EU Directive 2011/24/EU
on the application of patients' rights
in cross-border healthcare:

Legislation Guidance for Patient Organisations

1. Introduction

The EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was adopted on 19 January 2011 and published in the EU's Official Journal on 9 March 2011. It will enter into application on 25 of October 2013.

The purpose of this guide is to provide basic information about the Directive's content, and the rights it provides to patients. It also aims at highlighting areas where patient organisations can contribute to the implementation of the Directive at national level. For more details on the provisions of the Directive and EPF's recommendations for their implementation, see "EPF recommendations for the implementation of Directive 2011/24/EU"

Patients' Rights in Cross Border Healthcare

Directive 2011/24/EU establishes for the first time the right of patients in Europe to seek healthcare in another Member State and be reimbursed for it. The right to healthcare in other Member States already existed prior to the adoption of this Directive; various EU regulations apply to unforeseen medical treatment that becomes necessary during a temporary stay abroad (Regulation No. 883/2004 on the coordination of social security systems, and the European Health Insurance Card).

For planned care, under the existing system a patient could apply for prior authorisation and be reimbursed for the care. Without prior authorisation, however, there was no guarantee that the cost of hospital care would be met. There had been several cases during the years in the European Court of Justice, most famously the Watts case that established the principle of reimbursement for cross-border healthcare (Case C-372/04, Watts). Therefore, the EU legislation regarding planned cross-border healthcare needed clarification.

The purpose of the Directive

The Directive clarifies that patients are entitled to seek healthcare abroad, including for planned care, and be reimbursed for it, in principle without having to seek prior authorisation. For non-hospital care, patients will be able to seek healthcare abroad without prior authorisation or other formalities, and claim reimbursement upon their return home. In the case of hospital care, patients will be able to choose their healthcare provider. The new Directive covers not only public but also private healthcare providers. It also clarifies practical questions regarding information to patients and the public.

Benefits for patients

Some of the key benefits the Directive offers to patients are:

- It recognises for the first time in EU law that patients have a right to cross-border healthcare and are entitled to be reimbursed for it.
- It establishes the patients' right to adequate information on cross-border healthcare, and creates national contact points to provide such information.
- It supports the continuity of cross-border healthcare: patients will have a right to a copy of their medical record and to appropriate medical follow-up in the home country.

- It calls for European cooperation regarding mutual recognition of prescriptions made abroad.
- It calls for Member States to cooperate with each other on the quality and safety standards for healthcare, and requires Member States to publish the standards and guidelines for quality and safety that apply in their territory.
- It establishes a European network on eHealth and a network on Health Technology Assessment.
- It calls for Member State cooperation in rare diseases through European reference networks, and cross-border cooperation on diagnosis and treatment of rare diseases.

All these incentives encourage sharing of knowledge and identification and transfer of best practices across Europe. They have potential to lead gradually to improved access to healthcare, and to better safety and quality of care throughout Europe.

While in EPF's view, the final compromise falls short of our ambitious vision, it is still an important milestone for patients: it creates a legal framework for the patients' right to seek healthcare in another Member State than their Member State of affiliation, and to be reimbursed for it. Moreover, the directive provides a legal basis for enhanced European cooperation in key areas of healthcare – Health Technology Assessment, eHealth, rare diseases, and healthcare quality and safety standards.

Patient organisations' engagement is key to successful implementation

EPF has had a long and intense involvement in the draft Directive, having worked closely with the Commission, the EU Presidencies, and Members of the European Parliaments throughout the first and the second readings to ensure that a patients' perspective was strongly reflected in the text. We emphasised in particular on equity and patient-centeredness of the provisions.

As many of the provisions of the Directive are optional or leave room for interpretation by Member States, much depends on the way the Directive is implemented. Its full impact on patients, and all the other involved parties, will only become clear in the course of the coming years. In order to make sure that the Directive is implemented in Member States in a way that adds value for patients, it is essential that patient organisations at national level involve themselves actively in the implementation.

2. Key dates

Entry into application of the Directive: 25 October 2013.
From this date onwards patients can use their rights under this Directive.

