FIT FOR FUTURE Platform Opinion

Topic title	Directive on the application on patient rights in cross-border healthcare
	2021 AWP
	Directive 2011/24/EU *Legal reference*
Date of adoption	10 December 2021
Opinion reference	2021/SBGR3/14
Policy cycle reference	☐ Contribution to (ongoing) legislative process *Commission work programme reference:*
	☑ Contribution to the (ongoing) evaluation process
	Evaluation of the Directive 2011/24/EU on the application on patient rights in cross-border healthcare CWP 2021, Annex II *Title of the ongoing evaluation*
	Ten years after the Directive's adoption, the evaluation assesses how the Directive's objective to facilitate access to safe and high quality cross-border healthcare in another Member State has been met and how the Directive has promoted patient rights and cross-border cooperation between Member States for the benefit of EU citizens. The evaluation looks into the approaches implemented by Member States in practice, how effectively these are working and what areas still act as barriers to patients seeking healthcare across borders. The evaluation examines as well how the Directive interacts with other legislation, in particular, Regulation (EC) No 883/2004 on the coordination of social security systems and in what ways it has provided EU added value in terms of patient rights to cross-border healthcare and patient choice of healthcare services in the EU. The evaluation examines as well whether the objectives of the Directive are still in line with current and future needs of patients in cross-border healthcare. The evaluation covers the time of application of the Directive in EU countries until the end of 2020 and includes the Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in

		another Member State. It covers EU-27 and EEA EFTA states (Norway, Iceland and Liechtenstein). A public consultation took place between 04 May 2021 - 27 July 2021.
	☐	Included in Annex VI of the Task force for subsidiarity and proportionality
		No
	☐	Other
		No
Have your say: Simplify!	*No relevant suggestions on this topic have been received from the public.*	

SUGGESTIONS SUMMARY

Suggestion 1:	**Redesign National Contact Points**
Suggestion 2:	**Tie prior authorisation with direct billing**
Suggestion 3:	**Introduce a common EU cross-border health bill template**
Suggestion 4:	**Create a network of regional "Healthcare abroad" points in all EU border regions**
Suggestion 5:	**Complement the triennial implementation report with a Cross-Border Healthcare Conference for regional authorities**
Suggestion 6:	**Make the use of European electronic health record (EHR) exchange format mandatory for Member States in cross-border healthcare**
Suggestion 7:	**Enable truly cross-border emergency care and transport**
Suggestion 8:	**Improve information on applicable tariffs**

SHORT DESCRIPTION OF THE LEGISLATION ANALYSED

Directive 2011/24 aims to facilitate access to safe and high quality healthcare in another EU country. Under the directive, EU nationals have the right to seek planned healthcare in another EU country. They can also claim reimbursement for treatment from their national health system or health insurance provider. Prescriptions are recognised anywhere in the EU. More than 200 000 patients a year take advantage of the system.

The directive has also triggered European cooperation in healthcare creating the European Reference Networks for rare and low prevalence complex diseases, promoting European e-health initiatives leading to the planned European Health Data Space and fostering health technology assessments within the EU. The COVID-19 pandemic has reinforced the importance of cross-border cooperation in healthcare illustrating also the benefits for health systems when capacities can be made available across borders in the EU.

Not included in this evaluation are the provisions on e-health that is being evaluated separately as part of the preparatory work on the legislative proposal for the creation of a European Health Data Space. Cooperation in health technology assessment is a proposal for a Regulation under negotiation and therefore also outside the scope of this evaluation.

Further sources of information

Have your Say entry page

Legislation framework webpage

Roadmap

Public consultation

Evaluative study on the cross-border healthcare Directive, March 2015

Impact Assessment of the Directive 2008 on patients' rights in cross-border healthcare

Commission Reports 20 and 2018 on the operation of the Directive on patients' rights in cross-border healthcare

Special Eurobarometer 425 "Patients' rights to cross-border health services in the EU"

Studies carried out by the European Commission available on the Europa website

Commission reports on Member States' data on cross-border patient mobility

Preliminary rulings of the Court of Justice of the European Union and citizen complaints

Special Report by the European Court of Auditors

Resolution of the European Parliament on the implementation of the Directive

Outlook Opinion of the Committee of Regions

PROBLEM DESCRIPTION

Existing evidence suggests the following issues:

The Directive came into force in April 2011, however due to its late transposition into national law compliance checks are still on going. By 2015, most EU countries had transposed the Directive's provisions. The evaluation assesses the performance of the Directive in the following areas:

- responsibilities of the Member State of treatment;
- responsibilities of the Member State where the patient is insured (reimbursement of costs for cross-border healthcare and the use of prior authorisation for reimbursement of healthcare costs);
- provision of information to patients by the National Contact Points on Cross-Border Healthcare;
- administrative procedures for cross-border healthcare;
- recognition of prescriptions issued in other Member States;
- mutual assistance and cooperation in healthcare in the border regions;
- development of the European reference networks, and;
- cooperation in rare diseases.

