

***Proposal for a directive on the application of patients'
rights in cross-border healthcare
(presented by the European Commission on 2 July 2008)***

[COM (2008)414 final]

***Joint Position Paper
of the European Social Insurance Platform***

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About the *European Social Insurance Platform (ESIP)*

The *European Social Insurance Platform (ESIP)* represents over thirty statutory social insurance organisations in fourteen EU Members States and Switzerland. These organisations are active in the field of health insurance, pensions, family benefits, occupational safety and accident insurance and unemployment insurance. The aims of ESIP and its members are to preserve high-profile social security for Europe; to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European decision-making process and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

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General Remarks

The draft Directive on the application of patients' rights in cross-border healthcare [COM(2008) 414 final] further opens up the discussion on the so-called "health services directive". It aims to create a "specific community framework for cross-border healthcare", which also includes "common principles in all EU health systems" and "European cooperation on healthcare".

A central element of the proposed Directive is that patients can seek medical services within the EU without authorisation and be reimbursed up to the amount that would have been paid for that treatment at home.

ESIP has already expressed in previous opinions¹ that there is no need to create further sources of law at European level in addition to national legislation and to Regulation (EC) 1408/71 and Regulation (EC) 883/04. All Member States can create national regulations for their citizens which would transpose the case-law of the European Court of Justice (ECJ) into national law. Further, ESIP supports the request to implement these rights in the Member States where this has not already been done.

Furthermore the proposed Directive grants responsibilities to the Commission which originally fall under the national competence of the Member States, in particular the list of specialised treatments and the list of specific criteria and conditions that the European reference networks must fulfil.

Positive elements

ESIP wants to underline that beside its critical comments on the proposed Directive it recognizes that the text contains several positive elements:

- References to the principle of subsidiarity which stipulates that Member States shall be responsible for the organisation, funding and control of health systems (article 5).
- Systems of professional liability insurance or similar arrangement will now have to be in place in all Member States (article 5, paragraph 1 lit. e).
- Patients will have means of making complaints and will be guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive (article 5 paragraph 1 lit. d).
- The Directive will not oblige Member States of affiliation to extend the basket of care and services assumed by their sickness funds (article 6, paragraph 3).

¹ Cf. "Consultation regarding Community action on health services" European Commission Communication of 26 September 2006 - Joint Position Paper of the European Social Insurance Platform submitted 30 January 2007.

- The rules applicable to the healthcare provided are those of the Member State of treatment (Article 11) which is not only an element of transparency but also guarantees quality.
- The mutual recognition of prescriptions and the intended introduction of a Community prescription template is useful (article 14).

Problematic elements

However, the above mentioned positive elements do not disguise the fact that the current version of the Directive still contains too many “grey areas”.

ESIP consequently draws the attention to the following elements:

- The relationship between the Directive and Regulation (EC) 1408/71 is not very clear (article 3).
- The definition of the “Member State of affiliation” is not sufficient (article 4).
- The planned list of specialised treatments should not be set up at European level. Furthermore, the Commission proposal steers towards prior authorization becoming the exception and the absence of any prior control becoming the rule (article 8).
- The requirements in terms of patient information (article 10) on the healthcare systems of other Member States are difficult to fulfil in practice in a continuously changing environment involving 27 countries.
- The establishment of national contact points (article 12) would generate a heavy bureaucratic burden which would not be cost-effective in relation to the limited scale of patient mobility.
- The comitology procedure adopted for the implementation of several sensitive provisions of the Directive (article 19), even if it does not directly exclude Member States, does not sufficiently involve the Member States and infringes upon the principle of Article 152 paragraph 5 of the EC Treaty.

Beyond these first key messages ESIP considers that the Directive as a whole requires deeper analysis, which motivates the following more detailed remarks.

Detailed Remarks

Article 3 – Relationship with other Community provisions – in relation to point 3 a) of the explanatory memorandum and recital (12)

The starting point of the ruling of the ECJ is that the national law of the Member State is the primary reference for insured persons seeking reimbursement of costs of health care received in another Member State. That national law may not be an obstacle to the freedom to provide services. This includes the freedom of the patient to seek health services in another Member State. Apart from this, the patient has rights derived from Regulation (EC) 1408/71. This Regulation gives the insured in another Member State in principle the same rights as the insured of that Member State.

