# SENATE OF THE REPUBLIC

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# **RESOLUTION OF STANDING COMMITTEE 12**

(Health and safety)

(Drafted by: RIZZI)

approved during the session of 8 April 2009

ON THE

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTH CARE – COM(2008) 414 FINAL (COMMUNITY ACT No 29)

pursuant to Article 144(1) and (6) of the Regulation

Submitted to the President's Office on 9 April 2009

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Committee 12 has examined the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care;

The main aim of the above-mentioned proposal for a Directive is to encourage free movement of European citizens to access health care within the European Union, and to clarify patients' entitlements and Member States' corresponding obligations with regard to treatment quality and safety, as well as financing;

It is appropriate to focus attention on certain problem areas of the Directive, which must be more clearly defined at EU level, while acknowledging the provision's importance for achieving an overall improvement in the quality of care across the EU and introducing a system for competitive comparison of each Member State's health service providers and health care systems;

Having assessed the above-mentioned Directive proposal favourably, the Committee calls on the Government to work with the EU institutions to ensure that:

- the need to develop the EU framework guaranteeing minimum standards for health care is properly assessed at EU level, in order to standardise health care systems which have widely varying levels of service reliability, and to make adherence to the framework compulsory through the introduction of specific penalties;
- the problem of health care service reimbursement mechanisms between the various Member States is given proper consideration, to ensure that free movement of patients does not lead to wide-ranging disputes between different countries on amounts of reimbursement and the timeliness of the corresponding payments. To this end, the possibility of setting up an EU guarantee institution to monitor trends in cross-border care and to arbitrate in any disputes over appeals should be considered;
- a guarantee clause similar to the one provided for under Article 8(3b) is also introduced for non-hospital care, which would allow a Member State to limit inflow of patients if health care demands on its own health service providers risked jeopardising the achievement of national policy targets concerning rationalisation of the hospital sector and average waiting times.

#### **OPINION OF STANDING COMMITTEE 14**

# (EUROPEAN UNION POLICIES)

(Drafted by: BOLDI)

8 April 2009

The Committee has examined the Community act;

The aim of the above-mentioned proposal is to establish a general framework for providing safe, efficient and high-quality cross-border medical care, without interfering with Member States' responsibilities for organising and delivering health care services;

As medical care was excluded from the scope of Council Directive 2006/112/EC [sic] of 28 November 2006 on services in the internal market, a specific instrument should be set up to clarify matters relating to cross-border medical care;

The proposal does not detract from the existing Community framework as regards coordination of social security systems for insured persons, but rather incorporates an alternative mechanism to enable all patients to more easily seek medical treatment in another Member State while retaining the right to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home;

In this respect, it is necessary to ensure that the case-law of the Court of Justice, according to which Member States must reconcile the principles and financing of their health care systems with fundamental liberty requirements, is consistently applied, and that national health service authorities are obliged to provide mechanisms for assuming the costs of care provided to their patients in another Member State;

The proposal also seeks to ensure appropriate cooperation between EU countries on health care, including free movement of patient medical records, mutual recognition of medical prescriptions and free movement of medicines, subject to measures safeguarding health;

The Committee welcomes the compromise amendments approved by the European Parliament's Committee on the Environment, Public Health and Food Safety on 30 and 31 March 2009 and, within the area of its remit, the Committee welcomes the proposal for a Directive and makes the following comments:

# a) Principle of subsidiarity

Since the proposal helps to regulate several cross-border aspects of free movement of health services, which could not be properly dealt with by individual Member States and which do not in principle seem to interfere with Member States responsibilities in organising and delivering health care services, the Committee considers that the proposal upholds the principle of subsidiarity;

# b) Principle of proportionality

Since the proposal goes no further than setting out the general principles of a Community framework and gives Member States considerable leeway in implementing these principles in light of national, regional or local conditions, the Committee considers that it upholds the principle of proportionality;

#### c) Merit

It would be advisable to focus greater attention on the issue of minimum quality standards for health care services in order to gradually harmonise the reliability of services provided by widely varying health care systems, while respecting Member States' responsibilities for organising and running those systems. This can also be achieved by allocating specific resources and by increasing cooperation in health care issues;

A provision should be set up to ensure payment of monetary compensation to patients for any harm suffered as a result of medical error during treatment abroad, and which would not make taking legal action difficult or very expensive. To this end, reference could be made to Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), and to Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II);

With reference to Article 6(4) of the proposal, which concerns the mechanism for calculation of cross-border health care costs to be reimbursed, it will be necessary to set a level of reimbursement which neither adversely affects patients' entitlement to seek treatment abroad nor encourages patient flow towards other Member States, considering that care provided abroad is in some cases cheaper than in the Member State of affiliation;

Furthermore, also with reference to Article 6(4), it would be appropriate to insert a provision allowing patients suffering from rare diseases the right to reimbursement even if the medical and drug treatments received (including those involving galenic formulation) are not provided for by the laws of the Member State of affiliation;

With reference to Article 8(2), it would be appropriate for the list of health care treatments defined as hospital care, to be drawn up and updated by the Member States, rather than the Commission, on the basis of criteria provided in Article 8(1);

It would be advisable to insert a guarantee clause, similar to the one provided for in Article 8(3b) (which refers to outflow of patients) to allow a Member State to limit inflow of patients if the level of health care demands on its own health service providers risked jeopardising achievement of national policy targets concerning rationalisation of the hospital sector and average waiting times.

In the context of provisions for recognising prescriptions issued in another Member State, as referred to in Article 14, it would be appropriate to specify that, under the authenticity requirement, prescriptions issued following long-distance medical consultations cannot be accepted.