Summary: The European Parliament and the Council of the European Union have adopted, on 09 March 2011, Directive on the application of patients’ rights in cross-border healthcare. This Directive has emerged as a result of the European Court of Justice jurisprudence on social security coverage of health care obtained outside the Member State of patient’s social security protection, starting with the well known judgement in Raymond Kohll v. Union des caisses de maladie. The focus of the Court has been on developing a set of patients’ entitlements in cross-border health care, emphasising the individual needs and circumstances of patients seeking health care abroad.

The aim of the paper is to investigate the Directive and determine whether it will add (once transposed into the national legal systems) to the current set of patient entitlements and make it easier for those patients to obtain socially covered health care outside the state of social protection, and to discuss the Directive’s application in Croatia, once the country joins the EU.

The paper first briefly describes the most important principles that have evolved through the Court of Justice case-law, concerning both the application of freedoms guaranteed by EU primary law (namely, freedom to provide and receive cross-border health care services) and the secondary legislation on co-ordination of social security systems within the Union. This is followed by a detailed analysis of the Patient Mobility Directive, namely focusing on the issue whether the Directive actually contributes to patient mobility in the EU, as well as on its relationship with national social security legislation, especially the Croatian one (since Croatia is to become a Member State a few months before the end of the transposition period). Emphasis is placed on the interaction between the social aspects of national legal framework and the internal market as the cornerstone of the European integration.
In the end, the paper submits that the Patient Mobility Directive’s impact on actual movement of patients across borders might prove to be, to large extent, counterproductive. Furthermore, the paper stresses the necessity of clarifying the EU legal framework and the need for closer cooperation and dialogue between the EU and the Member States’ relevant authorities, taking into account specificities of individual Member States.
I. Introduction

A body of case-law has been established in the recent years by the European Court of Justice, concerning freedom to receive health care treatments outside one’s state of social protection (the competent state), based on the internal market free movement rules of the Treaty on the Functioning of the European Union (hereinafter: TFEU). The crucial issue this case-law touches upon is whether those health care treatments should be paid for by the state of protection, and under what conditions. The approach by the Court has placed its emphasis on giving patients additional possibilities of cover, when compared to the already existing regulations on co-ordination of social security systems that have regulated the field for decades. These judgements have, also, created some ambiguities concerning different aspects of the described cross-border health care, with several problems hampering patients’ free movement.

The case-law and its casuistic approach created a necessity for developing a coherent legal instrument which will clarify patients’ rights when accessing health care abroad. As a result of this necessity, the Directive on the application of patients’ rights in cross-border healthcare (hereinafter: Patient Mobility Directive) has entered into force on 24 April 2011. The Directive’s purpose has been to codify the case-law. In addition to that, this piece of secondary EU legislation also regulates certain aspects of cross-border health care not defined by the case-law. The described development is significant from the Croatian perspective, because of its coming accession to the Union, and the need to adapt its legal framework to the EU rules.

The aim of the paper is to investigate the Patient Mobility Directive, from the viewpoint of the patient and his/her rights, and to determine whether these rights have been strengthened or weakened (or neither) by the new Directive, when compared to the co-ordination regulations and the case-law applying the Treaty, and how the Directive will influence Croatian regulation of health care obtained abroad, once the county joins the Union. For the purpose of this article, the notion of ‘health care’ is defined as including all the activities aimed at restoring and maintaining health in the best possible way, soothing the pain and making one’s health disorder more bearable by any other means.

The beginning of the paper contains the description of the EU social security co-ordination rules and the case-law, which represent the starting point on the analysis. This is followed by the section on the Patient Mobility Directive, covering its various aspects and their effects on the patients’ possibilities to access health care across Member States’ borders. Next, the Croatian legal framework is described. Then, a general assessment of the Directive and its relationship with the relevant European and Croatian rules is provided. Finally, the Directive’s impact in the overall context of cross-border health care within the Union is analysed.

II. Where do we start from?

1. Co-ordination of national social security systems

Possibilities for persons to access socially covered health care outside their state of social protection have been regulated on the European level since the beginning of the integration, by way of regulations. These regulations have been developed in order to facilitate free movement of persons within the EU. For free movement across national borders to be conducted, it is imperative to resolve situations where, due to differing national rules on determining their social security system’s scope of application, migrants may lose their social security entitlements. The loss occurs, for instance, when persons reside in a Member State which defines its social security system’s scope of application by referring to the place of person’s work. When a person falls under the social security systems of several countries at the same time we speak of positive conflicts of laws, while negative conflict of laws means that a person does not fall under any system at all.

