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

[COM (2008)414 final]

Joint opinion

of the German Social Security

Umbrella Organisations

presented on 2 September 2008

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The „Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V." (DSVAE) is a consortium of the German Social Security Umbrella Organisations. These have maintained an agency for joint European representation in Brussels since 1993, which is active on behalf of the statutory pension, health and accident insurance sectors. The agency keeps the national insurance organizations informed of all relevant developments in the European integration process, while maintaining and striving to intensify contacts with the European institutions. Another important mission of the agency is to effectively bring the guiding principles anchored in the German insurance system, such as solidarity and distance from the state, to bear in community political education.

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.

The German Social Security Umbrella Organisations however already expressed in previous opinions[1] that there is no need to create further sources of law at European level in addition to the national legislation, as well as Regulation (EC) No 1408/71 and Regulation (EC) No 883/04. Rightly the proposal directive expressly grants that the provisions of these above-named regulations take precedence over the directive. However, the question remains whether specific, currently in the proposal directive covered, elements could not also be regulated within the above-named regulations. This is already the case for supplementary reimbursements. All Member States could create national regulations for their citizens, which would transpose the case-law of the European Court of Justice (ECJ) into national law. This has already happened in Germany through the Gesundheitsmodernisierungsgesetz (Healthcare Modernisation Act) of 1 January 2004 (§ 13, para 4-6, SGB V[2]). According to this act, persons with statutory health insurance can seek non-hospital care and – with prior authorisation – hospital care in other EEA countries[3] and Switzerland based on a reimbursement of costs. At the same time, the legislature created the opportunity for the statutory health insurance funds to reach agreements directly with healthcare providers in other EEA countries. This is why the the German Social Security Umbrella Organisations supports the request to take over these rights in the Member States, where this has not already happened.

However, the proposed directive partly goes beyond the previous case-law of the ECJ on patient mobility, especially with the definition of hospital treatment and the prior authorisation for hospital care. Furthermore, the proposed directive grants responsibilities to the Commission, which originally come under the national jurisdiction 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 fulfill.

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1 Cf. for example common opinions of leading German social insurance organisations of 20 December 2006 on the communication of the European Commission "Consultation regarding Community action on health services" of 26 September 2006.
2 The so called SGB V is the fifths book of the Code of Social Law.
3 EEA = EEA = European Economic Area, viz. 27 EU Member States as well as Iceland, Liechtenstein and Norway.

Detailed Remarks

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

The German Social Security Umbrella Organisations favourably note that Article 3 clarifies the subsidiarity of the regulations of the proposed directive compared with the Regulation (EC) No 1408/71 and Regulation (EC) No 883/04.

Because according to the directive proposal the reimbursement-principle should not create incentives to prioritise patients from abroad ahead of domestic patients or undermining capital investment in the health system. "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" (recital no 12).

It should be noted that, at the present time, patient mobility is predominantly based on the European Health Insurance Card (EHIC) for emergency medical care and the E 112 form for planned medical care abroad, in other words in line with Regulation (EC) No 1408/71. 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 in the Member State of treatment.

Therefore it is assumed that patient mobility, based on the procedure for reimbursement of costs outlined in the proposed directive, is in practice also further on only a supplement to the existing procedure in Regulation (EC) No 1408/71, and not an equivalent alternative. In principle, priority should be given to the "benefits provided on behalf of the competent institution" laid down in Regulation (EC) No 1408/71. This is why the German Social Security Umbrella Organisations see the primary target – with regard to patient mobility – in implementing the Regulation (EC) No 1408/71 and in examining and correcting difficulties that arise in practice.

In the past few months complaints from insured persons have been accumulating, claiming that their EHIC has not been accepted by healthcare providers for treatment cases. The reason in many cases is that insured persons cannot recognise (e.g. due to a foreign language) if they are dealing with an authorised healthcare provider who is required to guarantee the use of healthcare based on 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 what would be charged under

Regulation (EC) No 1408/71. These persons then claim for a reimbursement of costs with their health insurance fund once they return to the Member State of affiliation; generally, however, the amount reimbursed by the health insurance company is often only a fraction of the real costs, which results in anger on behalf of the persons affected and negative headlines in the media.

