Editorial

The Transposition of the Directive on Patients’ Rights in Cross-Care Healthcare in National Law by the Member States: Still a Lot of Effort to Be Made and Questions to Be Answered

After a rather long period of preparation, the European Parliament and the Council adopted Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare. It entered into force on 24 April 2011, and had to be transposed by the Member States by 25 October 2013. With this Special Issue we aim to give an overview of whether and how the cross-border health-care directive has been transposed in a (non-representative) selection of EU Member States.¹

On 25 October 2013, Tonio Borg, the European Commissioner for Health, made a public statement on the entry into force of the Directive on Patients’ Rights in Cross-border Healthcare, stating amongst other things:

Today is an important day for patients across the European Union. As of today, EU law in force enshrines citizens’ right to go to another EU country for treatment and get reimbursed for it. From today, all EU countries should have transposed the Directive on Patients’ Rights in Cross-border Health Care, adopted 30 months ago, into their National law. For patients, this Directive means empowerment: greater choice of healthcare, more information, easier recognition of prescriptions across-borders (…). For patients to benefit from the rights granted by EU law, the law needs to be properly transposed and enforced. The Commission has provided a great

¹ The information is as of 1 December 2013.
deal of support to Member States during the transposition period. Now I urge all Member States to deliver on their obligations and fully transpose this Directive.

The last sentence in Borg’s statement seems to suggest that not all Member States had already transposed the Directive on 25 October 2013. The contributions to this special issue of the European Journal of Health Law confirm this suggestion. Of course, this does not come completely as a surprise. Although legally binding as to its contents, the very fact that transposition into national law is required creates an opportunity for different rules, even if this is not always intentional. Moreover, the Directive on Cross-border Care itself is not free from ambiguity as to the concepts used and the rules it contains. The contributions in this issue contain interesting evidence. It is not my intention to make a summary here. Rather, I would like to draw your attention to several topics regulated in the Directive about which divergent opinions exist in the legal literature and in the Member States and that could in future lead to new jurisprudence of the ECJ. In this regard I refer to the legal status of patient’s rights in Europe, the notion of ‘cross-border healthcare’ and long-term (health) care, the range of the right to information in the frame of national contact points and the way these contact points function, the information that has to be offered by healthcare providers and the choice between healthcare providers.

1 The Status of Patients’ Rights in Europe

1.1 The European Charter on Patients’ Rights
Thirty years ago, on 19 January 1984, the European Parliament approved a Resolution on a European Charter on the Rights of the Patient. In this Resolution, the European Parliament invited the Commission ‘to submit as soon as possible a proposal for a European Charter on the Rights of Patients’. It took more than 20 years to give effect to this resolution. In 2002 the Active


Citizenship Network drafted a European Charter of Patients’ Rights containing 14 patients’ rights. In its Opinion on Patients’ Rights of 26 September 2007 the European Economic and Social Committee of the EU ‘welcomed and acknowledged’ these 14 rights. Whether this indeed means that the Economic and Social Committee has ‘formally’ recognized these rights, is less obvious. More important is that the European Commission itself has stimulated the adoption of the final version of this Charter on 18 April 2008 by the Active Citizenship Network. In doing so, the EU authorities used an innovative method of producing norms not by taking legal action themselves, but by stimulating a citizens’ organization to draft a Charter. Although this Charter is legally not binding it has the merit to clarify what citizens may expect regarding their rights as a patient in all Member States of the EU.

1.2 The Application of Patients’ Rights in Cross-border Healthcare

The Directive refers to ‘the application of patients’ rights in cross-border healthcare’. The title as such raises a lot of questions that have not received a coherent answer in the already abundant literature on the Directive. The reference to (the application) of patients’ rights without any further clarification is not evident at all, given that in European law “patients’ rights” was (and still is) not a clearly defined notion at all. The title of earlier versions of the draft of the Directive did not even refer to patients’ rights as it sounded as follows: ‘Directive on safe, high-quality and efficient cross-border healthcare’. For some