Deadline for the adoption by the Commission of measures for the recognition of cross-border prescriptions (through *delegated acts*):

- Measures for better comprehensibility by patients of the prescription and instructions for use of the product, including indication of the active substance and dosage – 25 October 2012
- Measures for correct identification of medicinal products and devices prescribed in one Member State and dispensed in another – 25 October 2012
- Measures enabling health professionals to verify the authenticity of the prescription – 25 December 2012

Report by the European Commission on implementation of the Directive: 25 October 2015.
This report will be a key opportunity to assess whether the implementation of the Directive is a success from a patient perspective. Member States must help the Commission by providing all available information they have; therefore patient organisations should liaise with their Member State authorities and with the European Patients' Forum to provide their views on the implementation and their involvement in the process.

3. Key provisions in the legislation

3.1. Information to patients on cross border healthcare

One key provision of the Directive is the creation of national contact points (NCP) for information. The number and precise form they will take is left up to the Member State to decide, though it is required that they must have facilities to provide information and practical assistance to patients.

i. *National contact points in the Member State of treatment*

These must provide, on request, the following information:

- Information about healthcare providers
- Information on patients' rights
- Complaints procedures, mechanisms for seeking remedies, and legal and administrative options to settle disputes
- Information on the quality and safety standards and guidelines that apply in that Member State, including provisions on supervision and assessment of healthcare providers ("fitness to practice") and which providers are subject to those standards and guidelines (e.g. some standards may only apply to public/private healthcare)
- Information on the accessibility of hospitals for persons with disabilities
- Contact details of the national contact points in other Member States

The information should be easily accessible, made available by electronic means and in a format accessible to people with disabilities. National contact points should cooperate with each other, including with contact points in other Member States.

ii. *National contact points in the Member State of affiliation*

These must provide, on request, information on:

- The rights and entitlements of patients in the Member State, including the terms and condition for reimbursement of costs
- The procedures for accessing the entitlements of patients under this Directive
- The procedures for appeal and redress if patients consider that their rights have not been respected
- Patients must be informed clearly about what rights they have under the new Directive, and what rights under other EU legislation (Regulation (EC)No. 883/2004 on the coordination of social security systems), because sometimes the provisions of one or the other legislation may be more beneficial for the patient.

The information should be easily accessible, made available by electronic means and in a format accessible to people with disabilities.

iii. *Healthcare providers (in the Member State of treatment)*

Healthcare providers should provide all the necessary information to patients "to help individual patients to make an informed choice". This includes information on the treatment

options and their availability, the quality and safety of the healthcare, clear invoices and information on prices. They must also provide information about the healthcare provider's authorisation or registration status and professional liability provisions.

Healthcare providers are required to provide this information in the official languages of the Member State where they are established; if they wish they may also provide it in other languages.

3.2. Reimbursement of cross-border healthcare

The Directive covers all healthcare services provided by health professionals to patients to assess, maintain and restore their health, including the prescription and dispensation of medicinal products and medical devices[1]. The Directive does not apply to services of long-term care to support people in their daily routines (such as in care homes), organ transplants, or national vaccination campaigns.

i. *What care is reimbursed?*

Not all healthcare is automatically reimbursed. It is important to be aware that the decision on which healthcare is reimbursed, and at what level, is entirely the decision of Member States. However, Member States are required to provide clear information to patients regarding what types of healthcare are reimbursed, and to what levels.

In principle, patients are entitled to receive reimbursement for the same or similar healthcare, for the same amount that would have been given had the healthcare been provided in the home Member State. However, Member States are free decide to reimburse the full costs even if they exceed the normal limit, or they may choose to reimburse certain extra costs resulting for example from disability. This is up to the Member State to decide.

The Directive indicates that where the treatment is not part of the healthcare benefits in the home Member State, consideration should be given to the equivalent benefits for the patient.

ii. *Do patients have to pay up front?*

As a rule, patients who access planned cross-border healthcare under the Directive will have to pay the healthcare provider upfront, and will then be reimbursed by their home Member State. However, Member States may lessen the financial burden on patients by making use of a *prior notification*. Prior notification could work in two ways:

- Patients, in exchange for the notification, may receive a written confirmation of the level of reimbursement they are entitled to receive, before having the treatment.
- Or a Member State can decide to go further, and instead of asking the patient to pay upfront they can put in place a mechanism for a direct transfer of costs, using the

[1] Note however that the Directive does not affect national pricing and reimbursement rules. Thus, a patient may be prescribed a medicine or a device, but whether this is reimbursed and to what extent depends on the rules in place in the patient's home country. See also "Recognition of cross-border prescriptions".

existing system for the coordination of social security systems under Regulation No. 883/2004.

iii. ***Can reimbursement be refused?***

Yes, Member States can refuse to reimburse if they consider the service is not "the same or similar healthcare" as would have been provided in the home Member State, therefore interpretation of same or similar is key to ensure that equally effective healthcare is reimbursed.

