginally addresses mobility of healthcare providers. See also definition in article 4 (b).

(12) Given that it is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all type of healthcare in order to ensure the freedom to provide and obtain cross border healthcare which is the aim of the directive. Member States' authorities have to respect the shared overarching values of universality, access to good quality care, equity and solidarity, which have been already widely recognised by the Community institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States also have to ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States must respect the principles of freedom of movement within the internal market, non-discrimination inter alia with regard to nationality (or in the case of legal persons, with regard to the Member State in which they are established), necessity and proportionality of any restrictions on free movement. 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. **In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, Member States shall ensure that patients receive on request the relevant information on health and quality standards enforced in the Member State of treatment as well as on the characteristics of healthcare provided by a specific healthcare provider.**

**(12b) (new) In the light of the case-law of the Court of Justice (C-496/01), in the absence of harmonisation measures, Community law does not preclude a Member State from imposing, in the context of an authorisation scheme, its level of public health protection on healthcare providers established in another Member State which wish to offer services to patients insured in the first Member State. However, the conditions to be satisfied in order to obtain such authorisation may not duplicate the equivalent statutory conditions which have already been satisfied in the Member State of establishment.<sup>2</sup>**

...

(25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such a treatment is not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions. **This Directive recognises that entitlement to treatment is not always determined nationally by Member States and that Member States may organise their own healthcare and social security systems to provide for entitlement to treatment to be determined at a regional or local level.**<sup>3</sup>

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<sup>2</sup> This new recital was added in order to address concerns raised by some delegations, notably **DELETED**, that they wish to control quality and safety of healthcare delivered in another Member State by healthcare providers not submitted to regulation by the Member State of treatment.

<sup>3</sup> **DELETED**, supported by other delegations, asked for this sentence to be added in order to make clear the procedures for determining entitlements vary from Member State to Member State.

(29) Text proposed by the Commission to be replaced by:

**In the light of the case-law of the Court of Justice, making the assumption of costs by the national system of healthcare provided in another Member State subject to prior authorisation is a restriction to free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the reimbursement of the costs of healthcare 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.**<sup>4</sup>

...

(31) Text proposed by the Commission to be replaced by:

**In the light of the case-law of the Court of Justice, Member States may make the assumption of costs by the national system of hospital care provided in another Member State subject to prior authorisation. This requirement appears to be a measure which is both necessary and reasonable. Indeed 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, generally designed to satisfy various needs, must be possible. For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources.**

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<sup>4</sup> The aim of this redrafting of recital 29 is to recall the general principle of prohibition of prior authorisation schemes before setting out the derogation deemed justified for hospital care and specialised healthcare. See also new wording of article 7 (now last paragraph of article 6).

Such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied.<sup>5</sup> The same reasoning applies to specialised care which requires planning because it involves use of highly specialised and cost-intensive medical infrastructure or medical equipment or treatments presenting a particular risk for the patient or the population. With regard to the progress of technology and the different policies of Member States, whether this kind of healthcare is delivered within hospital or ambulatory care facilities is not the decisive factor for deciding whether it requires planning or not.

(31b) In the light of the case-law of the Court of Justice, the criteria attached to the grant of such authorisation must be justified in the light of the overriding reasons in the general interest capable of justifying obstacles to the freedom to provide hospital medical services: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all or the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival, of the population. Conversely, the refusal to grant prior authorisation may not be based solely on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/ or the nature of his disability at the time when the request for authorisation was made or renewed.

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<sup>5</sup> The aim of this redrafting of recital 31 is to recall at length the case law of the Court of justice, allowing a restriction to the free movement of services for some precisely identified overriding reasons in the general interest.

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

##### **Aim**

This Directive establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare. **provides rules for the access to safe and high-quality healthcare in another Member State and establishes cooperation mechanisms on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.**<sup>6</sup>

#### *Article 2*

##### **Scope**

This Directive shall apply to **the** provision of healthcare ~~regardless of how it is organised, delivered and financed or whether it is public or private~~ **as defined in article 4.**<sup>7</sup>

#### *Article 3*

##### **Relationship with other Community provisions**

⚡ This Directive shall apply without prejudice to:

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<sup>6</sup> This new wording is more in line with the aim actually pursued by the Directive, especially with regard to the amended text in article 5. Furthermore the provision of article 152 of the Treaty, recalling the competence of Member States in organising and delivering healthcare, is added here as a general principle applying to all the articles of the Directive. Hence the deletion of the first sentence of article 5.

<sup>7</sup> The definition of healthcare being a complex and potentially sensitive issue, article 2 refers directly to the definition set out in article 4.