It should also be mentioned in this context that there can be cases where application of the Regulation does not lead to full reimbursement. In these cases the patient has not only a choice between application of national law or the Regulation (alternative system), but under certain circumstances can invoke both (parallel system). The ECJ gives a simple formula for the calculation of the amount to be reimbursed if this is the case: The amount due by the competent institution for an equivalent treatment in the competent Member State, but not more than actual costs, minus the amount reimbursed or paid for on behalf of the competent institution under the Regulation.²

From ESIP's point of view the relationship between this Directive proposal and the Regulation (EC) 1408/71 is not made clear in the draft proposal. For example recital 23 says "the patient may choose which mechanism they prefer". The wording in Article 3 paragraph 2 is further misleading as it seems to narrow the scope of application of Regulation (EC) 1408/71. The Directive cannot with legal effect stipulate that, under the within mentioned circumstances, only the Directive, and not the Regulation, shall apply. ESIP therefore calls for the deletion of Article 3 paragraph 2 and calls for a clarification of the relation between the Regulation (EC) 1408/71 and the planned Directive in a recital.

In practice the lion's share of cases of treatment abroad can and should be handled under Regulation (EC) 1408/71. This Regulation covers: emergency medical care upon presentation of the European Health Insurance Card (EHIC) as well as planned medical care abroad, which has to be authorised by the competent health insurance body when the treatment in question cannot be given within the time medically justifiable, taking account the patient's current state of health and the probable course of the disease (E-form 112).

² See also paragraphs 47-49 in ECJ judgement C-372/04 (Watts), in particular: "The applicability of Article 22 of Regulation No 1408/71 to the situation in question does not mean that the person concerned may not simultaneously have the right under Article 49 EC to have access to healthcare in another Member State under rules on the assumption of costs different from those laid down by Article 22 (see to that effect Case C-368/98 (Vanbraekel and Others) paragraphs 37 to 53)."

Most cases of treatment received abroad fulfil these conditions: They can and should be managed under the Regulation. All Member States, health insurance bodies and healthcare providers should apply this Regulation. The remaining cases - which are very few - are cases where the patients wish to be treated abroad, even though they could receive the same treatment in their home country in a medically justifiable timeframe. The motivation for these patients is most often of a private nature, e.g. because they want to be treated in their country of origin, because their family or relatives are living abroad or because they want to be treated by a special physician (e.g. a designated expert in a specialised medical faculty). Therefore, it can be assumed that the procedure for reimbursement of costs outlined in the proposed Directive will in practice only supplement the existing procedures applicable under Regulation (EC) 1408/71 ensuring that there are no theoretical obstacles to the freedom of patients seeking treatment in another Member State, but is not an equivalent alternative.

Further, from ESIP's point of view the procedure for reimbursement of costs outlined in the proposed Directive contains in practice two essential obstacles to patients not contained in Regulation (EC) 1408/71. In other words, Regulation (EC) 1408/71 - which is predominantly operated on the benefit in kind principle - has the following two very important advantages for patients: socially equitableness and no financial risk.³

Therefore, ESIP calls for the precedence of "benefits provided on behalf of the competent institution" as laid down in Regulation (EC) 1408/71 and for the redirecting of efforts towards improving the implementation of this existing Regulation and analysing and solving the problems currently encountered in its implementation.

Over recent months, complaints have accumulated from insured persons claiming that their EHIC has not been accepted by healthcare providers for treatment given. The reason in many cases is that insured persons do not recognise (e.g. due to a foreign language) if they are dealing with an authorised healthcare provider who is required to guarantee services under the conditions of the EHIC. The insured persons obtain healthcare oblivious of this fact and are then confronted with private bills that need to be settled immediately and are often several times higher than those that would be charged under Regulation (EC) 1408/71. These persons then claim for reimbursement of costs from their health insurance body once

³ Socially equitable system: The patient does need to pay in advance, so that Regulation (EC) 1408/71 provides an equitable system which does not discriminate against patients who are simply not able to pre-finance treatment e.g. hospital treatment abroad.