Other exceptions to reimbursement of cross-border healthcare are provided in the Directive, under the principle of "overriding reasons of general interest" such as planning requirements. Member States must inform the Commission about any limitations of reimbursement of cross-border healthcare. This must be limited to what is necessary and proportionate.

Reimbursement may also be refused, under certain conditions, if it is for healthcare services subject to prior authorisation. See section below for further details.

3.3. Prior authorisation

Certain cross-border healthcare may be subject to prior authorisation by the home Member State. In principle, patients have the right to access cross-border healthcare without prior authorisation and be reimbursed for it. However, there are certain exceptions, for which Member States have the right to put in place a system of prior authorisation. They can do so only if based on the principle of "overriding reasons of general interest".

i. ***In what cases do patients have to ask for authorisation beforehand?***

Member States will have to make public the precise list of health services that are subject to prior authorisation. The exceptions are limited to:

- Healthcare which is subject to planning requirements, relating to ensuring access domestically, or the control of costs and avoidance of waste of resources, AND
    - either involves overnight hospital accommodation OR
    - use of highly specialised medical infrastructure or equipment.

  MS must notify the categories of such healthcare to the Commission.
- Healthcare which presents a particular risk for the patient or the general population;
- Healthcare by a provider that could raise "serious and specific concerns relating to the quality or safety of the care", to be judged on a case-by-case basis.

While the Directive does not provide a timeframe for the decision regarding prior authorisation, it mentions a "reasonable time", also taking into account emergency due to the patient's condition. *See also section 3.4. (administrative procedures)*.

ii. ***Can the Member State refuse prior authorisation?***

Yes, in some cases. In principle, Member States cannot refuse authorisation if the patient is entitled to it under the national legislation, and the healthcare cannot be provided domestically within a medically justifiable time-limit. This must be based on an objective medical assessment of the patient's condition, the history and probable course of their illness, the degree of pain and/or the nature of the disability.

However, prior authorisation may be refused if:

- The patient will be exposed to an unacceptable risk, that outweighs the potential benefit from cross-border healthcare
- It would expose the general public to a safety hazard
- The healthcare provider who is to provide the healthcare is suspected of not respecting standards and guidelines on quality of care and patient safety
- This healthcare can be provided in the home country within a justifiable time limit taking into account the state of health of the patient and probable course of the illness.

3.4. Administrative procedures for cross-border healthcare

The Directive sets rules for administrative procedures in the Member State of Affiliation linked to cross-border healthcare, and in particular for reimbursement and prior authorisation requests. These procedures must be easily accessible. Information related to these administrative procedures will be made publicly available.

i. ***How long will administrative procedure for patients' requests related to cross border healthcare take?***

"Reasonable" time limits must be set for dealing with the administrative procedures, and these must be made public. However, it is left up to national authorities to define what constitutes a "reasonable" time to take a decision on prior authorisation.

ii. ***What will Member State take into account when considering patients' requests?***

The Directive is based on the principle of non-discrimination: Member States of treatment must not charge higher fees for overseas patients than for national patients.

When considering requests, Member States must take into account the patient's medical condition, the urgency of the case, and individual circumstances. Request should be dealt with objectively and impartially. Individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare received in another Member State must be properly reasoned, subject to review and can be challenged in court, with provision for interim measures. See also *section 3.6. (rare diseases)*.

3.5. Safety, quality and continuity of care

The Directive makes specific provisions related to the safety and quality of care, including provisions to ensure continuity of care after the patient returns home.

iii. ***What are the key provisions related to safety and quality of care?***

The Directive states that cross-border healthcare has to be provided to patients in accordance with the safety and quality standards and guidelines in place in the Member State of treatment and, where applicable, EU legislation on safety standards.

Member States will be required to make publicly available their national standards and guidelines regarding quality and safety. The Directive also requires Member States to cooperate with each other on safety and quality standards and guidelines healthcare.

Furthermore, Member States must ensure that information contained in their national/local registers regarding specific health professionals' right to practise is made available upon request to other Member States.

