



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

EPF Recommendations for a patient-centred implementation

Introduction

These recommendations have been developed by the European Patients' Forum and its member organisations representing the interests of patients with chronic diseases throughout the European Union. They aim to provide the authorities and bodies in EU Member States tasked with the transposition and implementation of Directive 2011/24/EU with a set of recommendations to ensure that this Directive, as intended, brings tangible benefits for patients and represents a step forward for high-quality, safe, equitable, patient-centred healthcare throughout the Union.

Patient organisations have a wealth of expertise and experience that can help develop better services for patients and citizens. They are committed to sharing this expertise and contribute both at national and European levels to the successful implementation of the Directive. This document therefore also highlights areas where patient organisations can provide valuable input and support to the national authorities.

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Chapter II – Responsibilities of Member States with regards to cross-border healthcare

This chapter contains provisions on three core priorities for patients: information concerning cross-border healthcare, and provisions for safety and the quality of care.

Article 4: Responsibilities of the Member State of treatment

Article 4 specifies that Member States should take into account the principles of *universality, access to good quality care, equity and solidarity* and to apply the principle of *non-discrimination*. [Art. 4(1) and (3)] Member States should have in place, and apply, clear *quality and safety standards* for healthcare providers on their territory as well as Union legislation on safety standards. [Art. 4(1)b-c]. This information has to be made available to patients. [Art. 4(2)a].

Member States must further ensure that healthcare providers provide the *information* patients need to make an informed choice [Art 4(2)b], and that patients receive from the national contact point (see Article 6) relevant information on standards and guidelines, the status of health professionals, and accessibility of hospitals. [Art. 4(2)a] Member States are further called upon to ensure that prices of healthcare do not discriminate between domestic and non-domestic patients. [Art. 4(3-4)]

There must be *transparent complaints and remedies procedures* in place for patients, and systems for professional liability insurance or equivalent. Patients' *privacy* must be respected, and patients must receive a copy of their medical record. [Art. 4(2)c-f].

Recommendations

1. We recommend that Member States *refer to existing EU instruments and actions*, including the 2009 Council Recommendation on patient safety and quality of care¹ and the Joint Action on Safety and Quality of Care², when implementing this Article.
2. We encourage Member States to *cooperate with each other* and to *involve patient organisations* as well as health professionals in the development/implementation of guidelines and standards. The continued improvement of quality and safety throughout the European Union requires close cooperation between Member States to share experiences and good practices, lessons learnt, research outcomes, quality assurance systems, etc. Patient organisations have a wealth of expertise and can channel the direct patient experience during the “healthcare journey” to pinpoint areas of weakness or system failure, that is a valuable source of information for better health policy.
3. We encourage Member States to *agree on key indicators* at EU level to be able to identify and share good practices to improve quality for the benefit of patients and the sustainability of health systems.

¹ http://ec.europa.eu/health/patient_safety/policy/index_en.htm

² Launched on 24-25 May 2012, <http://ec.europa.eu/eahc/news/news129.html>

4. We strongly recommend that Member States apply the *same safety and quality standards to eHealth* as for conventional healthcare. This is crucial to ensure patient safety and confidence in eHealth tools and services. eHealth and telemedicine can play a crucial supporting role in continuity and safety of care in a cross-border context.
5. We recommend that Member States, together with patient organisations, draw up *guidelines on how to provide quality information to patients* to help ensure they make informed choice on their care, which ultimately benefits the sustainability of healthcare systems. These could refer to eventual guidelines developed at EU level.
6. We recommend that the mechanisms for complaints and redress should be *transparent, simple, effective, swift and easy to understand*, based on good governance principles and with clear information for patients on the procedures, their rights and various alternatives. Such mechanisms or information about them should be linked to the national contact points