No financial risk: Under Regulation (EC) 1408/71 benefits are defined by the Member State of treatment and are not limited to those applied by the Member State of affiliation for the same treatment. Therefore, in contrast to the cost reimbursement system, there is no risk that the patient is burdened with the costs of his or her own treatment. The treatment costs arising from such care are settled between the health insurance body of the Member State of treatment and that of the Member State of affiliation of the patient, so that patients themselves only need to cover the co-payments, if any, in the Member State of treatment. If co-payments are applicable, these can be reimbursed up to the level defined in the Member State of affiliation.

they return to the Member State of affiliation; often, however, the amount reimbursed by the health insurance body is only a fraction of the real costs, which results in anger on the part of the persons affected and negative headlines in the media. Furthermore, the EHIC is not always recognized by the healthcare providers who prefer to treat foreign patients on a private basis. Entry into force of the proposed Directive could further increase the problem. It is true that patients would in theory be able to choose the mechanism they preferred – benefits (in kind) provided by the competent institution under Regulation (EC) 1408/71 or reimbursement of costs – (Recital no. 20-22 and Article 3). However, the experiences described above show that in too many cases the patient is not given the choice.

ESIP thus envisages the danger that in many cases the provisions of Regulation (EC) 1408/71 which are more beneficial for patients will be contradicted or undermined in the long term. The problem of not recognising the EHIC needs to be solved at European level. Therefore, ESIP had already, within the framework of the public consultation by the European Commission prior to this draft Directive, called for⁴ healthcare providers who are prepared and obliged to provide benefits upon presentation of the EHIC to put up a sign, e.g. a symbol of the European Health Insurance Card (EHIC) in the reception area of the point of care (similar to credit card symbols in shops and restaurants). In this way, all affected persons – insured persons and healthcare providers - would know that the EHIC is accepted there and that the basis for settlement is Regulation (EC) 1408/71, which consequently means there are no private bills. Such a sign could be created in line with the present reform of the implementing Regulation (EC) 574/72.

Article 4 – Definitions

Article 4 defines the main terms used in the draft Directive such as “Member State of affiliation” (cf. Art. 4 h).

The draft Directive in its present form does not take into account so-called “resident foreigners”, e.g. the many retired people who have pension rights in one or more EU States, but live in another.

The draft Directive obviously assumes that the State of residence is always the State of affiliation. This is not the case however for the so-called “resident foreigners”; they are insured in the EU State from which they receive their pension. It is therefore important that it is also guaranteed in the Directive in line with Regulation (EC) 883/04 that it is the health insurance body at the place of residence of the pensioner that bears the costs arising from a planned treatment in a third EU Member State, when the health insurance body at the place of residence⁵ receives a flat rate payment for taking charge of the pensioners from the health insurance body of the Member State of affiliation

⁴ Cf. footnote no. 1 above.

⁵ According to the Regulation 883/04 the health insurance body at the place of residence is defined as “the institution which is providing benefits on behalf of the competent institution.”

(so-called “competent institution”). If this is not guaranteed, there is a danger that the insured person would have to bear the costs and would experience possible disputes over responsibility between the health insurance body at the place of residence and the competent health insurance body of the Member State of affiliation. Furthermore, there would be a danger that the competent institution would be subjected to an excessive cost burden (double payments).

Since the number of “resident foreigners” is so large, their interests must be taken into account and regulated. This could be achieved by supplementing Article 4 lit. (h) of the Directive as follows:

“When due to the application of Regulation (EC) 1408/71⁶ respectively Regulation (EC) 883/04⁷ 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 purpose of this Directive.”

Article 5 – Member State authorities responsible for compliance with common principles for healthcare

Article 5 specifies that Member States, taking into consideration principles of universality, access to good quality care, equity and solidarity, shall define clear quality and safety standards for healthcare provided on their territory “taking into account international medical science and generally recognised good medical practices” and introduce surveillance mechanisms for the attainment of these standards.

While paragraph 1 of the Article is a clear declaration of the Commission’s belief in the subsidiarity principle, ESIP feels that paragraph 3 interferes with the national competence of the Member States. ESIP sees no added value of such a competence of the Commission and therefore believes these matters would be better dealt within a framework like the Open Method of Coordination.

⁶ See Article 22 paragraph 3 subparagraph 2 in connection with Article 19.

⁷ See Article 20 paragraph 4 and Article 27 paragraph 5.

Article 7 and 8

ESIP points out that the ECJ in its judgements recognised the specific nature of health services provided by institutions for which planning is necessary.⁸ Following the argumentation of the ECJ a prior authorisation is a measure which is both necessary and reasonable because 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.