It should be noted, however, that the Directive falls short in that it does not require that the same safety and quality standards that apply to conventional healthcare should extend to eHealth. This is an area where patients can advocate.

iv. ***What provision is there to ensure continuity of care?***

Patients who have received treatment in another Member State are entitled to a record of the treatment. If medical follow-up proves necessary, the home country must provide the same follow-up as for treatment received in its territory. See also *section 3.7. (eHealth)*.

v. ***Recognition of cross-border prescriptions***

Prescriptions issued abroad must as a rule be recognised, though whether the medication is reimbursed is up to the Member State: the Directive does *not* affect national rules regarding pricing and reimbursement. The European Commission will prepare guidelines for the interoperability of ePrescriptions, and other measures to enable health professionals to verify the authenticity of prescriptions issued in other Member States. *section 3.7. (eHealth)*.

3.6. Patients with rare diseases

The Directive contains specific provisions to address rare diseases. Patients with rare diseases and their families are in a particularly vulnerable situation as for them, the decision to seek healthcare abroad is based on a global lack of expertise and/or the unavailability of treatment or even diagnosis in their own country.

The Commission will support the Member States in cooperating with each other to develop better capacity for the diagnosis and treatment of rare diseases. The main tool for this purpose will be European Reference Networks (see *section 3.7.*). Such reference networks already exist in some disease-areas, but the Directive gives them a legal basis and a specific focus on rare diseases.

Moreover, the Directive calls on Member States to exploit better the possibilities offered by Orphanet and the existing Social Security Regulation for the referral of patients abroad for the diagnosis and for treatments which are not available in the home country.

If a patient affected, or suspected to be affected, by a rare disease needs to apply for prior authorisation, a clinical evaluation may be carried out, and if no experts can be found in the

home country, the Member State can request scientific advice. See also: Administrative procedures.

This last provision of the Directive is rather vague, so it is important that patient organisations draw the attention of the national authorities to the specific problems faced by patients with rare diseases. The authorities should do everything they can to facilitate those patients' access to expert diagnosis and treatment, including exploiting the possibilities afforded by European cooperation.

3.7. Further cooperation: European Reference Networks, Health Technology Assessment, and eHealth

This section presents the provisions for enhanced European cooperation provided by the Directive, and assesses the opportunities for involvement of patient organisations at national and EU levels.

i. *European Reference Networks*

European Reference Networks already exist for some rare diseases. The Directive gives them a legal basis and clear objectives, and encourages Member States to facilitate the development of such networks. The ERNs bring together specialised centres and healthcare providers across Member States to pool resources and knowledge in order to:

- realise the potential of European cooperation in highly specialised healthcare for patients and healthcare systems;
- pool knowledge on prevention;
- improve diagnosis and delivery of high-quality, accessible and cost-effective healthcare for all patients with "a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare" (primarily rare diseases);
- reinforce research, epidemiological surveillance and training of health professionals;
- facilitate mobility of expertise, and develop and share information for developing diagnosis and treatment of rare diseases;
- encourage development of quality and safety benchmarks and help spread best practices; and
- help those Member States with small numbers of patients with particular conditions or lacking in expertise/technology to provide specialised services of high quality.

The Commission will adopt specific criteria that the ERNs must fulfil, as well as criteria required from healthcare providers wishing to join them.

The Directive doesn't mention patient organisations involvement in these Networks. However, the criteria developed by the EU Rare Diseases Task Force (2007) state that a reference network should have close links and collaboration with patient associations where they exist.[2] Furthermore, the Council Recommendation on rare diseases (2009) calls on

[2] Report "Centres of Reference for rare diseases in Europe: State-of-the-art in 2006 and recommendations of the Rare Diseases Task Force" (2007; see also the report "European Reference Networks in the Field of Rare Diseases: State of the Art and Future Directions" (2008), both available on the RDTF website. The Task Force was replaced by the European Union Committee of Experts on Rare Diseases in 2009 – see www.eucerd.eu

Member States to consult patient representatives on policy development, facilitate patients' access to updated information, and promote patient organisation activities.

ii. ***eHealth***

The Directive establishes a voluntary network for cooperation between the national authorities designated by Member States as responsible for eHealth. The network is given broad objectives to work towards enhancing the continuity, safety and high quality of healthcare. It will be drawing up guidelines on the data to include in patient summaries for continuity and safety of care across borders, and the use of medical information for public health and research.