The following core questions are guiding the evaluation:

- to what extent is the Directive relevant for meeting patient needs in cross-border healthcare?
- how effectively and efficiently does the Directive operate in practice?
- what administrative burdens and barriers do patients still face when seeking healthcare in another Member State and reimbursement thereafter?

(Source: Roadmap)

The Fit for Future Platform has acknowledged the issues raised by the legislation concerned as follows:

Regarding: modernisation and future proofing of existing laws, including via digitalisation, the efficient labelling, authorisation and reporting obligations, the simplification of EU legislation:

Unlike Regulation (EC) No 883/2004 and its iconic European Health Insurance Card, the cross-border healthcare directive has not yet made it to the general awareness of Europeans. Rare are those who have heard about it – and even fewer those who have used its mechanisms. In 2019 (the latest available data are from that year) only about 290 000 benefited from care abroad under the directive with just over 7000 patients requiring a prior authorisation (mainly because the treatment required an overnight stay). Most patient mobility – 70% - has been between neighbouring Member States, confirming that proximity is a key factor in seeking care abroad.

The overarching goal of the directive is to ensure that patients are empowered to make informed choices on how and where to receive safe, high-quality and efficient healthcare abroad, while enjoying the same rights and entitlements as they would domestically. Whether this objective has been met ten years after the adoption of the law remains open to question.

It is worth remembering that the first implementation report by the European Commission made clear that progress had been virtually zero and infringement procedures had been launched against almost all Member States. The second report, published three years later, welcomed the improvements made (transposition was deemed complete across all the EU-28) yet hinted at challenges still lying ahead in terms of completeness of measures.

The 2020 CoR outlook opinion and its RegHub consultation report confirm that the complexity and overwhelming requirements for accessing cross-border healthcare make it difficult for patients to use this tool. The experience of over 150 stakeholders involved in the consultation attest to the regions' ingenuity in developing their own cross-border strategies and projects. It depicts their struggles in figuring a way out of impasses and it points out to hurdles that need removing at national and European level in order to fully realise the potential of this unique piece of European law.

This F4F report recognises therefore that:

- the opportunities created by the Directive are not sufficiently well known by the European citizens and their health providers;
- the provisions of the Directive do not provide seamless access to information on care options abroad
- prior authorisation could be transformed from a hurdle to an enabler to care abroad;
- billing remains an obstacle and could be simplified;
- access to information on applicable fees needs improving

The specific issues encountered at local and regional level are:

The Directive explicitly foresees in article 10(3) that "*The Commission shall encourage Member States, particularly neighbouring countries, to conclude agreements among*

themselves. The Commission shall also encourage the Member States to cooperate in cross-border healthcare provision in border regions". Yet, as attested by the Reg Hub report, the regions do not feel sufficiently guided and supported to engage in cross-border healthcare cooperation. In their view, in order to set up and maintain successful cross-border care projects, regional authorities require more:

- information on available EU funding (especially long-term)
- political support
- interoperable systems to transfer medical data
- committed medical staff

More generally, the majority of regions felt the need to improve the flow of information between Brussels and the regions and called for better communication and awareness-raising activities.

SUGGESTIONS

Suggestion 1: Redesign National Contact Points

Description: The awareness of European citizens concerning the NCPs remains very low (the Eurobarometer estimated it at one point to be as low as 10%). Neither the name, nor its function seem anchored in people's mind. There are other "national contact points", such as for the Horizon Europe, and a simple browser search may deliver confusing results. When accessed through the general websites of national health systems, the NCPs are often not distinguishable as a separate entity. There are only a handful of regional Contact Points although 19 out of 27 MS operate decentralised health systems. Despite the "Toolbox" developed by the Commission in 2018 to improve the content of NCP webpages, they remain vague on key issues such as patients' rights, quality of care of reimbursement and are not written in plain language. Their informative value for patients remain very low.

It is therefore recommended to 1) where no specific name has been used to date[1] or the portal is not sufficiently well recognisable[2], to rebrand the NCP into "Healthcare abroad" points or gateways; 2) connect them all through the European Health Data Space and 3) oblige the Member States to provide information in accessible, non-bureaucratic way with easy-to-follow pathways.

Furthermore, it is suggested to explore the impact of the Regulation 2018/1724 and its Single Digital Gateway on the functioning of the NCP/HAPs as of December 2023.