This problem of not recognising the EHIC could further intensify with the entry into force of the directive. Foreign patients can decide which mechanism they prefer – benefits provided on behalf of the competent institution under Regulation (EC) No 1408/71 or reimbursement of costs – (recital no 20-22, article 3). Previous experience shows, however, that in exceptional cases authorised healthcare providers do not accept a valid EHIC from foreign patients, but compel them to receive care based on the basis of the reimbursement-principle. Otherwise, healthcare providers would have to settle the (lower) agreed domestic rates with the authorised health insurance fund chosen by the foreign patient according to the provisions of Regulation (EC) No 1408/71; foreign patients would only have to cover co-payments as codified in the law of the country of treatment.

The German Social Security Umbrella Organisations thus envisage the danger that in many cases the more beneficial provisions of Regulation No 1408/71 for patients during a temporary stay in another Member State will be contradicted or undermined in the long term. The problem of not recognising the EHIC needs to be solved at European level. Therefore, leading German social insurance organisations together with leading social security organisations from 13 other EEA countries, within the framework of the public consultation by the European Commission prior to this draft directive, have called for[4] healthcare providers who are prepared and obliged to settle benefits provided on behalf of the competent institution through the EHIC to put up a sign, e.g. a symbol of the European Health Insurance Card (EHIC) in the reception area of the surgery (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. It also sets out the basis for settlement through Regulation (EC) No 1408/71, which consequently means there are no private bills. A suitable basis could be created in line with the present reform of the implementing regulation (EC) No 574/72.

[4] Cf. Joint Position Paper of the European Social Insurance Platform - ESIP (Submitted 30 January 2007) - Consultation regarding Community action on health services - European Commission Communication of 26 September 2006.

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 persons belonging to so-called “resident foreigners”. This large group of people is made up of:

- frontier workers who live in one EU State and work in another, and
- retired people who have pension rights in one or more EU States, but live in another (e.g. German pensioners living in Spain).

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 in which they are working or from which they receive their pension. It is therefore important that it is also guaranteed in the directive in line with Regulation (EC) No 883/04 that it is the health insurance body in the place of residence of the pensioner that bears the costs arising from a planned treatment in a third EU Member State, when the institution, which is providing benefits on behalf of the competent institution affiliation (so-called “aushelfender Träger”), receives a flat rate payment for taking charge of the pensioners from the health insurance body of the Member State of affiliation (so-called “competent institution” or “zuständiger Träger”). 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 institution providing benefits on behalf of the competent institution and the competent institution itself. Furthermore, there would be a danger that the competent institution would be subjected to an excessive cost burden (double payments).

As regards frontier workers, the health insurance body of the Member State of treatment must cover the costs arising from planned treatment in a third Member State according to the provisions of Regulation (EC) No 883/04.

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 of the directive as follows:
“If, in application of article 22 paragraph 3 subparagraph 2 Regulation (EC) No 1408/71, article 20 paragraph 4 Regulation (EC) No 883/04 and article 27 paragraph 5, the insurance body in the place of residence is regarded as the competent institution, then the State of residence is regarded as the State of affiliation”.
This “technical” formulation has as its object that the health insurance body in the place of residence is liable for the costs in third Member States if this is specified in Regulation (EC) No 1408/71 and Regulation (EC) No 883/04. This applies in particular to pensioners living in other EU states.