Article 5 **Responsibilities of the Member State of affiliation**

Article 5 calls for the Member State of affiliation to ensure that the cost of cross-border healthcare is reimbursed according to the provisions of the Directive [Art. 5(a)] and that appropriate medical follow-up is available [Art. 5(c)] and that patients have a copy of their medical records [Art. 5(d)]. It also specifies that clear information must be available to patients regarding their rights and entitlements, particularly regarding reimbursement and including a system for appeal and redress if patients consider their rights have not been respected. [Art. 5(b)]

Recommendations

1. We recommend that patients should be informed of all their entitlements regarding reimbursement, including where applicable the possibilities to have certain extra costs reimbursed (e.g. those relating to disabilities or travel) or the possibility to benefit from a prior notification procedure in order to *reduce the patients' burden* of having to pay upfront.
2. We recommend that information to patients should include information concerning points (c) and (d).

Article 6 **National contact points for cross-border healthcare**

Article 6 contains provisions of key importance from the patients' perspective. The Directive sets out the right of patients to seek healthcare in another Member State, and provides patients with new choices. In order to make an informed decision concerning all this, patients want high-quality information that is relevant to their needs. All information provided by the healthcare providers and public authorities to patients should be accurate, reliable and patient-centred. This is a patient's fundamental right.

Article 6 provides that national contact points need to consult with patient organisations as well as other stakeholders [Art. 6(1)]. National contact points should cooperate with each other and the Commission [Art. 6(2)], and provide patients with accessible information that helps patients make use of their rights regarding cross-border healthcare. [Art. 6(3-5)]

Recommendations

1. We recommend that patient organisations are proactively informed concerning the establishment of the national contact point(s) and that their views are heard in the designation process. National contact points should engage with patient organisations from the very onset of the process, and continue to do so on a regular basis. Building up a regular partnership will be the key to *ensuring that the information provided meets the real-life needs of patients*, is provided in a format that is user-friendly and accessible, and is disseminated effectively.
2. Patient organisations can also adopt a key role in informing patient communities about the existence and role of national contact points, ensuring effective dissemination of information to the grassroots level. They can thus *complement and contribute to the efficient running of the national contact points*. To this purpose, we recommend that patient groups should be adequately resourced and supported.
3. We recommend that Member States apply the *Core Quality Principles*³ agreed by the High-Level Pharmaceutical Forum (2008) and endorsed by all EU Member States, as a guideline for all information provided to patients. These quality criteria should also be disseminated to healthcare providers.

Chapter III – Reimbursement of costs of cross border healthcare

It is essential that patients who need to access to healthcare, whether it is domestic or cross-border, can do so on an equitable basis – regardless of their social or economic position or ability to pay. Implementation of the provisions of this chapter based on the principles of equity and solidarity is crucial for the alleviation of health inequalities.

Article 7

General principles for reimbursement of costs

Article 7 states that costs incurred in cross-border healthcare by an insured person must be reimbursed if the healthcare is among the “benefits basket” in the Member State of affiliation [Art. 7(1)], with certain derogations pertaining to Regulations 883/2004 and 987/2009 [Art. 7(2)]. The level of reimbursement will be limited to the same level as for healthcare provided “at home”, though Member States are free to decide to reimburse a higher amount or other related costs, if relevant. [Art. 7(4)].

The mechanism for the calculation of costs of cross-border healthcare must be transparent and based on objective, non-discriminatory criteria known in advance. [Art. 7(6)] The administrative formalities or eligibility criteria imposed on patients may as a rule not be

³ Available online at http://ec.europa.eu/pharmaforum/docs/itp_quality_en.pdf

discriminatory or constitute an obstacle to free movement [Art. 7(7)], and reimbursement must not be subject to prior authorisation except in cases set out in Article 8. Any decisions to limit reimbursement on the grounds stated in paragraph 9 of this article must be notified to the Commission.

