Basic information

2008/0142(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Patients' rights in cross-border healthcare Amended by 2013/0192(COD) Amended by 2018/0018(COD) Amended by 2023/0369(COD) See also 2018/2108(INI) **Subject** 2.20 Free movement of persons 2.40.02 Public services, of general interest, universal service 4.10.10 Social protection, social security 4.20.05 Health legislation and policy 4.20.06 Health services, medical institutions	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	GROSSETÊTE Françoise (PPE)	21/07/2009

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	BOWIS John (PPE-DE)	28/08/2008

Former committee for opinion	Former rapporteur for opinion	Appointed
ECON Economic and Monetary Affairs	ETTL Harald (PSE)	22/10/2008
EMPL Employment and Social Affairs (Associated committee)	BRAGHETTO Iles (PPE-DE)	09/09/2008
ITRE Industry, Research and Energy	GROSSETÊTE Françoise (PPE-DE)	25/09/2008
IMCO Internal Market and Consumer Protection (Associated committee)	VERGNAUD Bernadette (PSE)	10/09/2008
JURI Legal Affairs	WALLIS Diana (ALDE)	22/09/2008

FEMM Women's Rights and Gender Equality	ZÁBORSKÁ Anna (PPE-DE)	17/09/2008

Former committee for opinion on the legal basis	Former rapporteur for opinion	Appointed
JURI Legal Affairs	FRASSONI Monica (Verts /ALE)	03/11/2008

Council of the European Union

Council configuration	Meetings	Date
General Affairs	3032	2010-09-13
Employment, Social Policy, Health and Consumer Affairs	2916	2008-12-16
Employment, Social Policy, Health and Consumer Affairs	2980	2009-11-30
Employment, Social Policy, Health and Consumer Affairs	3019	2010-06-07
Transport, Telecommunications and Energy	3072	2011-02-28

European Commission

Commission DG	Commissioner
Health and Food Safety	DALLI John

Key events

Date	Event	Reference	Summary
02/07/2008	Legislative proposal published	COM(2008)0414	Summary
02/09/2008	Committee referral announced in Parliament, 1st reading		
23/09/2008	Referral to associated committees announced in Parliament		
16/12/2008	Debate in Council		Summary
31/03/2009	Vote in committee, 1st reading		Summary
03/04/2009	Committee report tabled for plenary, 1st reading	A6-0233/2009	
23/04/2009	Decision by Parliament, 1st reading	T6-0286/2009	Summary
23/04/2009	Results of vote in Parliament		
23/04/2009	Debate in Parliament		
30/11/2009	Debate in Council		Summary
13/09/2010	Council position published	11038/2/2010	Summary
23/09/2010	Committee referral announced in Parliament, 2nd reading		
27/10/2010	Vote in committee, 2nd reading		Summary

05/11/2010	Committee recommendation tabled for plenary, 2nd reading	A7-0307/2010	
18/01/2011	Debate in Parliament		
19/01/2011	Decision by Parliament, 2nd reading	T7-0007/2011	Summary
28/02/2011	Act approved by Council, 2nd reading		
09/03/2011	Final act signed		
09/03/2011	End of procedure in Parliament		
04/04/2011	Final act published in Official Journal		

Technical information

Procedure reference	2008/0142(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amended by 2013/0192(COD) Amended by 2018/0018(COD) Amended by 2023/0369(COD) See also 2018/2108(INI)
Legal basis	Treaty on the Functioning of the European Union TFEU 114-p1
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/03152

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE415.355	20/11/2008	
Amendments tabled in committee		PE418.293	21/01/2009	
Amendments tabled in committee		PE418.320	21/01/2009	
Amendments tabled in committee		PE418.256	22/01/2009	
Amendments tabled in committee		PE418.342	22/01/2009	
Amendments tabled in committee		PE418.360	23/01/2009	
Amendments tabled in committee		PE418.304	02/02/2009	
Committee opinion	FEMM	PE415.154	11/02/2009	
Committee opinion	JURI	PE418.180	13/02/2009	
Specific opinion	JURI	PE420.157	13/02/2009	
Committee opinion	ITRE	PE415.295	17/02/2009	
Committee opinion	EMPL	PE413.995	04/03/2009	

Committee opinion	ECON	PE416.293	10/03/2009	
Committee opinion	IMCO	PE418.168	10/03/2009	
Committee report tabled for plenary, 1st reading/single reading		A6-0233/2009	03/04/2009	
Text adopted by Parliament, 1st reading/single reading		T6-0286/2009	23/04/2009	Summary
Amendments tabled in committee		PE450.566	07/10/2010	
Committee draft report		PE443.081	11/10/2010	
Committee recommendation tabled for plenary, 2nd reading		A7-0307/2010	05/11/2010	
Text adopted by Parliament, 2nd reading		T7-0007/2011	19/01/2011	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	12979/2010	07/09/2010	
Council position	11038/2/2010	13/09/2010	Summary
Draft final act	00006/2011/LEX	09/03/2011	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0414	02/07/2008	Summary
Document attached to the procedure	COM(2008)0415	02/07/2008	Summary
Document attached to the procedure	SEC(2008)2163	02/07/2008	
Document attached to the procedure	SEC(2008)2164	02/07/2008	
Document attached to the procedure	SEC(2008)2183	02/07/2008	Summary
Commission response to text adopted in plenary	SP(2009)3507	25/06/2009	
Commission communication on Council's position	COM(2010)0503	20/09/2010	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2011)0090	24/02/2011	Summary
Follow-up document	COM(2014)0044	03/02/2014	Summary
Follow-up document	COM(2015)0421	04/09/2015	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary

EDPS	Document attached to the procedure	52009XX0606(03) OJ C 128 06.06.2009, p. 0020	02/12/2008	Summary
EESC	Economic and Social Committee: opinion, report	CES1927/2008	03/12/2008	
CofR	Committee of the Regions: opinion	CDR0348/2008	12/02/2009	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2011/0024
OJ L 088 04.04.2011, p. 0045 Summary

Delegated acts

Reference	Subject
2014/2643(DEA)	Examination of delegated act

Patients' rights in cross-border healthcare

2008/0142(COD) - 03/02/2014 - Follow-up document

This report considers the effects resulting from Directive 2011/24/EU of the European Parliament and of `the Council on the application of patients' rights in cross-border healthcare, for insured patients wishing to be reimbursed for healthcare received outside their country of residence and in another EU Member State.

Specifically it considers the **potential effects of prior authorisation systems** introduced under Directive 2011/24 /EU and of the definition of the Member State responsible for reimbursing patients the costs of cross-border healthcare.

The Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare limited to specific types of planned healthcare, if such system is justified and proportionate.

