

Basic information	
2014/2643(DEA) DEA - Delegated acts procedure Criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil Supplementing 2008/0142(COD) Subject 4.20.06 Health services, medical institutions	Procedure completed - delegated act enters into force

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<div style="border: 1px solid red; display: inline-block; padding: 2px;">ENVI</div> Environment, Public Health and Food Safety		

Key events			
Date	Event	Reference	Summary
10/03/2014	Non-legislative basic document published	C(2014)01408	
10/03/2014	Initial period for examining delegated act 2.0 month(s)		
12/03/2014	Committee referral announced in Parliament		
20/05/2014	Delegated act not objected by Parliament		

Technical information	
Procedure reference	2014/2643(DEA)
Procedure type	DEA - Delegated acts procedure
Nature of procedure	Examination of delegated act
	Supplementing 2008/0142(COD)
Stage reached in procedure	Procedure completed - delegated act enters into force
Committee dossier	ENVI/7/15428

Documentation gateway			
European Commission			
Document type	Reference	Date	Summary
Non-legislative basic document	C(2014)01408	10/03/2014	

Criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

2014/2643(DEA) - 07/06/2010

The Council agreed on a draft directive concerning the application of patients' rights in cross-border healthcare, on the basis of a compromise proposal by the Spanish presidency.

During the Council meeting the discussions focused on four issues:

- the definition of the Member state of affiliation with regard to pensioners living abroad;
- reimbursement and prior authorisation;
- the legal basis;
- the provisions on e-health.

The two first issues remained open at the Employment Council meeting of 1 December 2009.

With regard to the **Member state of affiliation** (which concerned in particular the reimbursement of healthcare costs of pensioners living in the EU outside their home country and receiving healthcare in a third Member state), the Council agreed that as a general rule the Member State competent to grant a prior authorisation according to regulation 883/2004 (i.e. the Member State of residence) should reimburse the cost of cross-border healthcare for pensioners. If a pensioner is treated in his country of origin, this country would have to provide healthcare at its own expenses.

Concerning **healthcare providers**, the compromise seeks to ensure that patients looking for healthcare in another Member State will enjoy the quality and safety standards applicable in that country, independently of the type of provider. Furthermore, the Council agreed that Member States may adopt provisions aimed at ensuring that patients enjoy the same rights when receiving crossborder healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

Concerning the **legal basis**, the Council agreed on a double legal basis, striking a balance between the case law of the European Court of Justice on the application of Article 114 to health services and the Member States' competencies recognized by the Treaty as regards the organisation and provision of health services (according to Article 168 on public health).

As far as **e-health** is concerned, the ministers agreed on close collaboration between the Member States and the Commission in this field.

The draft directive also contains the following key elements:

- as a general rule, patients will be allowed to receive healthcare in another Member State and be reimbursed up to the **level of reimbursement applicable for the same or similar treatment** in their national health system if the patients are entitled to this treatment in their country of affiliation;
- in case of overriding reasons of general interest (such as the risk of seriously undermining the financial balance of a social security system) a Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare. Member States may manage the outgoing flows of patients by requiring prior authorisation for certain healthcare (those which involve overnight hospital accommodation, require a highly specialised and cost intensive medical infrastructure or which raise concerns with regard to the quality or safety of the care) or via the application of the "gate-keeping principle", for example by the attending physician;
- in order to manage **incoming flows of patients** and ensure sufficient and permanent access to healthcare within its territory a Member State of treatment may adopt measures concerning the access to treatment where this is justified by overriding reasons;
- Member States of treatment will have to ensure, via **national contact points**, that patients from other EU countries receive on request information on safety and quality standards on their territory in order to enable patients to make an informed choice;
- **cooperation between Member States** in the field of healthcare is strengthened, for example in the field of e-health and through the development of European reference networks which will bring together, on a voluntary basis, specialised centres in different Member States;
- the **recognition of prescriptions** issued in another Member State is improved; as a general rule, if a product is authorised to be marketed on its territory, a Member State must ensure that prescriptions issued for such a product in another Member State can be dispensed within its territory in compliance with its national legislation;
- sales of medicinal products and medical devices via the **Internet, long-term care services** provided in residential homes and access to and allocation of organs for the purpose of **transplantation** fall outside the scope of the draft directive.

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2014/2643(DEA) - 16/12/2008

The Council held a **public policy debate** on the proposal for a Directive on the application of patients' rights in cross-border healthcare on the basis of a progress report and a Presidency questionnaire.

All delegations wanted all the Court of Justice case-law on the application of the principle of free movement of goods and services in the field of health to be codified in the Directive.

The majority of delegations recommended that the Regulation on the coordination of social security systems (1408/71) should be supplemented by the Directive on cross-border healthcare and that a "third method" of reimbursement should be avoided.

So as not to compromise equal access to healthcare, the ministers asked that Member States should be able to make the use of cross-border healthcare subject to prior authorisation or to apply the "gatekeeping" principle, for example by the attending physician.

Delegations also wanted the Member State providing the healthcare to be responsible for giving patients information on the quality and safety of cross-border healthcare.

All delegations considered that the French Presidency's compromise proposal formed a good basis for future work.

However, the Commission representative entered reservations on the approach selected by the Presidency regarding the quality and safety of healthcare (Article 5) and prior authorisation (Article 8).

In its conclusions on the debate, the Presidency supported the idea of a balance between the rights of patients and of Member States. Mandatory reimbursement by a Member State should not exceed the level provided for by its own system. The Presidency also identified outstanding issues, inter alia the management of incoming patient flows, the definition of healthcare and the quality of care.

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2014/2643(DEA) - 30/11/2009

Despite substantial progress, the **Council did not reach political agreement** on a draft directive concerning the application of patients' rights in cross-border healthcare.

The discussions at the Council meeting focused mainly on the reimbursement of costs with regard to non-contractual healthcare providers. In the search for a compromise, the intention was to fully respect the case law of the European Court of Justice while preserving the Member States' rights to organise their health care system. The incoming Spanish Presidency undertook to continue the work and try to reach an agreement.

It should be noted that the Commission submitted this legislative initiative as part of the social agenda package of 2 July 2008, focusing on a triple objective: to guarantee that all patients have care that is safe and of good quality, to support patients in the exercise of their rights to cross-border healthcare; and to promote cooperation between health systems. The aim of the second objective is in particular to codify the case law of the Court of Justice relating to the reimbursement of cross-border healthcare.

The legal basis proposed is Article 95 of the Treaty (on the internal market) (qualified majority required for a Council decision; co-decision procedure with the European Parliament's first reading opinion voted on 23 April 2009).

The Council is expected to agree to change the legal basis for Articles 13 and 15 of the directive to Article 152 of the Treaty.