[1] Such as the German "EUpatienten.de";

[2] An example of a well-established and recognisable portal is the Finnish Kela.fi which hosts a sub portal EU-healthcare.fi dedicated to care abroad;

This suggestion might require the change to article 6 of the Directive changing its title from "National contact points for cross-border healthcare" to "Healthcare abroad points" (HAPs) and replacing NCP with HAPs throughout the whole text.

Expected benefits: Increased recognisability of the rebranded NCP; better searchability on browsers; plain language information with intuitive pathways should increase patients ability to access and understand their care options. The improved connectivity of rebranded NCPs should also lead to better mutual learning, cross-fertilisation and increased harmonisation of protocols and methods.

Suggestion 2: Tie prior authorisation with direct billing

Description: The directive makes it mandatory for patients to pay upfront for their product or treatment and be reimbursed back in their country of affiliation. When the treatment is exceedingly expensive or requires an overnight stay, there is usually an additional requirement to obtain what is known as "prior authorisation", i.e. a written promise that the health insurer will indeed cover the cost of treatment (and to what level).

Paying upfront has been recognised as a main barrier to access to care abroad. It is therefore recommended that where the prior authorisation is issued, instead of billing the patient, the health provider abroad should send the bill directly to the health insurer. If the cost of treatment exceeds the reimbursable amount, the patient should only be charged the outstanding difference.

NB this solution is broadly based on the provisions of article 9(5) Under Article 9(5) of the directive, enabling the Member States to apply the mechanisms covering financial compensation between the competent institutions as provided for by Regulation (EC) No 883/2004.

Given the differences in how the national health systems operate the payments and reimbursement processes internally, with regards to the Regulation and to the Directive, it is suggested to set up a dedicated working party, composed of European Commission's services and national expert representing health insurers and Ministries of Health. This group would be tasked with an evaluation of the status quo and elaboration of solutions to overcome this financial and procedural barrier to care abroad.

The group should evaluate the administrative procedures and workflows under both Directive and Regulation and decide whether changes need to be made just in the Directive, across both acts of law or whether a brand new solution needs to designed to better protect the interests of less well-off patients.

This solution should also valorise the experience of those Member States that do not operate a system of prior authorisation.

Ideally, in the end the work of the group should lead to an agreement on a revision of the article 8.

Expected benefits: This compromise solution would bring together experts from the Member States and the Commission to jointly design process and tools to make it possible to all patients, including those with limited means, to access the whole range of treatment options, including those abroad requiring a prior authorisation.. As such, it would increase equity and fairness. It would also streamline the payment modalities for health providers and insurers and make the whole process easier for all sides.

Suggestion 3: Introduce a common EU cross-border health bill template

Description: A large number of stakeholders participating in the CoR RegHub evaluation of the Directive highlighted the difficulty of issuing and receiving bills that do not fit with the models used locally. This results in a lot of back-and-forth, additional requests for information and modification, calls, requests for translation etc. – all hindering access. A standard common bill template would enable the patients to see clearly what are they charged for and would make it quicker to process the payment thanks to proper itemisation and comparable manner of defining cost of interventions.

The European Commission services should set up a working group with the Member States representatives to develop such a template.

Expected benefits: This solution would both save time and enable easier comparison between healthcare service and products.

Suggestion 4: Create a network of regional "Healthcare abroad" points in all EU border regions

Description: The EU has 40 internal land border regions, representing 40% of the Union's territory. These regions, according to DG REGIO, "*generally perform less well economically than other regions within a Member State*"[3] and their populations face difficulties in access to health, social and educational services. The RegHub report recognises that for these regions, healthcare cooperation presents significant advantages from medical, social and economic point of view. Creating regional "Healthcare abroad" points in all of these regions and connecting them under one umbrella is a natural step to build alliances, improve awareness among administrations and healthcare practitioners and enable better access to care.

In order to do so, the article 6, would require an additional subpoint "*Each Member State shall be encouraged to establish in its border regions "Regional Health Abroad Points" and communicate their names and contact details to the Commission. The Commission and the Member States shall make this information publicly available. Member States shall ensure that the regional HAPs consult with patient organisations, healthcare providers and healthcare insurers. The Commission shall establish a network for all regional HAPs*."

[3] New Cohesion Policy - Regional Policy - European Commission (europa.eu)

Expected benefits: a network of regional "Health abroad" points would generate more exchanges between regional authorities on health matter, improve general knowledge and enhance cross-border cooperation in neighbouring regions. This recommendation has been made in the CoR Reg Hub report 2020.