Two legal instruments: as from 25 October 2013, two legal instruments apply to the situation of patients seeking healthcare outside their country of residence: (i) Directive 2011/24/EU, and Regulations (EC) No 883/2004 and (EC) No 987/2009 of the European Parliament and the Council on the coordination of social security systems. **These two legal instruments both feature systems of prior authorisation.** Depending on the choices made by Member States, this may result in two systems of prior authorisation co-existing side by side. Given the overlap between the two systems there is the **clear potential for substitution effects to occur.**

As the Directive was due to be transposed by Member States into national legislation by 25 October 2013, there is obviously **no data available** at this point on the impact of the Directive, either alone or in interaction with the Regulations.

The report briefly describes the two instruments and then goes on to assess possible impacts of their interaction in two areas: **possible substitution effects between the prior authorisation systems used under the two instruments**; and the adequacy of the financial compensation for costs of healthcare paid between Member States under the Regulations. On the latter part it considers those cases where Member States receive fixed amounts intended to cover the costs of healthcare benefits in kind for pensioners.

The report notes that, due to the lack of available information, **no clear conclusions** can currently be drawn on either of these two issues. At this point in time –soon after the end of transposition deadline of the Directive - the Commission is not able to evaluate the use that Member States have made of the possibility of introducing prior authorisation systems under the Directive, and the possible substitution effects with the Regulations. For similar reasons, it is not possible for the Commission to whether there is any disproportionality resulting from the implementation of the Directive.

It is, however, possible at this point to **draw some conclusions** with a view to addressing both of these points fully in the report on the general operation of the Directive, which the Commission is required to present by 25 October 2015. This will be the first in a series of

triennial reports.

The main conclusions of the report are as follows:

- **Zero measurement**: to be able to assess the impact of the Directive on the number of patients using the Regulations, the report suggests the establishment of a "baseline" zero-measurement to capture patient mobility under the Regulations prior to the implementation of the Directive.
- Next, this zero-measurement needs to be compared with another measurement that will be made after transposition of Directive 2011/24/EU.
- **Data for future reports**: the report stresses the need to rectify the lack of statistical data regarding cross-border healthcare. Member States wishing to introduce a prior authorisation system under the Directive would need to **review their current systems of data collection** as the current data would, in most cases, not seen sufficient to justify an extensive system of prior authorisation.
- **Prior authroisation systems and procedural guarantees** : with regard to prior authorisation systems the concept of a medically-justifiable time limit should be the same under both instruments. Similarly, the procedural guarantees established under the Directive should be applied to any authorisation system under the Regulations.
- **Measures to be taken after transposition**: in order to be able to properly examine the effects of the Directive on the use of the Regulations and on the adequacy of the lump sums, it would be useful to develop the way in which data is collected
- **Improving the system of monitoring**: the development by Member States of a monitoring system under the Directive will pose a challenge of coordination with that established under the Regulations. Methodological issues need to be discussed to adjust these systems to the international standards on statistics. Member States should unify – as far as possible - the collection of information, for the sake of efficiency.

Patients' rights in cross-border healthcare

2008/0142(COD) - 04/09/2015 - Follow-up document

The Commission presented a Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

Directive 2011/24/EU came into force on 24 April 2011. It was due to be transposed by Member States by 25 October 2013. It clarifies the rights of patients to seek reimbursement for healthcare received in another Member State.

This report sets out the current state of play of transposition, and covers the most important and relevant provisions, such as the use of prior authorisation, the level of patient mobility, reimbursement practices, information to patients and cooperation under the Directive. It also report on the use of delegated powers.

The main conclusions of the report are as follows:

Transposition: infringement proceedings were launched against 26 Member States on the grounds of late or incomplete notification of such measures. As of 1 July 2015, four infringement proceedings remained open, and all four Member States concerned had made firm commitments to address the outstanding issues.

Patient mobility: the report noted that **patient mobility for planned healthcare remains low**, whilst patient mobility in terms of unplanned healthcare seems to be considerably higher. France, Luxembourg, and possibly Finland and Denmark appear to be exceptions to this general observation.

As regards **reimbursements made for treatment not subject to prior authorisation**, Finland, France and Luxembourg provided aggregate data for the Directive and the Social Security Regulations. Finland reported 17 142 reimbursement claims, France 422 680 and Luxembourg 117 962.

In the other 20 Member States, a total of 39 826 reimbursements were made specifically under the Directive: of this total Denmark alone accounted for 31 032.

The level of use of planned healthcare elsewhere is far below the potential levels suggested by the number of people indicating in the Eurobarometer survey that they would consider using cross-border healthcare. The Commission considered that there are a number of reasons why this may be the case.

1) **a number of Member States were late implementing the Directive**, which will impact on the numbers able to use it during 2014;

2) as also indicated by the Eurobarometer, **the number of citizens who are aware of their general rights to reimbursement is extremely low**. Even where citizens are aware of their rights, there are a number of Member States where it is difficult for patients to find out more about how to use these rights in practice;

3) whilst some Member States have implemented the Directive fully and are making considerable efforts to facilitate patients' rights to cross-border healthcare, **there are a considerable number of Member States where the obstacles placed in the way of patients by health systems are significant**, and which, in some cases at least, appear to be the result of intentional political choices:

- some of the current systems of prior authorisation are more extensive than the current numbers of requests would appear to justify;
- in many cases it is not clear exactly which treatments require prior authorisation;
- lower reimbursement tariffs than those used in the home Member State are a clear disincentive;
- there are a number of burdensome administrative requirements which may well deter patients.

It may be that that the natural demand for cross-border healthcare is relatively low for a number of reasons:

- unwillingness of patients to travel (e.g. because of proximity to family or familiarity with home system);
- language barriers;
- price differentials between Member States;
- acceptable waiting times for treatment in the Member State of affiliation.

The report notes that some of the demand that does exist may be catered for under local bilateral arrangements, which exist in some Member States. However, **it is not possible to conclude now that use of cross-border healthcare accurately reflects potential demand**.

However, the impact of the Directive should be considered more widely than simply cross-border healthcare. It has contributed to a number of important discussions going on in many Member States regarding healthcare reform.

National Contact Points and Information to patients: the Directive contains a significant number of provisions relating to transparency for patients on their rights, and on the quality and safety of healthcare services. This subject of **which information patients need**, and how it should be provided, is likely to be on the agenda for some time to come. The Directive provides a ready-made space (and forum, in the shape of the network of NCPs, which meets regularly) for the Commission and Member States to share ideas on how this challenge might be met.

So far, it is clear that there are significant differences between NCPs in the way they operate and the quality of the information they provide. There may well be merit in **exploring common approaches or guidelines** for the work of NCPs in future discussion.

