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## **Communication from the Commission - Consultation re- garding Community action on health services**

### **Summary**

The Swedish Association of Local Authorities and Regions (SALAR) is positive towards the Commission's initiative to clarify the rules concerning elective care in other EU countries.

The view of the Association is that EU should, under special regulations, require that patients must undergo medical evaluation in their home country before they are permitted to receive publicly financed elective care in another EU country. This is important to assure balanced health services for all Swedish citizens, even those patients who, for economic or other reasons, cannot travel to another EU country for elective care.

In Sweden, such medical decisions are preceded by a clinical assessment whereby the individual patient is evaluated in accordance with Swedish standard medical practice, as based on the provisions of the Health Services Act concerning prioritisation, second opinions, and the medical indications that more specifically define the need for treatment. The clinical assessment also assures that care is evidence-based and, where applicable, adheres to the national guidelines of the National Board of Health and Welfare. The decision to refer a patient for care outside of Sweden is based on a judgment that the patient cannot be offered care in Sweden in accordance with the provisions of the maximum waiting-time guarantee or the Association's recommendation allowing patients to select a caregiver.

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*Swedish Association Of Local Authorities and Swedish Federation Of County Councils in cooperation*

The Association has no objections that EU clearly confirms that pre-approval for publicly reimbursed elective care in another EU country is an issue that should be decided by the individual Member States. This is also in line with article 152 of the Treaty, which states, e.g. that “*Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.*”

The Association’s judgement is that those who have the possibility, under the current rules, to travel to another Member State for elective care are patients with the economic ability to pay for that care until they return to Sweden. They are patients who are healthy enough to travel abroad. To create legal opportunities for individuals, without pre-approval from the home country, to receive elective care in another Member State can lead to limitations in a country’s options to control costs and prioritise services. Further, public health could deteriorate for certain patient groups, since the individual Member States could have difficulty in maintaining a well-functioning healthcare system.

## **Introduction**

As Sweden becomes more global, the boundaries between countries are no longer as distinct. People move to other countries, work in other countries, and vacation in countries outside of Sweden to a much greater extent than they did 10 years ago. The fact that these options are available today creates certain challenges and opportunity for health services. The design of health services must adapt to the movement of people between countries. People should feel secure in visiting, working, and vacationing in other countries. They should not need to interrupt a planned visit and return to their homeland because of medical reasons. To assure this, a detailed set of rules exists for emergent and necessary care, providing a safety net for people within EU.

This greater mobility among EU citizens and the workforce has, in recent years, led to a greater need for Member States to collaborate regarding health services. However, it is important for this collaboration to build on unity among the states if health care is to continue developing according to each state’s basic principles to provide appropriate health care to their citizens, and the premise that health care is primarily a matter for the Member States.

The proposal to the European Parliament and the Council’s directive concerning services on the internal market, presented in January 2004, includes proposals that could affect health services directly and indirectly. The proposal that directly affected the individual member states was the proposal on reimbursement of health-care expenses, which was later withdrawn.

The memorandum from the Commission Consultation regarding Community action on health services has a broader scope than the official directive. This memorandum also addresses questions on safeguarding patients and managing reim-

bursement issues among the Member States. Further, the Commission also intends to create opportunities for patients to compare and choose among care providers in different countries, improve the information flow among Member States, and discuss ethical questions in conjunction with care in other Member States.

In the memorandum Consultation regarding Community action on health services, the EU Commission addresses several problems related to cross-border care that EU is attempting to solve.

The key issue for SALAR concerns the grounds on which Swedish patients should be able to travel to another EU country for elective care (regardless of whether it concerns inpatient or outpatient services) and have the cost of treatment reimbursed by tax money.

### Question 1

**How will today's cross-border care affect the long-term accessibility, quality, and economic stability of the healthcare system (at the local, regional, and national levels) and what trends are likely in the future?**

A basic and decisive issue for the EU Commission to take a position on concerns the grounds on which patients should be able to receive elective care in other EU countries. The goal of Swedish health services is to deliver appropriate health care on equal terms for all citizens. Also, those with the greatest need should receive priority for health care. The current EU rules concerning cross-border elective care are not fully in agreement with the basic principles for health services.

The current scope of elective care is so marginal that it does not cause any planning, financial, or prioritisation problems for the county councils. If the volume of care should continue to increase, in the long term it might cause problems in planning and financing. For the county councils, the principle issue concerns human equality and that need, and nothing else, should determine whether a patient receives care.