4 OJ EU, 2008 C10/70, 3-1.
5 In that sense, Rial-Sebbag et al., supra note 2, p. 559: ‘cette Charte a été formellement reconnue par le CESE’.
6 In 2007 T. Hervey stated visionary that ‘we may see the development of EU-level norms (probably in the first instance, soft law norms, such as an agreed EU Charter of Patients’ Rights) in this field’; T.K. Hervey, ‘EU law and national health policies: problem or opportunity?’, Health Economics, Policy and Law (2007) 6.
8 Rial-Sebbag, et al., supra note 2, p. 560.
9 Ibid., p. 550: ‘la question des droits des patients n’a jamais été envisagée comme telle, jusqu’à une période très récente, par les institutions européennes’.
commentators the reference to patients’ rights in the title of the Directive is outright erroneous because the Directive does not deal with patients’ rights in their common usage. To them, the Directive does not offer protection to such fundamental rights as patients’ rights are supposed to be.\textsuperscript{11} According to these authors the Directive only recognizes some values and principles but no patients’ rights in the sense they commonly have.\textsuperscript{12} This discussion relates to the meaning attributed to the first sentence of Article 4.1. of the Directive: ‘Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with’, etc. This disposition is clearly based upon the ‘Council conclusions on values and principles common to European Union health systems’.\textsuperscript{13} According to De La Rosa; ‘the Directive surprises the reader with its many references to European values in the area of public health’ and he wonders ‘to what extent do the rights identified by the Directive convey these values?’ For him it is clear that ‘the conversion of values into rights is doubtful.’\textsuperscript{14} Sauter defends another opinion; to him, patients’ rights in the title of the Directive refer: ‘

to a concept that is much broader in scope than the reimbursement of cross-border medical treatment (the “old” patients’ rights that the Court had developed in its case law). This broader concept is primarily linked to the common principles that are framed as obligations of the Member State of treatment (…) . These can in effect easily be rephrased as a set of “new” and potentially highly significant rights to cover all patients, not merely mobile ones. In this way “old” patients’ rights may be generating “new” ones.\textsuperscript{15}

Whereas to some it ‘appears from the Directive’s name (that) it improves the legal position of the patient substantially’,\textsuperscript{16} others consider the use of the

\textsuperscript{11} Rial-Sebbag, et al., supra note 2, p. 558.
\textsuperscript{12} See also R. Baeten, ‘The proposal for a directive on patients’ rights in cross-border healthcare’, in C. Degryse (ed.), \textit{Tenth Annual Report} (Brussels: European Trade Union Institute, Observatoire Social Européen, 2009), p. 177: ‘In this respect the document becomes a political declaration of intent rather than a piece of enforceable legislation’.
\textsuperscript{13} O.J. 2006, C 146/1.
notion “patients’ rights” merely as a trick to mask the real intentions of the Directive, namely organizing the harmonization of healthcare services which failed on the occasion of the General Services Directive.\(^{17}\) I will come back to this issue later on, but it remains a bit astonishing that the notion ‘patients’ rights’ only appears in the title of the Directive and not in the Directive itself.\(^{18}\)

2 Cross-border Healthcare

In addition, the notion ‘cross-border healthcare’ is not free from ambiguity. The General Services Directive does not refer to ‘cross-border services’ but to ‘services in the internal market’. All services delivered within the \(\text{EU}\), whether cross-border or not, can be considered as ‘services in the internal market’ which is a single whole. The Cross-Border Healthcare Directive however makes reference neither to services nor to the internal market. It deliberately avoids the term services and only speaks of healthcare.\(^{19}\) Moreover, it has created a dichotomy between cross-border healthcare that is governed by the Directive and the ‘non- cross-border’ healthcare which does not fall under its scope. Indeed, Article 1.1. stipulates that ‘this Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare (...) in full respect of national competencies in organizing and delivering healthcare’. This dichotomy is especially made visible in that the Directive does not only define healthcare as such (Article 3a) but also ‘cross-border healthcare,’ meaning ‘healthcare provided or prescribed in a Member State other than the Member State of affiliation’ (Article 3, e). However, this attempt to make a distinction between ‘internal’ healthcare and cross-border healthcare is deemed to fail.

\(^{17}\) N. De Grove-Valdeyron, ‘La directive sur les droits des patients en matière de soins de santé transfrontaliers. Véritable statut juridique européen du patient ou simple clarification d’un régime de mobilité?’ \textit{RTD eur.} (2011) 305: ‘trahissant de façon implicite mais certaine un positionnement du texte sur les droits des patients plutôt que sur les principes de libre circulation en raison de l’image clairement négative véhiculée par l’approche des soins sous l’angle de “services”, à connotation libérale’. See also Baeten, \textit{supra} note 12, pp. 157 and 177: ‘the directive suffers from the contradictions between its stated aims — ensuring patient’s rights — on the one hand and its real motivation — the establishment of an internal market for healthcare services — on the other’.