Cross-border collaboration: the pressures faced by health services are leading to increased interest in making better use of resources via cross-border collaboration. Whilst the initial work undertaken by the Commission so far has thrown up some suggestions for action at EU level (e.g. sharing of best practice from successful projects; development of checklists for those considering cross-border collaboration), it is clear that these would only work in support of national or local activities.

Cooperation between health systems has created a new framework for Member States' cooperation. This could deliver **tangible benefits** to health systems across the EU. To take just one example, the **European Reference Networks** (ERNs) **could seriously improve access to care for rare / low-prevalence and complex diseases where expertise is rare**. To realise this potential, ongoing support and commitment from all sides will be needed.

Initial work by the Commission shows that there is a limited number of **existing cross-border projects** which may provide valuable 'lessons learned' for future parties. It has also identified specific areas where greater cross-border collaboration could make a significant difference to patient outcomes, for example in **access to critical care for myocardial infarctions**.

Successful cross-border collaboration requires significant buy-in from local-level actors, with the support of national authorities. The next step is to **identify those EU activities and best practices which will help implement real cross-border collaboration** which delivers added value. Geographical areas which might benefit from such collaboration also need to be identified.

Telemedicine: the advance of technology means that 'telemedicine' services (including online pharmacies) are likely to become **more common and more significant** in the immediate future. It may therefore prove useful to consider whether and how the applicable rules (e.g. on applicable legislation; access to, and reimbursement for, treatment) need to be developed and clarified.

Delegated acts: the Commission is of the view that the delegated powers conferred by Directive 2011/24/EU should remain in force.

The field of **medicinal products and medical devices** is one where change may occur rapidly. Although exclusions from the principle of mutual recognition of prescriptions are not currently needed, such a need may arise in the future, and would need to be dealt with swiftly via a delegated act in order to safeguard public health.

Regarding **ERNs**, the first Networks will be established in 2016, and will then need to be evaluated. This evaluation is likely to mean that it is desirable to adjust the content of the current Delegated Act in the future.

Patients' rights in cross-border healthcare

2008/0142(COD) - 02/07/2008 - Document attached to the procedure

The purpose of this Communication is to set out a Community framework on the application of patients' rights in cross-border healthcare. It is accompanied by a Commission proposal for a Directive on the application of patients' rights in cross-border healthcare.

The vast majority of EU patients receive healthcare in their own country and prefer to do so. However, in certain cases patients may seek some form of healthcare abroad. Examples include highly specialised care, or in frontier areas where the nearest appropriate facility is on the other side of the border. In recent years a number of cases have been brought to the European Court of Justice that assert patients rights to reimbursement for healthcare provided in other Member States. Since 1998, the ECJ has consistently ruled that patients have the right to have their healthcare costs reimbursed in cases where it has been received abroad even if they could have received the same care at home.

Based on this case law the purpose of this Communication is to ensure a clear and transparent framework for the provision of cross-border healthcare within the EU in cases where the care is provided in a Member State other than the home country. In cases where this does happen, there should be no unjustified obstacles. The care should be safe and of good quality. The procedures for reimbursement of costs be clear and transparent. While respecting principles of universality, access to quality care, equity and solidarity, the objectives of this framework will, therefore be, a) to provide sufficient clarity about reimbursement rights for healthcare provides in another EU Member State and b) to ensure that the necessary requirements for high-quality, safe and efficient healthcare is ensured for cross-border care.

In order to achieve the objectives set out above, the Commission proposes the establishment of a Community framework for cross-border healthcare, as set out in the accompanying proposal for a Directive. As well as setting out relevant legal definitions and general provisions, this is structured around three main areas:

- **common principles in all EU health systems**: as agreed in June 2006 by the Council, setting out which Member State shall be responsible for ensuring compliance with the common principles for healthcare and what those responsibilities include, in order to ensure that there is clarity and confidence with regard to which authorities are setting and monitoring healthcare standards throughout the EU. Further cooperation amongst Member States will be promoted, in particular in upcoming Commission proposals for Communication and a Council Recommendation on Patient Safety and Quality of Health Services and for a Council recommendation on health care associated infections;
- **a specific framework for cross-border healthcare**: the directive will make clear the entitlements of patients to have healthcare in another Member State, including the limits that Member States can place on such healthcare abroad, and the level of financial coverage that is provided for cross-border healthcare, based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home;
- **European cooperation on healthcare**: the directive establishes a framework for European cooperation in areas such as, European reference networks, health technology assessment, data collection and quality and safety, in order to enable the potential contribution of such cooperation to be put effectively in practice and on a sustained basis.

By providing a clear legal framework regarding rights to reimbursement for cross-border healthcare, the proposal will reduce the inequalities inherent in the current uncertainty regarding the general application of the principles established by the case-law. Citizens will be sure about when they will and will not be reimbursed for care received in another Member State, and on what basis, and will have clear processes for any decisions or appeals. Member States may also take further steps to address such inequalities, such as through advancing costs, or making arrangements to reimburse healthcare providers directly rather than requiring patients to advance money.

Alongside the proposed directive, the existing framework for coordination of social security schemes would remain in place with all the general principles on which the regulations on coordination of social security schemes are based, including putting the patient receiving healthcare in another Member State on equal footing with the residents of that Member State, and the existing European Health Insurance Card. In terms of patients seeking planned cross-border healthcare, this regulation ensures that if the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they will be authorised to go abroad, and any additional costs of treatment will be covered by public funds. Whenever the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be granted and the benefits provided in accordance with that Regulation. This is explicitly recognised by the proposed directive. The Regulation (EC) No 1408/71 will therefore continue to provide the general tool and the "safety net" to ensure that any patient who cannot have access to healthcare in their own country within a reasonable time will be authorised to have that healthcare in another Member State.

Patients' rights in cross-border healthcare

2008/0142(COD) - 02/07/2008 - Document attached to the procedure

The purpose of this Commission Staff Working Paper is to set out the significant contributions that digital technology can make towards a renewed social agenda for Europe. It also identifies certain specific activities that the Commission will undertake until the end of 2008 to help citizens' well-being in the information society.

Not only does ICT technology have a large impact on the economy (for example, it accounts for 40% of Europe's productivity and 25% of the EU's GDP growth) it also has an impact in the social sphere. Digital technologies have empowered millions of citizens and marginalised groups to become more engaged in everyday activities. Healthcare and consumer services are becoming more easily available and more affordable thanks to higher efficiencies. Yet, in spite of the inclusive potential o the information society, it can also have negative effects such as new divides in terms of digital *haves* and *have not.* This is mostly based on factors such as education, age, income, geographic and sometimes cultural origin, education or disabilities. It is estimated that 30 – 40% of people in Europe still do not fully enjoy the benefits of the information society. Thus, the digital divide can have the effect of reinforcing the social divide. On the one hand, it puts a large part of the population at risk of exclusion from the knowledge society whilst on the other hand, digital exclusion reduces individual life chances for employment, training and access to quality services and world knowledge whilst hampering Europe's ability to develop into a fully functional digital economy.