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. This corresponds to the current practice in Germany with positive results.
The German Social Security Umbrella Organisations feel there is a need for greater clarity in the formulation of article 5 paragraph 3: "the Commission, in cooperation with the Member States shall develop guidelines to facilitate the implementation of paragraph 1". While paragraph 1 of the article is a clear declaration of the Commission's regard for the subsidiarity principle, leading the German Social Security Umbrella Organisations feel that paragraph 3 intervenes unnecessarily and excessively in the national flexibility of Member States to chose their own terms and should be rejected. For this reason, the German Social Security Umbrella Organisations advocate that the third paragraph of article 5 of the draft directive be removed.

Article 6 – Use of healthcare in another Member State

Article 6 stipulates the conditions and the level of costs according to which cross-border healthcare is reimbursed in application of this directive. The German Social Security Umbrella Organisations favourably note that according to paragraph 3 – as stated by the ECJ – the Member States may "impose 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".
The determination of the reimbursement of costs in article 6 corresponds to the rules that have been transposed into German law by the Gesundheitsmodernisierungsgesetz (Healthcare Modernisation Act) of 1 January 2004. In particular, paragraph 3 confirms the practice of authorised German health insurance funds that insured persons must comply with German eligibilities for benefits (e.g. authorised treatment and cost plan for dental prostheses, application procedure, use of the medical advisory service) even when the treatment is received in another EU Member State. For example, within the scope of responsibility of the German statutory accident insurance, a specially licensed physician, the so-called "Durchgangsarzt", must first be sought to assess the early activation of rehabilitation measures in the case of non-hospital care, who then takes charge of the remaining treatment process. Severe injuries caused by working accidents may only be treated in qualified hospitals which are specially licensed for this purpose.

Article 8 paragraph 1 – Definition of hospital care

The directive distinguishes between "non-hospital care" and "hospital and specialised care". In accordance with the directive, "hospital care" means healthcare which requires overnight accommodation for at least one night. In addition, hospital care should also include specialised care which has still to be determined. The Commission aims to draw up a list of such specialised treatments, which should be updated regularly.

The German Social Security Umbrella Organisations believe that just as the legislation of the Member State of affiliation applies with regard to the scope of services, national authorisation requirements and reimbursement levels, it is also the responsibility of that Member State to define the type of service (non-hospital or hospital care). It contradicts the crucial principle of subsidiarity (according to article 5 of the EC treaty) when such important terms are defined at European level. The intervention in the jurisdiction of the Member State of affiliation through the proposed definition of the term hospital care should be categorically rejected and the corresponding provision removed from the proposed directive.

This also applies for the catalogue of specialised care with prior authorisation, which the Commission would like to compile. Determining the range of treatments or individual services in such in-depth detail, as would be the case in such a catalogue interferes with the organisation of the healthcare system in the Member State and should therefore be categorically rejected. Besides, an EU-wide standardised use of both the hospital definition and the list of specialised treatments with prior authorisation could not be guaranteed due to the varying healthcare structures and the different financial capacity of each Member State. Member States would differ greatly in opinion as to what type of specialised care should be included in such a list.

For this reasons an agreement on a European-wide common definition of hospital care and a European-wide common list of specialised treatments is neither practical nor in agreement with the principles of subsidiarity. It is therefore proposed that each Member State draw up a national list of specialised treatments, which can then be published. It is also conceivable that the Commission would publish these national lists in its EU health portal.

Article 8 paragraph 3 – Prior authorisation for hospital care

Article 8 paragraph 3 allows Member States to provide a system of prior authorisation for hospital care once certain conditions have been met and proof has been furnished.

Therewith the directive proposal exceeds the jurisdiction of the ECJ, because the system of prior authorisation becomes a specific case.

The ECJ assumes, however, that a system of prior-authorisation is basically guaranteed in hospitals due to the specific nature of the healthcare services provided by hospitals. A system of prior authorisation is justified since 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.

Thus, the German Social Security Umbrella Organisations call for the use of a system of prior authorisation for hospital care to be put at the discretionary power of the individual Member States (without proving the conditions listed in Article 3). Moreover, a provision is missing in the proposed directive, which stipulates in which cases authorisation for hospital care in another EU Member State must categorically be granted to the insured person. A corresponding positive formulation by the ECJ[5] has already been transposed into German law (§ 13 para 5 SGB V).