To assure balanced health services for all Swedish citizens, even patients who cannot for economic or other reasons travel to another EU country for elective care, EU should, under special regulations, require that patients must undergo medical evaluation in their home country before they are permitted to receive publicly financed elective care in another EU country.

Article 152, paragraph 5 of the Treaty states that "*Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.*" The Association has no objections that EU clearly confirms that pre-approval for publicly reimbursed elective care in another EU country is a matter that should be decided by the individual Member States.

Patients who have the possibility to travel to another Member State for elective care are patients with the economic ability to pay for that care until they return to Sweden. They are patients who are healthy enough to travel abroad. To create legal opportunities for individuals, without pre-approval from the home country, to receive elective care in another Member State can lead to certain problems for a country's possibilities to control costs and prioritise services. Further, public health could deteriorate for certain patient groups, since the individual Member States might have difficulty in maintaining a well-functioning healthcare system.

## **Care in Sweden for people from other EU countries**

### **Acute care**

Insured individuals from other EU countries temporarily visiting Sweden have the right to receive acute care. Acute care refers to care that cannot wait until the patient returns to their home country. It also includes taking samples, medical check-ups, preventive maternal and child health care, and childbirth. Necessary interventions and special interventions such as dialysis, childbirth, medical devices, pharmaceuticals, etc are covered by a well-established system of regulations aimed to cover individuals who are temporarily in Sweden and who become acutely ill or have a chronic disease. Hence, a rather broad scope of healthcare interventions are clearly defined and regulated. The aim of a visit to Sweden should not, however, be to seek care since the person would not be covered by the right to acute care.

### **Elective care**

An individual who is insured under the provisions of regulation 1408/71 has the opportunity to apply to their local social insurance office to seek approval for financing elective care in another EU country, e.g. Sweden. The county councils have the possibility, but not the obligation to offer elective care to individuals from other countries according to the rules of the act governing export of municipal services and international aid. According to this act, such elective care may not infringe on the county councils' possibilities to offer appropriate care to their own citizens, as stipulated by the provisions of the Swedish Health Services Act.

### **Volume of EU care in Sweden**

In Sweden in 2005, there were 58 million outpatient visits to physicians and other healthcare professionals, and 1.5 million admissions to inpatient care. The county councils' net cost for health services was 160 billion Swedish kronor (SEK).

In 2005, Sweden provided care, mainly emergent and acute care, for about 25 000 patients from other EU countries. The cost for this care was 234 million SEK, corresponding to 0.15% of the county councils' net costs.

County council costs for the care of patients from other EU countries are reimbursed by the health insurance plans from the patients' respective countries. The limited volume of patients from other EU countries has not had negative consequences for Swedish health services as regards accessibility, quality, or finance. In recent years, the volume of these services has increased due to greater European collaboration, a larger union, and greater public awareness of their rights and opportunities in an integrated Europe. It is probable that the demand for acute care will increase somewhat in the coming years as the result of the increase in tourism.

### **Acute and elective care used by Swedes in other EU countries**

In 2005, Sweden paid 46 million SEK for the acute care of Swedes in EU countries outside of Scandinavia. Based on an agreement within Scandinavia, the costs for acute care are not debited to the country where the patient resides. Rather, it is the provider country that covers this cost. Sweden's costs for acute care in other EU countries will probably increase in the future as Swedes are travelling and residing in these countries to a greater extent.

Sweden also finances care in other EU countries in accordance with the rules in regulation 1408/71 and articles 49 and 50 of the EC Treaty. The scope of this care is discussed below.

During the period 2004 through July 2005, the Swedish Social Insurance Administration received 137 applications for pre-approval in accordance with regulation 1408/71, whereof 81 were approved. Of these 81 cases, the Swedish Social Insurance Administration paid for 20, and the county councils paid for the remaining 61. The county councils have the option to refer patients for care in other countries if it is found that the patient requires the care.

Since January 2004 it has been possible for patients, without pre-approval from the Swedish Social Insurance Administration, to be reimbursed for the healthcare expenses they incur in other EU countries. At that time, the Supreme Administrative Court established, with support from articles 49 and 50 of the EC Treaty, that health care and dental care are services that could be demanded across national borders. In practice, this means that an individual, without pre-approval from the Swedish Social Insurance Administration, can seek elective care in other EU countries. The individual pays the full cost of care and later applies for reimbursement from the Swedish Social Insurance Administration.