In order to address the digital divide the following societal challenges will be addressed in the course of 2008:

Demographic challenges

Between 2008 and 2013 the Commission will provide some EUR 150 million to support a new programme of applied research in ICT for more independent living for elderly people. With the action programme, the Commission seeks a triple win for Europe: improved quality of life and social participation for older people in Europe; new business opportunities for European industry; and more efficient and personalised health and social services. The implementation of the joint applied research programme will offer Europe a leading position in the "ageing well" ICT domain.

Improved health through advanced e-health services

In 2008 the Commission is expected to adopt a Recommendation on cross-border interoperability of electronic health record systems. By the end of 2008 the Commission will also propose a Communication on telemedicine and innovative ICT tools for chronic disease management and setting out actions that can help overcome the main barriers preventing the wider deployment of telemedicine – tele-monitoring and tele-homecare in particular.

Empowering EU citizens with digital and media literacy

One of the Commission's key objectives is to ensure that there is a clear European policy in place that is capable and able to tackle the challenge of basic digital literacy. In November 2007 a Digital Literacy Expert Group was established in order to provide the Commission with inputs for a Digital Literacy Policy Review. By the end of 2008, the Commission will present a staff working paper on digital literacy.

Access, affordability, e-accessibility for all

In June 2008 the Commission launched a web portal seeking to promote the exchange of broadband good practice. This portal will also provide an open discussion form on regulatory aspects, public procurement and strategic issues. As regards e-accessibility, the Commission has proposed strengthening e-accessibility requirements in the provision of e-communication services, including accessibility of the single European emergency number 112.

Patients' rights in cross-border healthcare

2008/0142(COD) - 24/02/2011 - Commission opinion on Parliament's position at 2nd reading

Article 294 (7), point (c) of the Treaty on the Functioning of the European Union (TFEU) provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament to the position of the Council at first reading regarding the proposal for a Directive concerning the application of patients' rights in cross-border healthcare.

The European Parliament voted in second reading a consolidated text which contains a number of amendments to the text of the Council Position at first reading. The text is the result of negotiations between the Parliament, the Council and the Commission. Most amendments are in line with the initial proposal of the Commission and thus acceptable in the light of an overall compromise.

The Commission therefore accepts all the amendments voted by the Parliament.

Patients' rights in cross-border healthcare

2008/0142(COD) - 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 **ingoing 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.

Patients' rights in cross-border healthcare

2008/0142(COD) - 23/04/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 297 votes to 120, with 152 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

The main amendments are as follows:

Aim: Parliament states that this Directive lays down rules for access to safe and high-quality healthcare in another Member State and establishes cooperation mechanisms on healthcare between Member States, whilst fully respecting national competencies in the organisation and delivery of healthcare. In the application of the Directive, Member States shall take into account the principles of good quality care and equity.

Scope: the Directive will apply to provision of cross-border healthcare regardless of how it is organised, delivered and financed or whether it is public or private. It shall be without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EEC) No 1408 /71 and its successor Regulation (EC) No 883/2004. The Directive shall not apply to health services whose main focus is in the field of long-term care, including services provided over an extended period of time whose purpose is to support people in need of assistance in carrying out routine, everyday tasks.

This Directive shall also not apply to **organ transplantation**. Due to their specific nature, they will be regulated by a separate directive.

Relationship with other Community provisions: Parliament added certain pieces of legislation to the list of this which apply without prejudice to this directive. It deleted the Commission’s text regarding Community legislation which takes precedence over this directive, including Directive 2005/36/EC on the recognition of professional qualifications;

In addition, it clarified that the Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State . Nor does the Directive affect patients' rights to be granted an authorisation for treatment in another Member State where the conditions provided for by the regulations on coordination of social security schemes, in particular Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004, are met.

Definitions: Members amended definitions for "healthcare", "cross-border healthcare" "health professional" "healthcare provider" "patient" "insured person" and "Member State of affiliation". It inserted some new terms, including “health data.”

Responsibilities of Member State of treatment: Parliament specified that patients and healthcare providers from other Member States must be provided with information by the national contact point of the Member State of treatment, inter alia by electronic means, on quality standards and guidelines, including provisions on supervision, and on availability, quality and safety, treatment options, prices, outcomes of the healthcare provided, accessibility for persons with disabilities and details of the healthcare provider's registration status and insurance cover or other means of personal or collective protection with regard to their professional liability.

It also stated that this Directive shall not oblige healthcare providers in a Member State either to provide healthcare to an insured person from another Member State or to prioritise the provision of healthcare to an insured person from another Member State to the detriment of a person who has similar health needs and is an insured person of the Member State of treatment.

Parliament inserted a list of standards that the Member State of treatment and affiliation must meet in order to **maximise patient safety**. This includes patients’ means of making a complaint, language requirements and the right to continuity of care. The Commission shall adopt measures necessary for achieving a common security level of health data at national level, taking into account existing technical standards in this field.

Member States shall have a transparent mechanism for the calculation of costs that are to be charged for the healthcare provided. This calculation mechanism shall be based on objective, non-discriminatory criteria known in advance and it shall be applied at the relevant administrative level in cases where the Member State of treatment has a decentralised healthcare system.

Responsibilities of Member State of affiliation: the Member State of affiliation shall reimburse the costs to the Member State of treatment or the insured person, which would have been paid for by its statutory social security system had equally effective healthcare been provided in its territory. If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision.. Parliament added that Patients affected by rare diseases should have the right to access healthcare in another Member State and to get reimbursement even if the treatment in question is not among the benefits provided for by the legislation of the Member State of affiliation.

Definition of hospital care: in order to correspond to the real nature of the services provided in practice, the definition of hospital care should refer to the definition in force in the patient's Member State of affiliation. Members deleted references to a specific list.

Prior authorisation: the prior authorisation system shall be based on clear and transparent criteria, and shall not constitute an obstacle to freedom of movement of patients. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that patients are expected only to pay upfront any costs that they would be expected to pay in this manner had their care been provided in the health system of their Member State of affiliation. Member States shall seek to transfer funds directly between the funders and the providers of care for any other costs. Prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way. Patients seeking to receive healthcare provided in another Member State shall be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

Parliament specified that there must be **appeal procedures** in the event of a refusal to give authorisation Patients with **rare diseases** shall not be subject to prior authorisation.