Cooperation with stakeholders is not mentioned in the Directive. Patient organisations at national level can advocate for their Member State to participate in the eHealth network, and highlight the importance of involving stakeholders in the functioning of the network. They can also offer to cooperate with the authorities in developing patient-centred eHealth systems at national level.

iii. ***Health Technology Assessment (HTA)***

The Directive establishes a voluntary network for cooperation between the bodies and authorities in Member States responsible for HTA. The Directive provides objectives and criteria for the HTA network, whose aim will be to support the exchange of information on relative efficacy; short and long-term effectiveness of health technologies, including on the methodologies for assessment; and to avoid duplication of work.

The Directive states that the HTA network should be based on principles of good governance, including transparency, objectivity, and "appropriate stakeholder consultation" – therefore patient organisations have a role in this process. Moreover, the HTA network can receive aid from the European Union in order to achieve its objectives. Aid can be granted, among other things, to facilitate the consultation of stakeholders on the work of the network.

4. Summary of opportunities for patient organisation involvement

4.1. Areas for patient involvement at EU level

EPF, with consultation of and input from member organisations

Included in the Directive (non-obligatory)

- European HTA network (Article 15): a voluntary network connecting the national authorities or bodies responsible for health technology assessment (HTA), designated by the Member States. The network should apply principles of good governance, including "appropriate consultation of stakeholders".

Opportunities to engage proactively

- Voluntary network connecting national authorities responsible for eHealth designated by the Member State (Article 14). There is no mention of stakeholder involvement; patient organisations at national and EU level should engage with the bodies responsible for eHealth.
- Patient organisations can provide feedback and advice to the Commission in raising awareness of patient communities regarding the possibilities that exist for referral abroad in cases of (suspected) rare diseases (Article 13).
- Linking your website with the Commission's information resources – including the website of DG Health and Consumers, the "Europe for patients" website, "Your Europe" webpage. (see Additional information, below).
- Input on the comprehensibility of the information on prescriptions and the instructions for use of medicines (Article 11(2) – please send any feedback to EPF.
- Input to the Commission's report on the implementation of the Directive from patient organisations' perspective – EPF will collect input through consultations.

4.2. Areas for patient involvement at national level

National patient organisations

Included in the Directive (obligatory)

- National Contact Points (Article 6) must consult patient organisations, but the extent of the topics or the regularity of consultations is not set by the Directive.

Included in the Directive (non-obligatory)

- Member States must give all the available information to the Commission for the Commission report on the implementation of the Directive (Article 20). Patient organisations can make their views available to Member States' authorities as well as to EPF or the Commission.

Opportunities to engage proactively

- Transposition into national laws: patient groups can liaise with the relevant ministries and parliament to make sure that proposed laws on, for example, reimbursement are patient-friendly.
- Patient groups can encourage national governments to set up a system for "direct payments" referred to in Article 9(5).

- Patient groups can advocate for the authorities to reimburse the travel costs and full cost of treatment referred to in Article 7 (4), recital 36, where appropriate and help the authorities to identify cases where this is particularly needed.
- Patient groups can give feedback on the transparent complaints procedures and mechanisms referred to in Article 4(2) and 6(3).

5. Further information on patients' rights in cross-border healthcare

Note: Information will be added to this section as more information becomes available.

Frequently asked questions and further information:

The European Commission's question and answer document on the Directive
DG Health and Consumers – cross-border healthcare
The Health EU Portal
Europe for Patients
Your Europe

Rules currently in application for patient mobility:

European health insurance card
Planned medical treatment

List of national contact points:

Information will be added when available

EPF member organisations with information on cross-border healthcare:

EURORDIS information resources specifically for patients with rare diseases
If your organisation has information specific to your country or disease-area that you would like to add to this list, please send it to EPF!

6. Glossary of key terms

Member State of affiliation: This is the Member State where the person is insured or entitled to sickness benefits.

Member State of treatment: This is the Member State where healthcare is provided to the patients, and in the case of care provided by telemedicine the Member State where the healthcare provider is established.

National Contact Points: Bodies (at least 1 per Member State) who will be responsible for providing information to patients and practical assistance for cross border healthcare (see point 3.1.)

Prior authorisation: It is a system that can be established by the Member State of affiliation in certain limited cases (see point 3.3) whereby the patients has to request an authorisation for the reimbursement of cross border healthcare. The Member State of affiliation can refuse to grant it for justified and limited reasons.

Transposition: The directive sets out general rules and objectives but leave Member States the choice as to how to attain them. This process is carried out by national governments and parliament and may involve local authorities. Member States will provide to the European Commission tables to show the link between the provisions in the directive and national dispositions. They have until October 2013 to adopt the necessary dispositions into their national law.