The number of Swedes reimbursed from the Swedish Social Insurance Administration for elective care outside of Sweden has continued to rise, but the volume is marginal. Between 2004 and June and 2006, the Swedish Social Insurance Administration received 2233 applications for reimbursement, whereof 2028 were approved at a cost of 26 million SEK. Somewhat over half of the approved cases were for dental care. The cost of dental care was, on average, lower than for

health care. Hence, the dental care costs comprised only 25% of the total cost of elective care. Of the patients who have received elective care within EU to date, over 30% travelled to Finland. These are mainly individuals residing in Norrbotten, near the Finnish border, who have elected to seek care in Finland. Other usual destinations for Swedes seeking elective care include Estonia, Germany, Poland, and Spain. Sweden's costs in the future for elective care in other EU countries depends, among other things, on the forthcoming EU adjustments regarding the authority that individual Member States shall have over decisions to pre-approve such care.

## Question 2

### **What clarification is needed as regards legislation, and who (authorities, purchasers, providers, patients, etc) needs to know what in order to create secure, high-quality, and effective cross-border health care?**

The Association sees no need at the EU level to regulate issues concerning good quality in health care, safety, etc as regards cross-border health services that county councils provide patients from other EU countries, or as regards referrals of patients to these countries. Such issues are a national concern, and in Sweden are regulated by the Health Services Act. The Act states that the goal of health services is to deliver appropriate health care on equal terms for all citizens. Services shall be provided with respect for the equality and dignity of all individuals. Another important goal is that those with the greatest need for care shall have priority in accessing health services. Further, health services shall be delivered so as to meet the standards for appropriate care. This means, in particular, that care should be of good quality and meet the patient's needs for secure care and treatment, it should be easily accessible, should respect the patient's self-determination and integrity, and promote good contact between the patient and health service personnel. The Health Services Act also specifies that the county councils should offer appropriate health services to people who do not live in Sweden, but have the right to health care according to the provisions of regulation 1408/71.

The Association shares the Commission's view that healthcare personnel need a good basis for making informed decisions concerning care in other Member States. In Sweden, these medical decisions are preceded by a clinical assessment whereby the individual patient is evaluated in accordance with standard Swedish medical practice, based on the provisions of the Health Services Act concerning prioritisation, second opinions, and the medical indications that more specifically define the need for treatment. The clinical assessment also assures that care is evidence-based and, where applicable, adheres to the national guidelines of the National Board of Health and Welfare. Decisions to refer patients for care outside of Sweden are based on a judgment that the patient cannot be offered care in Sweden in accordance with the provisions of the maximum waiting-time guarantee, or

the Association's recommendation allowing patients to select a provider within the country.

The quality improvement activities in Swedish health services stem from Section 2 of the Health Services Act, which stipulates that health services shall be of appropriate quality and maintain appropriate hygienic standards. It further stipulates that the quality of health services shall be systematically and continuously improved and assured. According to the Act, health services should be organised in a way that assures a high level of patient safety and quality of care.

The National Board of Health and Welfare plays a national role as a supervisory authority in the area of quality. The authority shall, among other things, work to assure good health, and health services of high quality, on equal terms for all citizens. The authority's duties particularly involve monitoring matters concerning quality and safety. The National Board of Health and Welfare publishes national guidelines on care and treatment that are intended to support the practice of health care and equalise any geographic differences in quality.

Patient safety, quality of care, and accessibility to care and services can be improved by using different types of IT support. IT tools do not yet provide the positive effects that are potentially possible. This is due in part to the wide variations in the use of IT in the healthcare sector, and in part to the incompatibility that prevents many IT systems from communicating with each other. Hence, a decision has been made regarding a national IT strategy for health services in Sweden. This should serve as the foundation for greater collaboration at the national level. Via the national IT strategy, Sweden also addresses the challenge in the EU Commission's action plan for e-health. EU's efforts should initially focus on assuring that the Member States have national IT capabilities to communicate nationally and, in the long term, the capabilities to communicate among Member States.