Procedural guarantees regarding the use of healthcare in another Member State: a new clause stipulates that Member States of affiliation shall ensure that patients who have received prior authorisation for the use of healthcare abroad will only be required to make upfront or top-up payments to the healthcare systems and/or providers in the Member State of treatment, to the extent that such payments would be required in the Member State of affiliation itself.

The Commission shall conduct a feasibility study into the **establishment of a clearing house** to facilitate the reimbursement of costs under this Directive across borders, healthcare systems and currency zones within two years of the entry into force of this Directive and if appropriate, present a legislative proposal.

Prior notification: Parliament inserted a new clause stating that Member States may offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a written confirmation of the maximum amount that will be paid. That written confirmation can then be taken to the hospital of treatment and reimbursement would then be made directly to that hospital by the Member State of affiliation.

European Patients Ombudsman: a further new clause makes provision for the Commission to present a legislative proposal to establish a European Patients Ombudsman within 18 months after the entry into force of the Directive. The European Patients Ombudsman shall consider, and if appropriate, mediate on patient complaints with regard to prior authorisation, reimbursement of costs or harm. He shall only be engaged once all the complaint options within the relevant Member State have been exhausted.

Duty of cooperation: Parliament inserted new clauses stating that Member States, particularly neighbouring countries, may conclude agreements with one another concerning the continuation or potential further development of cooperation arrangements. They shall guarantee that registers in which health professionals are listed can be consulted by relevant authorities of other Member States. They shall immediately and proactively exchange information about disciplinary and criminal findings against health professionals where they impact upon their registration or their right to provide services .

Recognition of prescriptions issued in another Member State: Members consider that the recognition of such prescription shall not affect: (i) national rules governing prescribing and dispensing, including generic substitution; ii) national rules governing the reimbursement of Community cross-border prescriptions; (iii) any professional or ethical duty that would require the pharmacist to refuse to dispense had the prescription been issued in the Member State of affiliation.

In addition, where a prescription is issued in the Member State of treatment for medicinal products which are not normally available on prescription in the Member State of affiliation, it shall be for the latter to decide whether to authorise exceptionally or to provide an alternative medicinal product deemed to be as effective.

Trial areas: a new clause states that the Commission, in cooperation with the Member States, may designate border regions as trial areas in which innovative cross-border healthcare initiatives can be tested, analysed and evaluated.

E-health: the use of e-Health and other telemedicine services: must (a) adhere to the same professional medical quality and safety standards as those in use for non-electronic healthcare provision; (b) offer adequate protection to patients, notably through the introduction of appropriate regulatory requirements for practitioners similar to those in use for non-electronic healthcare provision.

Cooperation on management of health technologies: the European Commission (rather than Member States) shall, in consultation with the European Parliament, facilitate the establishment of a network connecting the national authorities or bodies responsible for health technology assessment.

Patients' rights in cross-border healthcare

2008/0142(COD) - 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.

Patients' rights in cross-border healthcare

2008/0142(COD) - 02/07/2008 - Legislative proposal

PURPOSE: the establishment of a Community framework for cross-border healthcare.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: uncertainty regarding the general application of the right to reimbursement for healthcare services provided in another EU Member States has created obstacles to the free movement of both patients and health care services. This is best illustrated by the high number of patients who should have been entitled to reimbursement for cross-borders healthcare but who did not claim it.

In June 2006, the Council adopted conclusions on common values and principles in the EU’s Health Systems. These conclusions confirmed the need to clarify patients’ rights and entitlements in cases where they received health care in a country other than the one in which they reside. The Council’s conclusions also confirmed the need to enshrine these principles into a dedicated legal framework.

Similarly, the European Parliament has contributed extensively to discussions on cross-border healthcare. In April 2005, Parliament adopted a report on patient mobility and healthcare developments in the European Union, in March 2007 a Resolution on Community action on the provision of cross-border healthcare and in May 2007 a Report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market.

CONTENT: based on the concerns outlined above as well as ECJ jurisprudence the purpose of this Regulation is to establish a clear Community framework to facilitate cross-border healthcare. The proposed Directive will apply to all healthcare provisions, regardless of how it is organised, delivered or financed.

To realise the stated objectives three main themes are being proposed:

1) A specific legal framework regarding reimbursement of cross-border healthcare

The proposed Directive will provide sufficient clarity about the rules to be applied for the reimbursement of healthcare provided in other Member States and how the rights of the patients will be implemented in practice in line with the case law of the Court of Justice. It will be based on the following principles:

- Any non-hospital care to which citizens are entitled in their own Member State, they may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by their own system.
- Any hospital care to which they are entitled in their own Member State they may also seek in any other Member State. The directive allows Member States to provide for a system of prior authorisation for reimbursement of costs for hospital care provided in another Member State, if Member States can provide evidence that the outflow of patients resulting from implementation of this Directive has such an impact that it seriously undermines or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector. The costs of such hospital care provided in another Member State should also be reimbursed by the Member State of affiliation at least up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation.

The Member States of the patient may impose the same conditions that apply domestically, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care. This does not change the right of Member States to define the benefits that they choose to provide. If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, the proposed Directive will not

create any new entitlement for patients to have such treatment abroad and be reimbursed. In addition, the proposal does not prevent the Member States from extending their benefits in kind schemes to healthcare provided in other Member States a possibility already implemented by several Member States.

The proposed Directive will also clarify some relevant terms as well as the criteria for the procedures to be followed for cross-border care to ensure that these are objectively justified, necessary and proportionate. It will also require appropriate mechanisms to be put in place to provide information and assistance to patients through national contact points.

2) Guaranteeing quality and safety for cross-border healthcare

The proposed Directive will set out what the common principles in all EU health systems are, taking as a basis the June 2006 Council conclusions on "Common values and principles in European Union Health Systems" and the principle that it should be for the authorities of the Member State on whose territory the healthcare is provided to ensure compliance with such common principles. The Directive would make clear that the Member States' authorities would be responsible for ensuring that healthcare is provided according to clear standards of quality and safety as defined by the Member State in advance; that healthcare providers will make all relevant information available to patients; that patients have the right of redress if they suffer harm from the healthcare they receive; and finally that access to, and the privacy of, medical records is guaranteed. Member States will retain responsibility for setting the standards that apply to healthcare provided in their country. By clarifying which Member State is responsible in any given situation, the Directive, once approved, will guarantee a high level of both quality and safety throughout the Union's health care sector.

Future practical European cooperation on healthcare

The proposed Directive also sets out provision for enhanced European cooperation given the scale of cross-border health care provision The framework established by the Directive will help to realise the potential of this European added-value. It makes provision for developing future practical cooperation at European level by establishing European reference networks; assessing innovative health technology; and promoting e-Health.