Suggestion 5: Complement the triennial implementation report with a Cross-Border Healthcare Conference for regional authorities

Description: In light of the article 20(1) "*the Commission shall by 25 October 2015 and subsequently every 3 years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council*". The review of the implementation of the Directive must move beyond a technocratic exercise between the Commission and health ministries of Member States. To gain more visibility and political momentum, the process should be made inclusive, participative and open to public[4]. In the RegHub assessment of the Directive, several regions highlighted the value of attending major events on cross-border healthcare (such as the 2018 Conference) and called for more opportunities of the kind to "debate ideas and potential projects" as well as "to inject some dynamism into existing structures and contacts".

It is therefore recommended to amend the article 20 by adding subpoint 4 "*The Commission will organise a Cross-Border Healthcare Cooperation Conference every three years to present the findings of the implementation report to the regional and local authorities*".

Expected benefits: increased visibility of the Directive; tighter scrutiny for the Member States; regular networking opportunities for public authorities and civil society organisations; learning and match-making opportunities for regions.

Suggestion 6: Make the use of European electronic health record (EHR) exchange format mandatory for Member States in cross-border healthcare

Description: In a recent public consultation on digital health, respondents acknowledged the differences between EHRs as one of the main obstacles to exchanging health data and advancing digital health and care in Europe. Currently, most citizens cannot easily access their health data electronically across borders. This administrative and legal obstacle has also been highlighted by some of the hubs.

Better access to health data across borders would improve the quality and continuity of care. It would also lead to reduced healthcare costs, by eradicating e.g. the unnecessary duplication of medical tests and procedure.

It is therefore recommended to amend the articles 3, 4 and 5 as following:

[4] Including e.g. patients' organisations, carers' organisations, health professionals, health insurers and other relevant civil society organisations;

- article 3 – complement with the new subpoint (n) defining electronic health record as "*collections of longitudinal medical records or similar documentation of an individual, in digital form*"

- article 4.2.(f) - in order to ensure continuity of care, patients who have received treatment are entitled to an electronic medical record of such treatment **issued in the European EHR exchange format** , and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

- article 5(d) patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records **issued in the European EHR exchange format**, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Expected benefits: Lower costs, less duplication in testing, comparability of data and ease of transmission and access to medical records.

Suggestion 7: Enable truly cross-border emergency care and transport

Description: the most frequently mentioned reason to consider a new cross-border healthcare project, according to the RegHub consultation, is to develop cooperation in emergency care. A lot of existing - Interreg and others – projects have dealt with this issue to date, with varying degrees of success. National laws, defining the shade of roof alarm siren or the number of decibels it can emit, stand in the way of successful pooling of resources and quicker response time in case of accidents. In addition, the closure of the borders due to COVID-19, further affected the movement of patients and medical professionals.

It is therefore recommended, in line with the Commission's Guidelines on EU Emergency Assistance in Cross-Border to complement the Directive's article 10.3 with an additional point: "*The Member States, particularly neighbouring countries, shall be encouraged to conclude agreements among themselves to allow emergency transport services to have priority within the transport system ("green lane" or "care corridors") and to operate freely on both sides of the border to reduce response time and deliver care and transport to the nearest healthcare facility."*

Expected benefits: Economies of scale, better provision of emergency care, quicker response time and more lives saved.

Suggestion 8: Improve information on applicable tariffs

Description: In general, information on the scale of applicable fees is not readily available. In its report, the Parliament called on the Member States "*to urge healthcare providers and hospitals to supply patients, in advance, with an accurate and up-to-date estimate of the cost of treatment abroad, including medicine, honoraria, overnight stays and supplementary fees*". This lack of comparable information can partly be due to complaints, made by some

Member States during the transposition period, that the existing public tariffs did not represent a comparable price because important elements, for example regarding general taxation (e.g. capital investment costs), were not represented in the public tariff which did not fully recover costs. Member States are therefore allowed to build a comparable cost-based price for the actual cost of the health service (based on objective and non-discriminatory methodology) for any given intervention.

The findings of the RegHub report clearly confirm that a scale of applicable medical fees is not readily available. If it is available, the list is for the most part only shared with public and contractual healthcare providers. It is not easily accessible for patients.

It is therefore recommended to amend the article 4.4 by adding "*Member States shall urge healthcare providers and hospitals to supply patients, in advance, with an accurate and up-to-date estimate of the cost of treatment abroad, including medicine, honoraria, overnight stays and supplementary fees*".

Expected benefits: Increased transparency; ease of access to patients, health professionals and insurers.

ABSTENTIONS

- 2 Member States

DISSENTING VIEWS

A Member State can agree with the idea that the Member States continue to develop the cooperation in the field of sharing health data to help patients get continuous care even in different Member States. It is important to try to find ways for patients to electronically look at and to transfer/print health data. However, it should not be made mandatory to use the European EHR format.

Rationale for dissenting views on the suggestions:

The Member States need to be able to continue developing their own systems and formats. The obligation should be to make sure the format used is compatible with the EHR format to enable international transfers.