### **Question 3**

**Which country's authorities should be responsible for which issues (e.g. clinical follow-up and economic responsibility)? Is this question answered the same way for all types of cross-border care described in section 2.2 above?**

### **Question 4**

**Who should be responsible for patient safety in conjunction with cross-border care? How can patients be compensated if harmed?**

The Association sees no need to change the national responsibility, e.g. for clinical follow-up, economic responsibility, and patient safety as a result of the care provided in Sweden to patients from other EU countries, or when people residing in Sweden receive care elsewhere within EU.

From the outset, the Health Services Act establishes that health services shall meet the patient's need for safety. According to the Association, issues on patient safety in Sweden comprise a fundamental dimension in healthcare quality. Patient safety has emerged as a strategic management issue that the national healthcare system must address with the same dignity as other management issues.

The National Board of Health and Welfare has a national responsibility as a supervisory authority in the area of quality. Among other responsibilities, this authority aims to assure access to good health and high-quality health services on equal terms for all citizens. In particular, this authority monitors issues related to quality and safety.

The National Board of Health and Welfare has issued instructions regarding management systems for quality and patient safety in health services. The instructions specify that providers should establish management systems for quality and patient safety directed at continuous long-term improvement and assurance of healthcare quality. Systematic quality improvement efforts should aim at, e.g. preventing harm to patients, and should adhere to the aims of the organisation, the identified and prioritised healthcare needs, and care processes.

Sweden participates in the high-level group created within EU to discuss and monitor questions about patient mobility and, by sharing experiences, to support modernisation of health services within the union. This work group prioritises, e.g. the urgent issue concerning patient safety. The Association is positive towards greater exchange of experiences on patient safety, via conferences dealing with questions on how EU countries disseminate knowledge and promote research. Other countries' experiences provide a good foundation for individual Member States to develop their national regulations on patient safety.

Regarding blood and plasma, EU issued the Blood Directive establishing quality and safety norms for collecting, controlling, processing, storing, and distributing human blood. The aim of the directive is to protect public health and prevent transmission of infectious diseases in conjunction with transfusion of blood and blood components. This directive was incorporated in Swedish law on July 1, 2006.

The Association believes that even in the future it will be an important national concern for the individual Member States to decide on rules for financially compensating patients harmed by health services.

The Swedish Act on Injury to Patients applies when harm occurs in conjunction with health services in Sweden. Compensation is paid for personal injury of patients if it is probable that the injury was caused in conjunction with care, treatment, etc. These regulations also apply to patients from other EU countries who, while temporarily living and working in Sweden, require necessary and acute care and elective care in Sweden, according to regulation 1480/71.



The Act on Injury to Patients also applies to patient injuries that arise in conjunction with health services in other countries, under the condition that the patient holds residency in Sweden and has been referred by the county council, which is also the payer of care.

Compensation for patient harm is based on the legal principles for awarding damages, which means that the patient receives compensation corresponding to that which would have been awarded if the case were tried in a court of law. It may include compensation for lost income, pain, and suffering. In the event of death, reasonable compensation is paid for burial expenses and, in some cases, for lost means of support as well as special compensation for families.

According to EU regulations, if patients who are residents of Sweden receive necessary, acute and elective care in other EU countries, they are not covered by the Swedish Act on Injury to Patients since they were not referred by their home county council. In these cases, the patient must use the national and legal remedies for healthcare injury that apply in the country in question. The Association also notes that these individuals may also refer to the national provisions that apply to economic reimbursement for ambulance, automobile, or aircraft transportation from another EU country to their homeland. This is not covered by regulation 1408/71. In Sweden, as a rule, private household or travel insurances cover these home transports.

### Question 5

**What measures need to be taken to assure treatment of patients from other Member States while assuring balanced health services for all (e.g. through economic reimbursement for treatment provided in the “receiving” country)?**

The Association sees no reason to change the regulations governing health care as regards care provided by county councils (necessary, acute, and elective) to people from other EU countries. Since Sweden joined EU, the county councils have been able to offer appropriate health services to this group without negatively affecting the care responsibilities specified by the Health Services Act. The county councils obligation to provide appropriate health services in Sweden to working and vacationing people from EU is specifically addressed in the Health Services Act.

To assure balanced health services for all Swedish citizens, even patients who cannot for economic or other reasons travel to another EU country for elective care, EU should, under special regulations, require that patients must undergo medical evaluation in their home country before they are permitted to receive publicly financed elective care in another EU country. The Association reiterates that



the primary goal of the national legislation on health care in Sweden is to provide appropriate health care on equal terms for all citizens.