Futhermore, ESIP considers that a treatment list for specialised care must be set up by the Member States, because this is clearly a Member State responsibility.

Therefore ESIP suggests the following formulation of Article 7 and 8:

Article 7 - Non-hospital care

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care and non-specialised 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.

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 care shall mean healthcare which requires overnight hospital accommodation of the patient in question for at least one night.
2. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, specialised care shall mean healthcare included in a specific national 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.
3. This national list shall be set up and may be regularly updated by the Member State of affiliation.
4. 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.

⁸ See e.g. ECJ-judgement C-157/99 (Geraets-Smits and Peerbooms), paragraphs 76-80.

5. The Member State of affiliation may provide a system of prior authorisation for reimbursement by its social security system of the cost of specialised 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 relevant sector to avoid overcapacity, imbalance in the supply of care and logistical and financial wastage, the maintenance of a balanced medical service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

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.

6. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraphs 4 and 5.

7. The authorisation shall be accorded where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he/she cannot be given such treatment within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness.⁹

Article 10 – Information for patients concerning the use of healthcare in another Member State

ESIP is pleased to note that Article 10 asks Member States of affiliation to ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State. There can sometimes be a significant difference in costs for many specific treatments between the Member States with the result that patients are subject to a financial burden if their health insurance company does not bear the full costs but only reimburses the domestic rate in line with the reimbursement procedure in the State of affiliation. The most competent institution for this information is the respective health insurer of the patient. Patients should consult their health insurer before they plan a treatment abroad.

⁹ Cf. Article 20 paragraph 2 of the Regulation (EC) 883/04.

Article 12 – National contact points

“Appropriate information for patients” should, among other things, be guaranteed in future through national contact points. These should provide patients with “information on all essential aspects of cross-border healthcare” in order to achieve the “objectives of the internal market”. A distinction is made between “administrative information” (procedures to be followed, timetables for reimbursement, etc.) and “technical information” (costs, timetable for availability, outcomes).

A contact point where the patient receives the information needed in this special case is necessary but ESIP would prefer to see this function handed over to public institutions, e.g. the social security bodies. The establishment of additional structures would increase the administrative burden and the need for coordination in an unnecessary manner. The links to each national health institution with information on their healthcare system could be published on an EU Health Portal.

Chapter IV – Cooperation on healthcare

In ESIP’s view many elements contained in this chapter would be more easily dealt with in the framework of the Open Method of Coordination rather than in a Directive.

Article 14 – Recognition of prescriptions issued in another Member State

The mutual recognition of prescriptions set out in the draft Directive is in principal welcome. It is important that only medicines that are approved both in the Member State of treatment and the Member State of affiliation are considered.

ESIP welcomes the intended introduction of measures as described in Article 14 paragraph 2 a) and b) since the pharmacist must be able to verify the authenticity of the prescription. The intended introduction of a Community prescription template is useful, in particular given that the long term goal should be to introduce an EU-wide standardised e-prescription. In addition, it is important to promote and encourage drug prescription within the framework of INN (International Nonproprietary Name).

ESIP points out that 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. After Article 14 paragraph 1, point b the following sentence should be inserted: "The reimbursement is based only on relevant provisions of the Member State of affiliation."

Article 15 – Development of European reference networks

ESIP welcomes the intention of the Commission to facilitate the development of the European reference networks of healthcare providers. The ability to guarantee highly specialised medical care in the EU is very important, especially in an expanded European Union with large differences between Member States in terms of size, economic resources and financial capabilities.

The establishment of a reference network, however, should remain limited to the field of rare diseases. For existing national networks of excellence¹⁰, integration in the concept should be examined. Furthermore, the financial aspect should first be clarified before such a network extends to the treatment of patients and not only an exchange of knowledge and experience.

In principle, it should be ensured that where financial resources from the European Union are used to construct or equip medical centres of reference, this should not result in unfair competition between them and existing facilities. The extensive measures specified in the draft Directive, such as the compilation of a list of specific criteria and conditions which the European reference networks should fulfil, including the conditions and criteria for healthcare providers who would like to join the European reference networks, relate to basic national affairs regarding the structuring of healthcare systems, which have clearly been assigned to the authority of Member States.