**(aa) <sup>8</sup> Directive 2005/36/EC on the recognition of professional qualifications;**

**(ab) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market;<sup>9</sup>**

- (a) Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector<sup>10</sup>;
- (b) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>11</sup> and Directive 2001/83/EC on the Community code relating to medicinal products for human use;
- (c) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use<sup>12</sup>;
- (d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services<sup>13</sup>.

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<sup>8</sup> These two directives were included in the first paragraph of article 3 as the Council legal service considered that the first sentence paragraph 2 had the same legal meaning.

<sup>9</sup> OJ L 178, 17.7.2000, p. 1.

<sup>10</sup> OJ L 201, 31.7.2002, p. 37. Directive as last amended by Directive 2006/24/EC (OJ L 105, 13.4.2006, p.54).

<sup>11</sup> OJ L 136, 30.4.2004, p.1. Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).

<sup>12</sup> OJ L 121, 1.5.2001, p.34.

<sup>13</sup> OJ L 18, 21.1.1997, p. 1.

- (e) Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin.
- (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 **and its implementing Regulation**.~~<sup>14</sup>
- (g) Regulation (EC) 1082/2006 of 5 July 2006 on a European Grouping of territorial cooperation (EGTC).<sup>15</sup>
- (h) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.**
- (i) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.**<sup>16</sup>
- (j) Directive 92/49/EEC on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance, as regards the implementing powers conferred on the Commission.**<sup>17</sup>

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<sup>14</sup> OJ L 166, 30.4.2004, p. 1.

<sup>15</sup> OJ L 210, 31.7.2006, p. 19.

<sup>16</sup> **DELETED** required these two directives to be added to the list.

<sup>17</sup> Following a question raised by **DELETED**, this directive was added in order to solve any potential conflict between the two directives.

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.~~<sup>18</sup>
3. [shifted to Paragraph 1]
4. ~~Member States shall apply the provisions of this Directive in compliance with the rules of the EC Treaty.~~

#### *Article 4*

#### **Definitions**

For the purposes of this Directive, the following definitions shall apply:

- (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~~ **health services and goods provided or prescribed by health professionals to patients to assess, maintain or restore their state of health or prevent them from becoming ill, regardless of the ways in which is it organised, delivered and financed at national level or whether it is public or private;**<sup>19</sup>

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<sup>18</sup> Paragraph 2 of article 3 was deleted, in so far as it generated more confusion than clarity. Point (f) deemed sufficient and further clarification on the interaction between the authorisation procedure have been introduced in article 9. All references to the social security regulations anticipate the adoption of the implementing regulation of Regulation 883/2004.

<sup>19</sup> The former definition referring to regulated health professions was considered to be too

- (b) "cross-border healthcare" means healthcare provided in a Member State other than that where the patient is an insured person;<sup>20</sup> ~~or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established;~~
- (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~~
- (d) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC **or a person legally exercising healthcare activities in the Member State of treatment;**
- (e) "healthcare provider" means any natural or legal person legally providing healthcare on the territory of a Member State;
- (f) "patient" means any natural person who receives or ~~wishes~~ **seeks** to receive healthcare in a Member State;
- (g) "insured person" means a person who is insured **as defined in Article 1c of Regulation (EC) No 883/2004;**
- (i) ~~until the date of application of Regulation (EC) No 883/2004: a person who is insured in accordance with the provisions of Articles 1, 2 and 4 of Regulation (EC) No 1408/71;~~
- (ii) ~~as from the date of application of Regulation (EC) No 883/2004: a person who is an insured person within the meaning of Article 1(c) of Regulation (EC) No 883/2004;~~

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limited as it did not cover the whole scope of the jurisprudence of the Court of justice on free movement of services and goods in the health sector. Another aim of this redrafting was to bring it in line with the scope of Regulation 883/2004. Therefore point (a) was redrafted and the definition of health professionals brought in line (extension to authorised professionals).

<sup>20</sup>

See above, cross-border healthcare limited to patients' mobility.

- (h) "Member State of affiliation" means the Member State where the patient is an insured person **or the Member State where the patient resides if this Member State is not the same as the former;**<sup>21</sup>
- (i) "Member State of treatment" means the Member State on whose territory cross-border healthcare is actually provided;
- (j) "medicinal product" means a medicinal product as defined by Directive 2001/83/EC;

**(j a) "medical device" means a medical device as defined by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices or by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices;**<sup>22</sup>

- (k) "prescription" means a medicinal prescription as defined by the Directive 2001/83/EC ~~including prescriptions issued and transmitted electronically (ePrescriptions)~~ **or any prescription for a medical device issued by a professional person qualified to do so;**

**(k a) "health technology" means a medicinal product or a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.**<sup>23</sup>

- (l) "harm" means adverse outcomes or injuries stemming from the provision of healthcare.<sup>24</sup>

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<sup>21</sup> This sentence was added in order to ensure consistency with the provisions of Regulation 883/2004.