Recommendations

1. We strongly recommend that Member States adopt the necessary provisions to ensure that patients enjoy the *same rights* when receiving cross-border healthcare as they would enjoy when receiving healthcare at home, as provided for in Art. 7(5).
2. When considering whether the cross-border healthcare is within the benefits to which the person is entitled under the health insurance system [Art. 7(1)], we encourage Member State to focus on the *equivalent benefits of the treatment for the patient*, rather than strictly the same method of treatment. This is in the spirit of Recital 34 and helps ensure the decision is based primarily on medical considerations.
3. We recommend that in cases of (suspected) rare diseases, where the treatment in question is not within the basket of benefits, Member States should use all appropriate tools e.g. Regulation 883/2004, centres of reference and mutual cooperation, to ensure the patient's access to appropriate expert diagnosis and treatment. See also the recommendations under Article 8.
4. We recommend all Member States to offer patients a system of prior notification, and to make use of the possibility to transfer funds directly, as provided in Article 9(5).
5. Furthermore we strongly recommend that Member States *use the opportunity to cover extra costs* beyond the strict reimbursed amount, in particular costs related to disability or travel in certain cases. A transparent, objective list of criteria for coverage of such costs should be drawn up in cooperation with stakeholders including patient organisations.

Article 8

Healthcare that may be subject to prior authorisation

Article 8 provides the exceptional reasons for which Member States may subject cross-border healthcare to prior authorisation [Art. 8(2)], and specifies that such a system must be limited to what is necessary and proportionate and may not constitute a means of discrimination or unjustified obstacle to free movement of patients [Art. 8(1)]. Member States must make publicly available which healthcare is subject to prior authorisation as well as all relevant information on the system of prior authorisation. [Art. 8(7)]

For requests for prior authorisation, it must be checked whether the conditions of Regulation 883 are met and if so, authorisation must be granted under the Regulation unless otherwise requested. [Art. 8(3)] Concerning patients with (suspected) rare diseases, an expert clinical evaluation may be carried out, and Member States may seek scientific advice if experts are not available [Art. 8(4)].

In principle, prior authorisation may not be refused if the patient is entitled to the healthcare in question and that healthcare cannot be provided domestically within a medically justifiable time limit. An objective medical assessment should be carried out taking into

account various factors relating to the patient's condition including the degree of pain and nature of disability [Art. 8(5)]. The limited reasons for refusing prior authorisation are set out [Art. 8(6)].

Recommendations

1. We recommend that comprehensive information concerning any system of prior authorisation, including the criteria, the application of those criteria and the relevant procedures, should be made available to the public through the national contact points.
2. Timely diagnosis and prompt treatment is crucial to avoid complications of diseases and consequently increased healthcare costs, both for patients and the health system. We recommend that Member States consult with patient organisations regarding any prior authorisation systems they plan to put in place, in order to *ensure that such a system does not become an obstacle to equitable access* to healthcare. Please see also recommendations under Article 9.
3. Time is a particular concern in the case of rare diseases, where patients often undergo a number of consultations before being diagnosed correctly.⁴ Therefore, we recommend that a *maximum time limit* should be set for receiving prior authorisation, *after which patients should automatically be granted authorisation*. This should be developed in consultation with expert healthcare professionals and patient organisations.
4. We further recommend that expert scientific advice be requested in every case of (suspected) rare disease. A global lack of expertise is the major reason for patients with rare diseases having to seek cross-border healthcare.

Article 9

Administrative procedures regarding cross-border healthcare

The administrative procedures relating to cross-border healthcare must be based on objective, non-discriminatory criteria which are limited to what is necessary and proportionate [Art. 9(1)]. Information relating to the administrative procedures must be made publicly available [Art. 9(2)] in assessing requests for cross-border healthcare, the patient's individual medical needs must be the deciding factor, and requests must be dealt with within a reasonable time. Such time frames must be made public in advance. [Art. 9(3)]. Decisions must be reasoned and subject to review and capable of being challenged [Art. 9(4)].