\(^{18}\) With the exception of Article 6,3, be it in a wholly different context.

Very recently Paul Scheffer has written, be it in another context: ‘The use of the term “internal borders” to refer to the national boundaries within Europe involves a choice in itself, of course, because by talking about an internal border I am assuming Europe to be a single whole’. Therefore, the limitation to ‘cross-border healthcare’ in the title of the Directive should not be taken too literally. The definition of ‘patient’ in Article 3h of the Directive does not refer to cross-border healthcare, and this is already considered by some authors as sufficient argument that the Directive not only applies to the so-called mobile or cross-border patients, but also to the so-called domestic or internal patient.

Others consider the second sentence of Article 4.3 of the Directive as an increase of the rights of these domestic patients, as it gives the Member States the ability to protect local needs by not responding to outside demands for treatment, subject to an overriding principle of non-discrimination. In addition, Article 5c of the Directive points in the direction that the Directive does not succeed in limiting its field of application to mobile patients. This provision requires a Member State of affiliation to ensure that when a patient has received cross-border healthcare and a medical follow-up proves necessary, that the same medical follow-up is available as would have been if that healthcare had been provided on its territory. This supposes that such medical follow-up is indeed available to domestic patients. It is interestingly to note that several contributions to this special issue confirm that the application of the Directive is not limited to mobile patients. In Latvia, the Directive ‘will improve realization of patients’ rights domestically and cross-border wise’. In Luxembourg, ‘the Directive has inspired the final draft act on rights and obligations of the patient’.

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3 Services in the Field of Long-term Care

Not all (cross-border) healthcare is covered by the Directive. According to Article 1.3, the Directive is inapplicable to:

(a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;
(b) the allocation of and access to organs for the purpose of organ transplants\(^\text{25}\) and
(c) public vaccination programmes.

The exclusion of services in the field of long-term care has been especially subjected to critical remarks. The preamble (Recital 14) is very vague and short about the reason(s) why the Directive is inapplicable to services in the field of long-term care: ‘This Directive should not apply to services where the primary purpose is to support people in need of assistance in carrying out routine, everyday tasks’. Formulated like that, the exclusion of long-term care seems to regard (rightly in my opinion) social care and support, which are not part of healthcare. However, the recital continues as follows:

More specifically, this Directive should not apply to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined a life as possible. Thus, this Directive should not apply, for example, to long-term care services provided by home care services, in assisted living facilities and in residential homes or housing (“nursing homes”).

What is meant as a clarification of the first sentence of this recital, in fact creates confusion. Not only social care and support but also care of a mixed nature (healthcare and social care) seems to be excluded if it is long-term care. However, with growing numbers of chronically ill patients often suffering from more than one disease, it may be difficult to draw the line between social and health care. Moreover, some argue that the Directive is biased against chronically ill patients and the long-term sick that need longer and perhaps more complex forms of long-term social and healthcare and social security

support. In that respect, the Directive can be seen as discriminatory.\textsuperscript{26} It is to be expected that it may lead to new jurisprudence of the ECJ.\textsuperscript{27} According to another author, the Directive is in line with ECJ jurisprudence.\textsuperscript{28}

4 National Contact Points

Although De La Rosa is sceptical that the Directive contains individual rights of patients (\textit{supra}, Section 1), he nevertheless agrees that ‘the Directive has a clear focus on the patient's right to information’.\textsuperscript{29} It is not exaggerated to state that appropriate information is the basic requirement to enable patients to exercise their (other) rights on cross-border healthcare in practice (see Recital 48). An important mechanism for providing information to patients is to establish one or more national contact points within each Member State.

Article 6.1 of the Directive obliges each Member State to designate one or more national contact point for cross-border healthcare and communicate their names and contact details to the Commission. The Commission and the Member States have to make this information publicly available. Member States also have to ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers.