Patients' rights in cross-border healthcare

2008/0142(COD) - 02/12/2008 - Document attached to the procedure

OPINION OF THE EUROPEAN DATA PROTECTION SUPERVISOR on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

On 2 July 2008, the Commission adopted a proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. The proposal was sent by the Commission to the European Data Protection Supervisor (EDPS) for consultation, in accordance with Article 28(2) of Regulation (EC) No 45/2001.

The proposal aims at establishing a Community framework for the provision of cross border healthcare within the EU, for those occasions where the care patients seek is provided in another Member State than in their home country. The objectives of this framework are twofold: (i) to provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States; and (ii) to ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care.

Conclusions of the EDPS: the EDPS expresses support to the initiatives of improving the conditions for cross-border healthcare. He expresses concerns, however, about the fact that EC healthcare related initiatives are not always well coordinated with regard to ICT use, privacy and security, thus hampering the adoption of a universal data protection approach towards healthcare.

Moreover, the EDPS welcomes that reference to privacy is made within the current proposal. However, a number of amendments are needed in order to provide clear requirements, both for the Member States of treatment and affiliation, as well as to properly address the data protection dimension of cross-border healthcare. These amendments are as follows:

- a definition of health data should be included in Article 4, covering any personal data that can have a clear and close link with the description of the health status of a person. This should in principle include medical data, as well as administrative and financial data relating to health;
- the introduction of a specific article on data protection is strongly recommended. This article should set clearly the overall picture, describing the responsibilities of the Member States of affiliation and treatment and identifying the main areas for further development, i.e. security harmonisation and privacy integration, especially in e-health applications;
- it is recommended that the Commission adopt a mechanism in the framework of this proposal for the definition of a commonly acceptable security level of the healthcare data at national level, taking into account existing technical standards in this field. Additional and/or complementary initiatives, including all concerned stakeholders, the Article 29 Working Party and the EDPS, should also be encouraged;
- It is recommended that the notion of 'privacy-by-design' be incorporated in the proposed Community template for e-Prescription (also at semantic level). This should be explicitly mentioned in Article 14(2)(a). The EDPS wishes to be informed about and involved in further actions taken on this issue through the proposed comitology procedure;
- it is recommended to specify the language of Article 18 and to include a more explicit reference to the specific requirements relating to subsequent use of data concerning health as laid down in Article 8(4) of Directive 95/46/EC.

Patients' rights in cross-border healthcare

2008/0142(COD) - 19/01/2011 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

It adopted its position at second reading in accordance with the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise reached between the European Parliament and the Council.

They amend the Council's position at first reading as follows:

Scope and application: it is stipulated that this Directive also aims at clarifying the relation with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.

Responsibility of the Member State of treatment: the amended text stipulates that cross-border healthcare shall be provided in accordance with the standards and guidelines on quality and safety laid down by the Member State of treatment and with Union legislation on safety standards, taking into account the **principles of universality, access to good quality care, equity and solidarity**.

Patients should receive from the national contact point upon request relevant **information** on the standards and guidelines, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities.

Healthcare providers provide relevant information to help individual patients to make an **informed choice**, including on treatment options.

There are **transparent complaints procedures** and mechanisms in place for patients, in order to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive.

The principle of non-discrimination with regard to nationality shall be applied to patients from other Member States. This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by overriding reasons of general interest, such as planning requirements to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources. Such measures shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination and shall be made publicly available in advance.

Responsibility of the Member States of affiliation: the Member State of affiliation shall ensure that where a patient has received cross-border healthcare and where medical follow-up proves necessary, the **same medical follow-up is available** as would have been if that healthcare had been provided on its territory. In addition, patients who seek to receive or do receive cross-border healthcare should have remote access to or have at least a copy of their medical records.

National contact points for cross-border healthcare: the Commission and the Member States shall make the **information as regards the national contact points publicly available**. Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers. They shall facilitate the exchange of information and cooperate closely with each other and with the Commission.

In order to enable patients to make use of their rights, national contact points in the Member State of treatment shall provide them with the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

The information shall be easily accessible and be made available by electronic means and in formats accessible, as appropriate, **to people with disabilities**.

General principles for reimbursement of costs: the amended text stipulates that the Member States of affiliation may decide to reimburse the full cost of cross-border healthcare **even if this exceeds the level of costs that would have been assumed had the healthcare been provided in its territory**.

Member States of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that sufficient documentation setting out these costs exists.

The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources.

Member States shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed as authorised.

Healthcare that may be subject to prior authorisation: the Member State of affiliation may provide for a system of **prior authorisation** for reimbursement of costs of cross-border healthcare. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and **may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients**.

Healthcare that may be subject to prior authorisation shall be limited to healthcare which: (i) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources and (ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment. Member States shall notify the categories of healthcare to the Commission.

When a patient affected or suspected of being affected by a **rare disease** applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice.

The text stipulates that the Member State of affiliation **may not refuse to grant prior authorisation** when the patient is entitled to the healthcare in question, and when this healthcare cannot be provided on its territory within a time-limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.

Administrative procedures regarding cross-border healthcare: Member states shall set out **reasonable time limits** within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member states shall take into account: (a) the specific medical condition, (b) urgency and individual circumstances.

Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a **case-by-case basis**, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

It is stated that this Directive is without prejudice to Member States' right to offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply. In other cases Member States of affiliation shall ensure that patients receive reimbursement without undue delay.

Recognition of prescriptions issued in another Member State: the amended text stipulates the recognition of prescription **shall not affect any national rules** recognising for ethical reasons the right of the pharmacist to refuse to dispense, had the prescription been issued in the Member State of affiliation.

In addition, where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation, that Member State shall take all necessary measures, in addition to the recognition of prescription, in order to ensure continuity of treatment.

Rare diseases: the Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

- make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;
- make patients, health professionals and payers of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases.

eHealth: the Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States. Amongst the objectives of the eHealth network, the text highlights the need to work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and quality healthcare.

The objectives shall be pursued in due observance of the principles of data protection.

Patients' rights in cross-border healthcare

2008/0142(COD) - 09/03/2011 - Final act

PURPOSE: the establishment of a Community framework facilitating access to safe and high-quality cross-border healthcare.

LEGISLATIVE ACT: Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

CONTENT: The new directive **provides clarity about the rights of patients who seek healthcare in another Member State** and supplements the rights that patients already have at EU level through the legislation on the coordination of social security schemes (regulation 883/04). It meets the Council's wish to fully respect the case law of the European Court of Justice on patients' rights in cross-border healthcare while preserving member states' rights to organise their own healthcare systems.

Sales of medicinal products and medical devices via internet, long-term care services provided in residential homes and the access and allocation of organs for the purpose of transplantation fall outside the scope of the Directive.