Member States may offer a voluntary system of prior notification, which will confirm the amount to be reimbursed to the patient. Member States may also apply to cross-border healthcare the mechanisms of direct financial compensation already existing under Regulation 883. In any case patients should receive reimbursement without undue delay. [Art. 9(5)]

⁴ See for example the results of the EurordisCare surveys: "The voice of 12,000 patients", EURORDIS (2009). Available online at <http://www.eurordis.org/publication/voice-12000-patients>

Recommendations

1. We recommend that Member States work with patient organisations and healthcare professionals to draw up *guidelines on what constitutes a reasonable period of time* in various cases. In any case, a maximum time limit should be set to protect the patient's right of equitable access to healthcare.
2. We encourage all Member States to provide a *system of prior notification*, whereby patients who obtain such notification can be reassured on the amount they will be reimbursed.
3. Upfront payment and having to cover extra costs related to travel etc. can prevent less well-off patients from accessing the healthcare they need, which would be incompatible with the common European principles of universality, equity and solidarity⁵. We strongly recommend that Member States make *use of the possibility to transfer funds directly* between the competent institutions through existing mechanisms, and to cooperate with each other to facilitate direct compensation.
4. We encourage Member States to consult with patient organisations to clarify the implications of upfront payments on patients and their families, and to explore possible options for direct payments.

Chapter IV: Cooperation in healthcare

Chapter IV contains crucial provisions from the patients' perspective. We encourage Member States to take up, and make full use of, the opportunities for further cooperation in the areas of quality and safety, eHealth and health technology assessment. This, we hope, will contribute to on-going progress towards better safety and quality of care for patients across the Union, whether at home or abroad.

Article 10

Mutual assistance and cooperation

Article 10 asks Member States to render mutual assistance and to cooperate with each other in order to implement the Directive, particularly concerning standards and guidelines for quality and safety of healthcare, and the exchange of information between the national contact points [Art. 10(1-2)]. Member States are encouraged to conclude agreements among themselves and to cooperate regarding border regions [Art. 10 (3)]. An important patient safety provision is included, namely that Member States of treatment must ensure that information on the right to practice of health professionals listed in their national or local registers is made available to the authorities of other Member States via the Internal Market Information System. [Art. 10 (4)].

⁵ Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01)

Recommendations

1. The same recommendations apply regarding standards and guidelines on safety and quality as under Article 4.
2. We further recommend that information concerning the right to practice of health professionals should be available to patients and the public through an easily accessible medium, e.g. a web-based platform.

Article 11

Recognition of prescriptions issued in another Member State

Continuity of care is crucial for the safety and quality of cross-border healthcare. Whilst the Directive does not affect national rules concerning prescribing, dispensing or reimbursement, Member States must in principle recognise prescriptions issued in other Member States for medicinal products or medical devices authorised to be marketed on their territory. Restrictions are limited to concerns for the protection of human health or legitimate doubts concerning the authenticity, content or comprehensibility of an individual prescription. The Member State of affiliation must also take all other necessary measures to ensure continuity of treatment. [Art. 11 (1)]

The Commission will adopt measures to ensure the interoperability of ePrescriptions, including a list of key elements to be included in them and measures to facilitate the correct identification of products prescribed and dispensed across borders. The Commission will also adopt measure for better comprehensibility of information to patients concerning prescriptions and instructions for use. [Art. 11 (2)]

Recommendations

1. We recommend that to ensure the safety of patients and the high quality of care, Member States, health professionals' and patients' organisations should cooperate to ensure that information to patients on cross-border prescriptions is clear, patient-centred and easy to understand.

Article 12

European Reference Networks

The provisions in Article 12 are key to establish European-wide cooperation for high-quality care, particularly for rare diseases. Though such networks already exist, the Directive provides them with a legal basis and clear objectives [Art. 12(2)]. The Commission will develop specific criteria that such networks must fulfil, and criteria required from healthcare providers wishing to join such networks [Art. 12 (4)].