According to Article 6.3 the national contact points of the Member States of affiliation have to provide patients information concerning healthcare providers in order to enable them to make use of their rights in relation to cross-border healthcare. The national contact points in the Member States of treatment also play a very important role in this regard according to Article 4.2. of the Directive (\textit{infra}). It is beyond doubt that these national contact points form an indispensible link in the chain of delivering cross-border care.\textsuperscript{30} De La Rosa

\textsuperscript{26} Szyszczak, \textit{supra} note 22, p. 111; in the same sense, P. Quinn and P. De Hert, ‘The European patients’ rights directive: a clarification and codification of individual rights relating to cross border healthcare and novel initiatives aimed at improving pan-European healthcare co-operation’, \textit{Medical Law International} 12(1) (2012) 19: ‘The exclusion of assisted living from the directive has given ammunition to those critics who claim that the directive is biased against those suffering from chronic diseases’.


\textsuperscript{28} De la Rosa, \textit{supra} note 14, at note 23.

\textsuperscript{29} \textit{Ibid.}, p. 36.

\textsuperscript{30} Fr. Pennings, ‘The draft patient mobility directive and the coordination regulations of social security’ in J.W. van de Gronden et al. (eds.), \textit{Health Care and EU Law}, (The Hague: Asser Press, 2011), p. 158, who states that these national contact points ‘may help patients to
rightly points to the fact that the Directive is vague about the way these contact points should actually work. He suggests that more detailed provisions might have been viewed as an infringement of the competence of the Member States. Other academics have minimalized the role of the national contact points. For instance, Delnoij and Sauter state that ‘the national contact points provide primarily procedural information concerning the right to reimbursement’. The Directive obliges the Commission and the Member States to make information on the national contact points public. According to the information made public by the Commission, at least 9 Member States had not even established a national contact point at all by 25 October 2013. Other Member States have reduced the national contact point to nothing more than an e-mail address where interested patients can ask for information. In the remaining Member States the national contact points have a website, but most of the times it only contains minimal information. Only the German and the Irish national contact points already offered detailed information, both for their own citizens and for persons intending to seek healthcare in these countries, on 25 October 2013. This very disappointing picture is more or less confirmed in several contributions in this special issue.

The authors of the contribution on the transposition of the Directive in the Netherlands rightly point to the fact that the Directive is not even particularly clear about the language in which the information should be provided by the national contact point: there is no obligation upon Member States to deliver information in languages other than the official languages of the Member States concerned (Article 4.5 and Recital 48). Only a limited number of Member States have made information available in English, but as already mentioned, most of the time the information offered is minimal. Article 4.5 only applies to information referred to in Article 4, which means information to be given by the national contact points of the Member States of treatment.

But one should not lose sight of Article 6.5 of the Directive that stipulates that the information referred to in Article 6 ‘shall be easily accessible’. Article 6.3 enumerates the information that the national contact points of the Member States of treatment have to provide to patients to enable them to make use of their rights in relation to cross-border care. This information has

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to be given to these patients upon their request. According to De La Rosa, this regards ‘collective information’, but in light of the requirement that the information had to be given at the request of a particular patient, this can be disputed.\(^3^3\) The contents of this information includes a specific provider’s right to practice, or any restriction on its practice, as well as information on patient’s rights, complaint procedures and mechanisms for seeking remedies, according to the legislation of that Member State, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare. But it is not limited to this information, as Article 6.3 also refers to the information referred to in Article 4.2(a). This provision requires the Member State of treatment, through its national contact point to provide, again upon request of the patient, ‘relevant information’ on the standards and guidelines on quality and safety laid down in that Member State, 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. Thus, the requirement that the information has to be made available in ‘an easy accessible way’ is not limited to information referred to in Article 6.3, but also that stated in Article 4.2(a). One may wonder whether information in a language that one cannot understand is not by definition difficult, or even impossible to access? If we agree on this, this information (also) has to be offered in the language that is understood by a growing number of people in the European Union; namely, English.

5 Information by Healthcare Providers

Member States of treatment not only have an obligation to ensure that patients receive relevant information from the national contact persons. They also have to ensure that healthcare providers offer “relevant”\(^3^4\) information to help idi-

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34 The proposal of the Directive required even ‘all relevant information’; Sauter, Harmonisation, supra note 15, p. 20.
individual patients to make an informed choice (Article 4.2b). This article contains a not limitative enumeration of such information:

- on treatment options; on the availability, quality and safety of the healthcare they provide; that they provide clear invoices and clear information on prices as well as on their authorization or registration status, their insurance cover and other means of personal or collective protection with regard to professional liability.