The new directive contains the following provisions:

- cross-border healthcare shall be provided in accordance with standards and guidelines on quality and safety laid down by the Member State of treatment, the Union's legislation on safety standards and taking into account the **principles of universality, access to good quality care, equity and solidarity**;
- healthcare providers must provide relevant information to help individual patients to make an **informed choice**, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability;
- the Member State of affiliation shall ensure that where a patient has received cross-border healthcare and where medical follow-up proves necessary, the **same medical follow-up** is available as would have been if that healthcare had been provided on its territory;
- as a general rule, the costs of cross-border healthcare shall be reimbursed to the patient or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory;
- the Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare **based on overriding reasons of general interest,** such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources;
- Member States may introduce a **system of prior authorisation** to manage eventual outflows of patients. This system would, however, be limited to healthcare that needs to meets planning requirements, such as: i) overnight hospital accommodation; ii) care that requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment; iii) treatments that present a particular risk for the patient or the population; or iv) treatment dispensed by a healthcare provider that could give rise to serious and specific concerns relating to the quality or safety of the care;
- the Member State of affiliation may **refuse to grant prior authorisation** for the following reasons: i) the patient will be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable; ii) the general public will be exposed with reasonable certainty to a substantial safety hazard; iii) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety; or iv) this healthcare can be provided on its territory within a time limit which is medically justifiable;
- to **manage inflows of patients**, and to ensure sufficient and permanent access to treatment on its territory, a Member State of treatment may adopt measures regarding access to treatment, where it is justified by overriding reasons of general interest (such as planning requirements to ensure permanent access to a balanced range of high-quality treatment or the wish to control costs and avoid the wastage of resources);
- Member States shall establish **national contact points** responsible to provide patients with information on their entitlement to benefit from cross-border healthcare and on the practical aspects, such as, for example, information regarding healthcare providers, the quality and safety of treatments and the accessibility of hospitals for **persons with disabilities**, to allow patients to make informed choices. The Commission will also help the Member States to create European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases;
- Member States shall set out **reasonable periods of time** within which requests for cross-border healthcare. When considering a request for cross-border healthcare, Member States shall take into account i) the specific medical condition; and ii) the urgency and individual circumstances. Individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are **properly reasoned** and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings. A Member State of affiliation must ensure that patients receive r**eimbursement without undue delay**;
- cooperation in healthcare between Member States was strengthened, for example, in the area of **eHealth** and thanks to the creation of a European network that will bring together, on a voluntary basis, the national authorities responsible for eHealth; rare diseases are another field of cooperation in which the Commission will assist the Member States to work together on diagnosis and treatment capacities;
- the **recognition of prescriptions** in another Member State has been improved. Generally speaking, if a medicinal product is authorised to be marketed on their territory, the Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force. A pharmacist retains the right when, by virtue of national rules, he can refuse, for ethical reasons, to dispense a product that was prescribed in another Member State where he would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

No later than 25 October 2015 and thereafter every three years, the Commission must provide a **report** on the application of the Directive.

ENTRY INTO FORCE: 24/04/2011.

TRANSPOSITION: 25/10/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts in respect of measures that would exclude specific categories of medicinal products or medical devices from the recognition of prescriptions. The powers to adopt delegated acts shall be conferred on the Commission for a period of five years from 24 April 2011.The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it. The European Parliament or the Council may object to the delegated act within a period of two months from the date of notification (this period may be extended by a further two months). If the European Parliament or the Council objects to a delegated act, it shall not enter into force.

Patients' rights in cross-border healthcare

2008/0142(COD) - 20/09/2010 - Commission communication on Council's position

The Commission accepted in full, in part or in principle 92 out of 120 amendments adopted at the first reading as it considered that these amendments clarified or improved the Commission proposal and were consistent with the general aim of the proposal.

Major problems when adopting the position of the Council at first reading were as follows:

Scope of prior authorisation: the Commission proposal foresees that the Member State of affiliation may not impose a system of prior authorisation for non-hospital care. However, as regards on one hand hospital care and on the other specialised care included in list established at Union level through a regulatory procedure, the proposal foresees that the Member State of affiliation may provide for a system of prior authorisation "to address the consequent outflow of patients due to the implementation" of the Directive and to prevent the financial balance of the Member State's social security system and/or the planning and rationalisation carried out in the hospital sector from being seriously undermined or being likely to be seriously undermined.

The position of the Council at first reading introduces the possibility for the Member State of affiliation to make the reimbursement of costs of certain types of cross-border healthcare (hospital, specialised care and healthcare which could raise serious and concrete concerns related to the quality or safety of the care) subject to prior authorisation without any explicit request to demonstrate an outflow of patients resulting from the freedom of mobility or any risk to the system. The text simply foresees that the system of prior authorisation shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.

The introduction of a system of prior authorisation as proposed by the Presidency text is based on a very restrictive interpretation of the jurisprudence.

Furthermore, the position of the Council at first reading refuses the adoption of a list at EU level of specialised healthcare subject to prior authorisation. It only provides that the Member State of affiliation shall make publicly available which healthcare is actually subject to prior authorisation. The Parliament took the same approach. The Commission considers that a list at EU level would have provided better transparency and more legal certainty.

The Commission is convinced of the need to ensure that patients seeking healthcare in another Member State can exercise their rights as confirmed by the Court in its settled case-law and without undermining the rights granted under Regulation 883/2004.

Conditions for refusal of a prior authorisation: the Council introduces a non-exhaustive list of criteria for refusing individual prior authorisation, which may, in the Commission's view, create legal uncertainty for the patients. Firstly, the mere fact that the position of the Council at first reading provides for a non-exhaustive list of criteria creates legal uncertainty. Secondly, without a clearer delineation of their scope and modalities of application, the criteria introduced by the Council do not provide enough legal certainty.

This list also includes a criterion based on patient safety risk: it would be extremely useful to clarify that this criterion cannot be interpreted as allowing such ground for refusal, if the same assessment is not carried out for care received domestically.

eHealth: in its initial proposal the Commission had included an article on "eHealth" whose aim was to establish the framework for the adoption, through a comitology procedure, of measures to achieve the interoperability (standards and terminologies) of information and communication technology systems in the field of healthcare.

After some discussions, Member States have eventually agreed to initiate a formal cooperation on eHealth at EU level and have identified three concrete priority areas for patient safety and the continuity of cross-border healthcare: (i) identification and authentication of health professionals; (ii) list of essential data to include in patient summaries; (iii) and use of medical information for public health and medical research.

The Commission believes that the Council text is more precise than the Commission's initial proposal, but lacks working methods, such as provisions giving the Commission the power to adopt measures to implement the work at EU level.