Furthermore, prior authorisation seldom presents – as is often alleged – a bureaucratic burden for the affected persons, but rather it serves to clarify on a preliminary basis financial issues in the interest of the patient. There can sometimes be a significant difference in costs for many specific treatments within 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.

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

[5] Cf. e.g.: judgement in case C-157/99 Smits (Geraets) and Peerbooms, esp. 90 in conjunction with 103 und 108. Cf. also: judgement in case C-385/99 Müller-Fauré and van Riet, esp. 91 and 109.

be followed, timetables for reimbursement, etc.) and “technical information” (costs, timetable for availability, outcomes). The German Social Security Umbrella Organisations would prefer to see this function handed over to competent institutions such as social security bodies for instance. The establishment of additional structures would increase the administrative burden and the need for coordination in a unnecessary manner.

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.

The German Social Security Umbrella Organisations welcome the intended introduction of measures as described in Article 14 para 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.

The German Social Security Umbrella Organisations point out that the issue of mutual recognition of prescriptions has to be clarified in conjunction with the question of reimbursement. It is important that a reimbursement is only possible for medicinal products, which are authorised 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 on relevant provisions of the Member State of affiliation."

Article 15 – Development of European reference networks

The German Social Security Umbrella Organisations welcome 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 high differences among Member States in terms of size, economic resources and resulting financial capabilities.

The establishment of a reference network should however remain limited to the area of rare diseases. For existing national networks of excellence 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, an integration in the concept

should be examined. Furthermore, before it comes to treating the patient via an exchange of knowledge and experience, the financial aspect should first be clarified.

In principle, it should be ensured that where financial resources from the European Union are used to construct or equip medical centers of reference, this should not result in competition with existing facilities. The extensive measures of the Commission specified in the draft directive, such as for example the compilation of a list of specific criteria and conditions which the European reference networks should fulfill, 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 clearly have been assigned the authority of Member States.

Article 16 – E-health

From the point of view from the German Social Security Umbrella Organisations the provisions in this directive proposal should remain focused on the important core elements of cross-border healthcare. They feel 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. 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. They bear no proportion to the expected use for patients nor the limited share of cross-border healthcare compared to the entire volume of the European healthcare market.

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 para 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 fulfill.

These measures should be passed within the context of the comitology procedure (here: regulatory procedure). Although this procedure provides an involvement of the Member States, the Member State representatives cannot add any drafts of their own, because the right of initiative is reserved to the Commission. Furthermore the Member States have no veto right since the opinion of the committee is voted by qualified majority. An involvement of the member states which is natured in this way is not sufficient and infringes specially against the principle of article 152 paragraph 5 of the EC treaty, that the responsibility of Member States for the organisation of health services and medical care is fully retained. Also an integration of the social security systems is not planned, even though they possess practical and technical experience and subsequently bear the financial consequences of the committee's decisions.

The German Social Security Umbrella Organisations therefore reject this procedure and are in favour to let the Member States solve the open issues with the participation of the social security institutions.

This opinion has the support of all members of the Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V.:

- **AOK-Bundesverband, Bonn**
- **Bundesverband der Betriebskrankenkassen, Essen**
- **Bundesverband der Innungskrankenkassen, Bergisch-Gladbach**
- **Bundesverband der landwirtschaftlichen Krankenkassen, Kassel**
- **Verband der Angestellten-Krankenkassen, Siegburg**
- **Arbeiter-Ersatzkassen-Verband, Siegburg**
- **Knappschaft, Bochum**
- **Deutsche Gesetzliche Unfallversicherung, Berlin**
- **Bundesverband der landwirtschaftlichen Berufsgenossenschaften, Kassel**
- **Gesamtverband der landwirtschaftlichen Alterskassen, Kassel**
- **Deutsche Rentenversicherung Bund, Berlin**