<sup>22</sup> This additional definition was required by **DELETED**.

<sup>23</sup> This additional definition was required by **DELETED**.

<sup>24</sup> The definition of harm was not modified despite the request of several delegations because of the changes of the wording in article 5.

## CHAPTER II

### MEMBER STATE ~~AUTHORITIES~~<sup>25</sup> RESPONSIBLE FOR COMPLIANCE WITH COMMON PRINCIPLES FOR HEALTHCARE

#### Article 5

##### Responsibilities of authorities of the Member State of treatment

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:~~

**When healthcare is provided in another Member State than the Member State of affiliation of the patient<sup>26</sup>, or in a Member State other than that where the healthcare provider is established<sup>27</sup>, such healthcare is provided according to the legislation of the Member State of treatment in accordance of paragraph 2 of this article.<sup>28</sup>**

- 1a. Healthcare shall be provided according to standards and guidelines on quality and safety defined by the Member State of treatment. The Member State of treatment shall ensure that:**

- (a) ~~mechanisms are in place for ensuring that healthcare providers are able to meet such standards, taking into account international medical science and generally recognised good medical practices;~~ **patients receive upon request information on such standards and guidelines, including provisions on supervision and assessment;<sup>29</sup>**

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<sup>25</sup> The word “authorities” was taken out on request of a few delegations (**DELETED**).

<sup>26</sup> Amendment in line with changes to article 4(h).

<sup>27</sup> The words “resides, is registered or” were deleted because they appeared not necessary, the establishment covering these concepts.

<sup>28</sup> Article 11 was merged with article 5 since they pursue similar aims.

<sup>29</sup> The word “assessment” was added, as suggested by EMPL proposed amendment (see Braghetto report).

- (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;~~
- (c) healthcare providers provide **patients with information**<sup>30</sup> ~~all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided, including in terms of quality<sup>31</sup>, as well as and details of the healthcare provider's registration status, their insurance cover or other means of personal or collective protection with regard to professional liability;~~
- (d) patients have a means of making complaints **and there are mechanisms in place to seek and are guaranteed**<sup>32</sup> remedies and compensation when they suffer harm arising from the healthcare they receive;
- (e) systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;
- (f) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;
- (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.

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<sup>30</sup> The redrafting of the heading and of the first indents of paragraph 1 were required by a vast majority of Member States. Indeed, they wished article 5 to be limited to provisions enabling patients to make an informed choice, in full respect of national competencies in organising and delivering healthcare.

<sup>31</sup> EMPL amendment

<sup>32</sup> The text was amended in order to bring it in line with the objective pursued, i.e. the guarantee of means to seek compensation and not the guarantee of compensation.

2. [deleted, as already in Article 3]

~~3. In so far as it is necessary to facilitate the provision of cross-border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, shall develop guidelines to facilitate the implementation of paragraph 1.~~

## CHAPTER III

### USE OF HEALTHCARE IN ANOTHER MEMBER STATE

#### Article 6

##### Healthcare provided in another Member State

1. Subject to the provisions of ~~this Directive, in particular~~ articles 7, 8 and 9, the Member State of affiliation shall ensure **the reimbursement of costs incurred** ~~that~~ by an insured persons travelling to another Member State with the purpose of receiving healthcare ~~there~~ or seeking to receive healthcare provided in another Member State **if the healthcare<sup>33</sup> in question is among the benefits to which the insured person is entitled in the Member State of affiliation.**<sup>34</sup>

~~, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall 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.~~

- (1a)** ~~In any event,~~ It is for the Member State of affiliation to determine the healthcare ~~that is paid for which the insured person is entitled to receive the reimbursement, the level of reimbursement and the level of co-payment for which the person is liable,~~ regardless of where it is provided.<sup>35</sup>

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<sup>33</sup> In this context, healthcare seems to be a more appropriate word than treatment.

<sup>34</sup> This paragraph was reworded to make it clear that the aim of this article is to stress not the right to free movement but the right to reimbursement of cross-border healthcare if this healthcare is part of the entitlements in the Member State of affiliation.

<sup>35</sup> This sentence stands out as a separate paragraph in order to highlight its importance.

2. [shifted to paragraph 3a]
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~~ **assumption** of healthcare costs as it would impose if ~~the same or similar~~ **this**<sup>36</sup> healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons, **services and goods**.
- (3a) 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 **by the member State of affiliation** had ~~the same or similar~~ **this** healthcare been provided in **its territory** ~~the Member State of affiliation~~, without exceeding the actual costs of healthcare received.
4. **For the purpose of the provisions of paragraph 4**, Member States shall have a mechanism for calculation of costs that are to be **assumed** ~~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.<sup>37</sup> ~~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.~~
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.