If patients from other EU countries travel to Sweden specifically to receive elective care the county council has the possibility, but not the obligation, to offer such care. A county council can therefore receive such EU patients for elective care if, concurrently, the county council can offer appropriate health services to residents of the county council and give priority to care of residents with the greatest need for health services.

As regards economic reimbursement to the county councils that care for individuals from other EU countries, the Association does not see any need to change current regulations. When a county council provides care for these EU patients, and patients who live in another county council in Sweden, the provider county council shall receive reasonable reimbursement for their services. The question of what constitute reasonable reimbursement is regulated by a special contract among the county councils, a national agreement on out-of-county care. A determination of whether the price for a service is reasonable can be based on comparisons with other similar interventions, or on comparisons with one's own or other's actual costs. The provider county council along with all other county councils within the respective health services region, following joint review, makes decisions on the level of reasonable reimbursement. These decisions, which are published as a regional pricelist, also consider, e.g. a judgement of what constitutes "reasonable" in the individual case. The pricelists apply, e.g. to highly specialised care, care at county and county district hospitals, primary care, and a variety of ancillary services.

### **Question 6**

**Is there a need to discuss other healthcare-related issues concerning temporary movement of staff or establishment of care providers in other Member States – issues that have not already been addressed in the Community law?**

The Association sees no need in this context to review the question of temporary movement of staff among EU countries.

Regulations on temporary movement of staff among EU countries are addressed in the "posting of workers directive" that regulates conditions for workers. The intent is that workers sent to other Member States to perform services shall not be subjected to inferior working conditions. The Commission intends to publish a report in the spring of 2007 on how Member States are implementing this directive.

The county councils are not directly affected by the posting of workers directive, since, according to the localisation principle in the local government act, the

county councils may only establish and operate services within their own geographic area, and not in other countries.

If county councils employ healthcare staff from other EU countries, the posting of workers directive does not apply since these people are employed by the county council and are not workers sent to Sweden by employers in other EU countries. The regulations intended to facilitate free movement of physicians within EU are found in Council Directive 93/16/EEC. This directive provides that every Member State shall allow physicians, with certified education or expertise from another Member State, to practice medicine without invoking special conditions, such as supplementary education or special language skills. The National Board of Health and Welfare decides whether to approve applications by physicians from other countries to work as a physician in Sweden. The Association notes that these EU regulations make it easier for county councils to recruit physicians from other countries.

The Association sees no need for further regulations concerning the establishment of private practitioners in EU. A private practitioner that wants to practice in Sweden and receive public financing from a county council is required to have a contract procured in accordance with the law governing public procurement (1992:1528). The rules regarding competition and equal opportunity apply. Private physicians can be granted a contract if they submit the most economically attractive bid, in accordance with the procurement process. Another possibility for physicians and physiotherapists is to practice in accordance with the national fee scale. Currently, it is not common to grant new contracts of this type, but if such contracts are granted there can be no discrimination towards applicants.

Providers, both Swedish and foreign, also have the opportunity to establish themselves in Sweden without contracting with a county council. In such cases, the providers determine their own prices, which patients pay out-of-pocket. The reimbursement provisions of the Health Services Act do not cover these providers.

#### **Question 7**

**Are there other areas where legal provisions need to be strengthened for the different healthcare and social security systems? What improvements are proposed by those affected, i.e. providers and social insurance institutions, to facilitate the delivery of cross-border care?**

#### **Question 8**

**How can the Community's actions contribute toward supporting healthcare systems in the Member States and different actors within these sectors? Are there areas that have not been addressed above?**

### Question 9

**What tools are appropriate to apply at the EU level to solve the various problems in health care? What areas require Community legislation, and in what areas are measures other than legislation needed?**

In health care there are several areas where EU can work for improvement. However, the Swedish Association of Local Authorities and Regions does not favour EU using healthcare legislation as its primary approach. EU should work on positive measures to promote desired changes in health care, and EU should always recognise that health services are a national concern, as stated in Article 152, paragraph 5 of the Treaty: *“Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.”*

The Swedish Association of Local Authorities and Regions is positive towards EU taking the initiative in several areas to create uniform regulations and develop health services. For example, the Association refers to the EU Blood Directive, which enhances the potential to improve safeguards for the individual patient. The Association is also positive towards creating different centres for highly specialised health services.

The Swedish Association of Local Authorities and Regions



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