In conclusion, the Commission takes the view that the position of the Council at first reading contains elements departing from the Commission's proposal which may create **risks of legal uncertainty**. In order to allow the legislative process to move forward, the Commission did not stand against the position adopted by the Council by qualified majority in order to allow the legislative process to move forward. **The Commission indicated to the Council in the attached declaration that it reserves the right to support European Parliament amendments during second reading on eHealth**, the scope of the prior authorisation, increasing legal certainty for patients, and assuring that the proposed Directive does not undermine the rights granted under Regulation 883/2004.

Patients' rights in cross-border healthcare

2008/0142(COD) - 13/09/2010 - Council position

The Council posiition at first reading was adopted by a qualified majority. The Polish and Slovak delegation voting against with the Romanian delegation abstaining.

The Council accepted 16 amendments in full and 15 in large part adopted by the European Parliament (EP) at first reading.

It should be noted that the Council included a double legal basis for the Directive (Article 114 and 168 of the Treaty), which was supported by the Commission.

Subject matter and scope: the Council takes the same line as the EP, that the Directive should on the one hand provide for rules to facilitate access to safe, high-quality cross-border healthcare and promote cooperation between the Member States, while on the other hand fully respecting national competence for organising and delivering healthcare. The Council is of the opinion that Article 1(2) covers all the different types of healthcare systems in the Member States and therefore that the wording “whether it is public or private” is unnecessary and misleading.

Like the EP, the Council recognised the need to exclude long-term care from the scope of the Directive, thus following the EP, and limited the exclusion of organ transplantation to access to and allocation of organs. The Council added the exclusion of public vaccination programmes against infectious diseases.

The definition of "healthcare" is consistent with the EP's amendments and covers healthcare that is provided (treatments) or prescribed (medicinal products and/or medical devices) while dropping the reference to professional mobility.

Relationship with Regulation (EC) No 883/2004 on the coordination of social security system: the Council agrees with the EP that the Directive should apply without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EC) No 883/2004. This framework allows the Member States to refer patients abroad for treatment that is not available at home. The Council's position is that when the conditions of the Regulation are met, prior authorisation must be given pursuant to that Regulation, since in the majority of cases this will be more advantageous to the patient. Nevertheless, the patient can always request to receive healthcare under the Directive.

Member State of treatment (MST): the Council groups together all the responsibilities of the MST in one article. The main responsibilities of the MST are those that the EP asked for. Furthermore, while recognising the principle of non-discrimination with regard to nationality against patients from other Member States, the Council introduced the possibility for the MST, where justified by overriding reasons of general interest, to adopt measures regarding access to treatment aimed at fulfilling its responsibility to ensure sufficient and permanent access to healthcare within its territory to its insured persons.

The Council followed the thrust of the EP's amendment on the necessity for systems to be in place for making complaints, and mechanisms for patients to seek remedies in accordance with the legislation of the MST if they suffer harm arising from the healthcare they have received. In addition, the Council included additional guarantees for patients (e.g. application of the same scale of fees by healthcare providers to cross-border patients).

Member State of affiliation (MSA): as a general principle for reimbursement of the costs of cross-border healthcare, the MSA would have to have a mechanism for calculation of such costs. It can also introduce a system for prior authorisation based on non-discriminatory criteria, limited to what it is necessary and proportionate and applied at the appropriate administrative level. This goes along with what the EP proposed in amendments.

Prior authorisation: the Council agreed to the general principle that reimbursement of the costs of cross-border healthcare must not be subject to prior authorisation in line with the EP's amendment. The prior authorisation system that the MSA may introduce pursuant to the Directive, and as an exception to the above-mentioned principle, has to be based on clear and transparent criteria, should avoid unjustified obstacles to the freedom of movement of persons and thus reflects the thrust of the EP's amendments. The MSA may limit the application of the rules on reimbursement for cross-border healthcare by overriding reasons of general interest or to providers that are affiliated to a system of professional insurance in the MST. In this respect, the Council opted for a different approach than proposed by the EP.

The basic principles for the procedure for granting the prior authorisation are detailed in the Council's position, and include the obligation to give the reasons for refusal, e.g. the healthcare is provided by providers that raise serious and concrete concerns related to compliance with the applicable quality and safety standards and guidelines. The Council limited the healthcare that may be subject to prior authorisation to healthcare that the EP defined as "Hospital care" and took the approach of focusing on the factors justifying it. The Council agrees with the EP that there should not be a common EU-wide list of healthcare, but that it is for the Member States to define it.

Pensioners living abroad: when pensioners and members of their families whose MSA is listed in Annex IV to the Regulation reside in a different Member State, this MSA has to provide them with healthcare at its own expense when they stay on its territory. If the healthcare provided in accordance with the Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation, and is provided in the territory of the Member State that, according to the Regulation, is, in the end, responsible for reimbursement of the costs, the costs should be assumed by that Member State.

Direct payment and the concepts of prior notification and of vouchers: the Council rejects the EP's amendments as it considers them contrary to the competence of the Member States to organise their health systems, in particular when it comes to the regulation of upfront payments.

Equal treatment of patients and extension of entitlements to reimbursement: the Council has not incorporated the amendments on this issue in order to respect the principle of equal treatment for all insured persons from the same MSA regardless of the MST. The explicit reference to particular pieces of legislation on equal treatment is unnecessary as the principle is embodied in the Council's text. The Council's position states that the Member States have to ensure that all patients are treated equitably on the basis of their healthcare needs, which reflects the EP amendment.

Goods used in connection with healthcare: the Council has not included the definition of "goods used in connection with healthcare" proposed by the EP and prefers to use the definitions of "medical device" and "medicinal product" that already exist in EU legislation and would not pose transposition and implementation problems.

Continuity of care: the Council considered that ensuring continuity of care is an important aspect of the provision of cross-border healthcare and that it should be achieved through practical mechanisms, the transfer of personal data, e-health and sharing of information between health professionals. In agreeing on these aspects, the Council drew on the relevant parts of the EP's amendments.

Information for patients and the National Contact Points (NCPs): in conformity with the EP's amendments, the Member States must provide patients on request with relevant information on the safety and quality of the healthcare provided as well as on their entitlements and rights. The NCPs have to cooperate with each other and with the Commission. In addition, the NCPs have to provide patients with information concerning healthcare providers, and, on request, on any restrictions on their practice. They should also provide information to patients on procedures for complaints and for seeking remedies and on provisions on supervision and assessment of healthcare providers. All this information should be easily accessible, including by electronic means.

Data collection and protection: the Council's text includes several provisions creating obligations in relation to the protection of personal data on the MST and MSA and in relation to e-Health reflecting the existing EU legislation on protection of personal data.

Patients' rights in cross-border healthcare

2008/0142(COD) - 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.