Delnoij and Sauter have rightly pointed out that this provision raises a lot of questions. For example, what is “relevant” information and who decides this? Will information about quality, safety and availability be made available in a format that will make it comparable between Member States? There is nothing in the Directive that suggests this, but if that view is taken, a number of issues remain unresolved, such as: what kind of standards would be needed to make information enabling choice comparable, and who would set such standards? Could there be competing standards allowing some degree of comparison either nationally or between (sets of) Member States. The Directive provides no mechanism for this. According to Van der Meij the Directive will not have much added value in this respect given the fact that factual information to enable patient choice is often hardly available at national level.

This point of view is confirmed by several contributions in this special issue. According to Schwebag, ‘it has yet to be seen how the different healthcare providers will implement this provision’. In Latvia, ‘information available on the internet sites of healthcare providers is quite general’. In Finland ‘especially the public health providers do not generally have transparent quality information or information on prices of services (. . .) Currently many healthcare providers could not easily answer to the question what is the actual cost of the treatment provided to the patient’.

36 Delnoij and Sauter, supra note 30, p. 271.
38 Schwebag, supra note 24.
39 Olsena, supra note 23.
The obligation to inform patients imposed by Article 4.2(b) is further complicated by the second sentence of this article that states:

To the extent that healthcare providers already provide patients residing in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States.

This provision can be considered as a limitation of the contents of the information that has to be provided to patients on the basis of the first sentence of this article.41

It is important to note that the Directive imposes an obligation upon the Member States, and not on healthcare providers. Only on the basis of relevant national law can a healthcare provider that does not offer such information be held liable.42

6 Choice of Healthcare Providers

In the debate in the Council on the proposal for a Directive, the choice of the providers to be covered by the Directive was the major outstanding issue until the very last moment. Many Member States preferred to exclude healthcare providers who have not been contracted by national health insurers from the scope of the Directive, because treatment of such providers is not reimbursed at national level. Reimbursing cross-border treatment by non-contractual providers would lead to ‘reverse discrimination’.43

Under the Spanish Presidency, in the first half of 2010 a compromise was reached on a provision allowing the refusal to grant prior authorization for care that

is to be provided by a healthcare provider that raises serious and specific concerns relating to respect of standards and guidelines on quality and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through

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41 In this sense, Van der Meij, supra note 37, p. 390; and Delnoij and Sauter, supra note 31, p. 271.
accreditations systems established by the Member State of treatment (Article 8.6 c).

These ‘accreditations systems’ seem to be the relic of the contracting system. Baeten and Palm however, doubt whether through this quality and safety exception, cross-border healthcare delivered by private or non-contracted providers in the Member State of treatment could be systematically submitted to prior authorization. The evidence in several contributions in this issue indicates that they are right. Ironically enough, as a consequence of the Directive, a Spanish patient may be reimbursed for an intervention carried out in a private hospital or medical centre in another EU Member State, but may not be reimbursed if the intervention is carried out in a private centre in Spain.44

According to Kattelus, implementation of the Directive has proved quite challenging in Finland mainly due to three reasons. One of them is the quite unique healthcare system there. On the one hand, there is a public healthcare system run by approximately 330 municipalities and financed by taxes, state subsidies and patients’ contributions. On the other hand, there are private services whose costs are only partially (20 to 60 per cent of the total) reimbursed by private medical insurance to the patient. This is partly state-financed in addition to the contributions of employers and employees. From the patient’s point of view, the public system is significantly less expensive than the private one. Due to a political compromise in the proposed law on cross-border healthcare, the reimbursement for the costs of treatment in another Member State will be granted by the (private) medical insurance. Finnish patients making use of cross-border healthcare will thus receive the same reimbursement as when using private healthcare services in Finland. In other words, the Finnish patient will not be in an equivalent situation when using public healthcare services in Finland or in another Member State. Kattellus rightly wonders whether this solution is in accordance with EU rules which has to be tested in the years to come.45

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Conclusions

The Directive on Cross-border Healthcare is one of the most important legislative achievements in European health law, in both a practical and an academic sense. By clarifying the rights of patients who make use of cross-border healthcare, the Directive will in the longer run lead to a more harmonized way of delivering healthcare, of interpreting and applying rights of patients in the European Union. Moreover it is an invaluable stimulus for comparative research in the field of European health law. We hope that through this special issue, the Journal contributes to such kind of research, and that it may form the basis for yet more contributions in this field. We also suggest that the European Association for Health Law creates an interest-group on patient rights in cross-border care that would serve as a forum for research and discussion.

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