Recommendations

1. We recommend that Member States involve patient organisations in the centres of expertise and European Reference Networks, where such organisations exist. This is in accordance with the criteria developed by the European Rare Diseases Task Force⁶. Patient organisations are a source of valuable expertise on the needs of patients, particularly in rare disease areas. They can thus contribute valuable knowledge to the work of centres of excellence, and also ensure that healthcare providers and networks address patients' unmet needs. Further, patient organisations play a key role in the effective dissemination of information to patient communities.

Article 13 Rare diseases

The Commission will continue to support cooperation between Member States at European level on rare diseases, in particular through the Orphanet database, the European reference networks, and the possibilities offered by Regulation 884/2004 for referral of patients to other Member States for diagnosis and treatments which are not available in the Member State of affiliation.

Recommendations

We recommend Member States to cooperate with each other *and with rare disease patient organisations* in order to address the specific problems faced by patients with rare diseases, to ensure equitable access of patients to timely, accurate diagnosis and appropriate treatment and support services.

Article 14 Cooperation on eHealth

Article 14 sets up a voluntary network on eHealth connecting the national authorities designated as being responsible for eHealth in Member States. the objectives of this network will be to cooperate 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 the continuity of care and ensuring access to safe and high-quality healthcare. The network will also draw up guidelines data to be included in patient summaries for sharing between health professionals, and methods for using medical information for public health and research.

⁶ Report "Centres of Reference for rare diseases in Europe – State-of-the-art in 2006 and Recommendations of the Rare Diseases Task Force" (2007), available online at http://www.orpha.net/testor/doc/RDTF_anna/WG/StandardsofCare/reports/RDTFContributiontoEC06FINALVERSION.pdf

Recommendations

1. Effective patient information, shared electronically, is a crucial patient safety support for cross-border care. We recommend that all Member States designate a national body to participate in the European eHealth network.
2. We strongly recommend that to ensure patient safety, the same safety and quality standards should be applied to eHealth services as to non-electronic health services. See also the recommendations under Article 4.
3. Involving end-users will help build confidence in eHealth tools and develop them for the benefit of patients. Patients can also play a key role in identifying what data is needed for safe continuity of care, and provide advice on the uses of medical information for public health and research purposes. We recommend therefore that national bodies involved in eHealth should engage with patient organisations.

Article 15

Cooperation on health technology assessment

Article 15 creates a voluntary network connecting national bodies responsible for HTA, and specifies that the network shall be based on the principles of good governance, including transparency, objectivity, independence of experts, fairness of procedure, and also stakeholder consultation. [Art. 15(1)] The network is given clear objectives [Art. 15(2)] In order to fulfil these objectives the network may be given Union aid [art. 15(3,5)]. The Commission will adopt the necessary measures for its establishment and functioning [Art. 15(4)].

Recommendations

1. We recommend that patients are meaningfully involved in the HTA network both at European and national level. Patients are individual experts who know precisely how a disease impacts on their daily life, and how specific treatments can influence its quality. Involving patients meaningfully in HTA processes allows for a better matching of the medical and social needs of patients and the effectiveness and sustainability needs of healthcare systems.
2. We further recommend that the HTA network encourage the exchange of information and experiences about patient involvement in HTA in different Member States.

Chapter V: Implementing and final provisions

Article 20

Reports

Article 20 specifies that the Commission will report on the operation of the Directive by 25 October 2015 and every three years thereafter. Member States are required to provide all the necessary information to help the European Commission to draw up its reports. The report will focus particularly on patient flows, the financial dimensions of patient mobility,

the implementation of Article 7(9) and Article 8, and the functioning of national contact points and European reference networks.

The Commission will prepare a report specifically on the effects of Article 3(c)(1) and Article 8, by 25 October 2013.

Recommendations

1. Patient organisations are willing to work as constructive partners in monitoring and assessing the situation, by providing their perspectives on how the Directive is implemented, what works well, and suggestions for future improvements. We recommend that Member States seek the views of patient organisations before sending their information to the Commission.