Article 16 – E-health

In ESIP's view, the provisions in this Directive proposal should remain focused on the important core elements of cross-border healthcare. ESIP feels that a provision on e-health does not belong to these core elements and should therefore be deleted from the draft Directive. Moreover, several other European sources of law already exist on this topic (e.g. the so-called "e-commerce directive" 2000/31/EC) or are planned.

Article 18 – Data collection

The provisions for the collection of statistical data entail considerably more administrative costs. These costs bear no relation to the expected use by patients nor the limited share of cross-border healthcare compared to the entire volume of the European healthcare market.

¹⁰ Which are existing e.g. in the area of statutory accident insurance with their high level of specialisation in treating serious complications after accidents, e.g. polytrauma, paraplegia or third degree burns.

Article 19 – Committee

Article 19 authorises the Commission to adopt the following measures:

- to draw up a list of treatments that are considered as hospital treatments even if they do not require overnight accommodation according to Article 8 paragraph 1 a);
- to fix accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State;
- to compile a list of specific criteria and conditions that European reference networks must fulfil.

According to the draft Directive, all these measures shall be taken within the context of the comitology procedure (here: regulatory procedure). Although this procedure involves the Member States, the Member State representatives cannot propose the text because the right of initiative is reserved by the Commission. Furthermore, the Member States have no veto right since the opinion of the committee is voted by qualified majority. Such involvement by the Member States is not adequate and in contradiction to the principle of Article 152 paragraph 5 of the EC Treaty, which states that the responsibility of Member States for the organisation of health services and medical care shall be fully retained. Furthermore, involvement of the social security institutions in this procedure is not envisaged, even though they dispose of significant practical and technical experience and will subsequently bear the direct financial consequences of the committee's decisions.

This Article gives the European Commission prerogatives which go beyond those intended according to the principle of subsidiarity. ESIP prefers to let the Member States resolve these open issues amongst themselves with the close cooperation of the social security institutions, e.g. through the Open Method of Coordination.

This position paper has the support of the following organisations in so far as the matter lies within their field of competence:

AUSTRIA	HVSVT	Hauptverband der österreichischen Sozialversicherungsträger, Vienna
BELGIUM	ONP/RVP	Office National des Pensions/Rijksdienst voor Pensioenen, Brussels
CZECH REPUBLIC	CSSZ	Czech Social Security Administration, Prague
FINLAND	FAII	Federation of Accident Insurance Institutions, Helsinki
	TVR	Finish Unemployment Insurance Fund, Helsinki
France	FNMF	Fédération Nationale de la Mutualité Française, Paris
	CNAF	Caisse Nationale d'Allocations Familiales, Paris
	CNAM	Caisse Nationale d'Assurance Maladie, Paris
	CNAV	Caisse Nationale d'Assurance Vieillesse, Paris
	CCMSA	Caisse Centrale de la Mutualité Sociale Agricole, Paris
GERMANY	AOK-BV	AOK-Bundesverband, Berlin
	BKK-BV	Bundesverband der Betriebskrankenkassen, Essen
	IKK-BV	Bundesverband der Innungskrankenkassen, Bergisch Gladbach
	LKK-BV	Bundesverband der landwirtschaftlichen Krankenkassen, Kassel
	VdAK	Verband der Angestellten-Krankenkassen, Siegburg
	AEV	Arbeiter-Ersatzkassen-Verband, Siegburg
	Kn	Knappschaft, Bochum
	DGUV	Deutsche Gesetzliche Unfallversicherung, Berlin
	BLB	Bundesverband der landwirtschaftlichen Berufsgenossenschaften, Kassel
	DRV	Deutsche Rentenversicherung Bund, Berlin
	GLA	Gesamtverband der landwirtschaftlichen Alterskassen, Kassel
ITALY	INPDAP	Istituto Nazionale di Previdenza per i Dipendenti Dell'Amministrazione, Rome
	INPS	Istituto Nazionale della Previdenza Sociale, Rome
LUXEMBOURG	ALOSS	Association Luxembourgeoise des Organismes de Securite Sociale, Luxembourg
THE NETHERLANDS	SVB	Sociale Verzekeringsbank, Amstelveen
	CVZ	College voor Zorgverzekeringen, Amstelveen
ROMANIA	CNAS	Casa Națională De Asigurări De Sănătate, Bucharest
SWITZERLAND	SUVA	Schweizerische Unfallversicherungsanstalt, Lucerne