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<sup>36</sup> The words “same and similar” were deleted in order to reinforce the prerogative of the Member State of affiliation to determine entitlements (it is up to the Member State affiliation to what extent it reimburses similar treatments). Furthermore the deletion of these concepts aims at avoiding further caselaw.

<sup>37</sup> The last sentence was deleted in so far as it deemed redundant with the provisions of previous paragraphs.

6. [former Article 7] **Subject to the provisions of articles 8 and 9**, the Member State of affiliation shall not make the reimbursement of the costs of ~~non-hospital~~ **healthcare** 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.~~<sup>38</sup>

*Article 7*

**~~Non-hospital care~~**

[shifted to Article 6(6)]

*Article 8*

**Hospital and specialised care**

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 as defined by the legislation of the Member State of affiliation**<sup>39</sup> **which is made subject to planning in so far as it involves overnight accommodation of the patient in question for at least one night or requires use of highly specialised and cost-intensive medical infrastructure or medical equipment or involves treatments presenting a particular risk for the patient or the population.**
  - (a) ~~healthcare which requires overnight accommodation of the patient in question for at least one night.~~
  - (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~~

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<sup>38</sup> See above, rationale for new recital 29. It is henceforth a general provision, not limited to non-hospital care. Article 8 provides for a derogation from this general rule.

<sup>39</sup> It shall be up to Member States to set up a national list of hospital and specialised care, in accordance with the criteria set out in this article. Paragraph 2 was deleted.

- ~~healthcare involving treatments presenting a particular risk for the patient or the population.~~
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 accordance with the regulatory procedure with scrutiny referred to in Article 19(3).~~
3. The Member State of affiliation may **make the reimbursement** of the costs of hospital care **and specialised care as defined by the Member State of affiliation in accordance with paragraph 1 provided in another Member State subject to prior authorisation.**<sup>40</sup> ~~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 treatment capacity or medical competence on the territory of the concerned Member State.~~
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.
5. [transferred to the new paragraph 9 below]

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<sup>40</sup> See justification set out in new recital 31.

- 6. For any request by an insured person of authorisation to receive healthcare in another Member State, the Member State of affiliation shall check whether the conditions of the Regulation 883/2004 are met and, if that is the case, grant the prior authorisation pursuant to the Regulation.**
- 7. The Member State of affiliation shall specify in advance and in a transparent way the criteria for refusal of the prior authorisation related to overriding considerations of general interest<sup>41</sup>.**
- 8. In any event, the Member State may refuse to grant a prior authorisation if the same treatment can be provided on its territory, within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of illness of the person concerned.<sup>42</sup>**
- 9. The Member State of affiliation shall make publicly available the list of hospital and specialised care and all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 2.**

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<sup>41</sup> This provision was moved from article 9 to article 8. See in line with new recital 31 (b).

<sup>42</sup> This sentence was added to state explicitly the criterion for refusal. There is no direct reference to Regulation 883/2004, even though the conditions for refusing prior authorisation are identical (see article 26 of Regulation).

## Article 9

### **Procedural guarantees regarding the use of healthcare in another Member State**

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(2) ~~reimbursement~~ **and assumption** of costs of healthcare incurred in another Member State<sup>43</sup> ~~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.~~
2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within **reasonable maximum** time limits set out and made public in advance by the Member States. **Urgency and individual circumstances shall be taken into account when dealing with such requests.**
3. ~~Member States shall specify in advance and in a transparent way the criteria for refusal of the prior authorisation referred to in Article 8(3).~~

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<sup>43</sup> The reference to article 6.3 was deleted in so far as it concerned gatekeeping measures applying to the use of all types of healthcare (not specifically to cross-border healthcare) and therefore should be a clear competence of Member States.

~~4. 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:~~

~~(a) the specific medical condition,~~

~~(b) the patient's degree of pain,~~

~~(c) the nature of the patient's disability, and~~

~~(d) the patient's ability to carry out a professional activity.~~

3.5. Member States shall ensure that any administrative decisions regarding the use of healthcare in another Member State are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures....

*Article 11*

[merged with Article 5]

*Article 12*

[not yet examined]

**CHAPTER IV**  
**COOPERATION ON HEALTHCARE**

*Article 13*

[not yet examined]

*Article 14a (new)*

**Cooperation on quality and safety of healthcare<sup>44</sup>**

**Member States shall cooperate in the area of quality and safety of healthcare.**

*Articles 14 to 23: not yet examined.*

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<sup>44</sup> This new article was added to recall explicitly the commitment of Member States to cooperate in the area of quality and safety of healthcare (in line with amendments to article 5).