Of course, if one’s social security entitlements are lost due to him/her crossing the border, that person will have a strong disincentive for exercising his/her free movement rights guaranteed by the Treaties. Therefore, co-ordination regulations have been established to replace the bilateral agreements between the Member States and to provide for a coherent system of protection of migrants’ social security entitlements. For these reasons, co-ordination may be defined as follows:

Co-ordination rules are rules intended to adjust social security schemes in relation to each other (as well as to those of other international regulations), for the purpose of regulating transnational questions, with the objective of protecting the social security

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position of migrant workers, the members of their families and similar groups of persons.\(^4\)

It is important to distinguish between co-ordination and harmonisation. Under co-ordination, there is no adjustment of national rules which do not deal specifically with migrants, while harmonisation involves changes of national rules applicable to all persons covered by those rules. This means, for instance, that each Member State is free to define its own package of socially covered health care (the range of health care services) that it covers. There is no harmonised European basket of covered health care.\(^5\)

As noted, the co-ordination system aims at facilitating free movement of persons within the EU. For this reason, there is an explicit legal basis in the TFEU, which enables the Union to adopt co-ordination measures concerning free movement of economically active persons and their dependants.\(^6\) There is also TFEU art 21(3), dealing with EU citizenship, which enables the EU to adopt co-ordination measures regarding economically non-active persons.

The underlining idea of the co-ordination is that Member States retain the autonomy to define their social security systems and can prevent the EU from significantly interfering with their national framework. This is visible in the fact that TFEU art 21(3) requires unanimity in the Council, in order for social security measures to be adopted (with consulting the Parliament). TFEU art 48 requires ordinary legislative procedure (including qualified majority voting in the Council and co-decision with the Parliament), but with one significant restriction. When a draft legislative act would affect important aspects of one Member State’s social security system, that Member State can block decision-making in the Council and refer the proposed act to the European Council, which then decides by way of unanimity.\(^7\) Therefore, the unanimity requirement is still present,\(^8\) and the possibility of blocking the procedure is called “emergency brake”.\(^9\) In a Union which consists of 27 Member States (soon to be 28) it is extremely hard to find a consensus, much harder than it was at the beginning of the integration process, with only six Member States within the communities. This makes adoption of new co-ordination rules, or amendments to the existing ones, a cumbersome endeavour.

Co-ordination regulations deal with three different situations in which persons obtain health care (the relevant notion of ‘sickness benefits in kind’ means those benefits which are intended to supply, make available, pay directly or reimburse the cost of medical care and ancillary services, which includes, also, long-term care) in a state which is not the state of their social protection. The first situation is when a person resides outside the Member State

\(^4\) Pennings (n 3) 6.
\(^5\) Pennings (n 3) 6-7; See, also, Case 238/82 Duphar BV and others v The Netherlands State [1984] ECR 523.
\(^6\) EEC Treaty art 51 (equivalent to former EC Treaty art 42 and today’s TFEU art 48) was used as a legal basis to adopt Regulation 1408/71 and subsequently Regulation 883/2004 (n 2). EEC Treaty art 7 (equivalent to former EC Treaty art 12 and today’s TFEU art 18) prohibiting discrimination on the basis of nationality was used for the adoption of Regulation 1408/71 (n 2). EEC Treaty art 235 (equivalent to former EC Treaty art 308 and today’s TFEU art 352) was used both for amending Regulation 1408/71 (n 2) and adopting Regulation 883/2004 (n 2), regarding economically non-active persons. EC Treaty art 63(4) (today’s TFEU art 79(2)) was used to extend the scope of application of Regulation 1408/71 (n 2) to third-country nationals.
\(^7\) Treaty on European Union art 15(4).
\(^8\) On ordinary legislative procedure see TFEU art 294.
in which that person is socially protected and obtains health care in the state of residence. These can be cases when the person in question is working in the state of social protection (competent state) and resides in another Member State, or when he/she is receiving pension from one or more Member States, and resides in a Member State which does not pay any part of the pension. In these cases, the competent Member State covers health care on basis of tariffs of the state of residence (also for covered person’s family members). Legislation of the state of residence also determines the range of health care the patient is entitled to. The patient can only access those providers who are attached (employed or contracted by) to the state of residence’s social security system and he/she only pays directly to the health care provider if the legislation in the state of residence requires that (the two states’ social security institutions settle the rest of the payment). \(^{10}\) Since this situation is not the focal point of the case-law and the Patient Mobility Directive, it will not be described in detail.

The second situation of cross-border health care concerns persons who are temporarily outside the competent state and a need arises for them to obtain health care in the state of temporary stay (for instance, when a tourist brakes a leg or suffers appendicitis while on holiday – unplanned health care). In this case, the covered person (and his/her family members) is entitled to health care which becomes necessary, taking into consideration the nature of the health care benefits in question and the expected length of stay, in the state of stay (by presenting European Health Insurance Card, or EHIC). This includes benefits with an aim of ‘preventing an insured person from being forced to return before the end of the planned duration of stay to the competent State to obtain the treatment he/she requires. The purpose of benefits of this type is to enable the insured person to continue his/her stay under safe medical conditions, taking account of the planned length of the stay.’ \(^{11}\)

Competent state pays for health care on basis of tariffs of the state of stay (state of treatment) and the patient can only access those providers who are attached (employed or contracted by) to the social security system in the state of treatment. The patient only pays directly to the health care provider if the legislation of the state of treatment demands that. If a pensioner (also his/her family members) receiving pension from the competent state receives health care in that state, he/she is entitled to full coverage by the competent state if that state

\(^{10}\) Regulation 883/2004 (n 2) art 1(va), 17, 23-24; In general, co-ordination regulations use *lex loci laboris*, or the law of the place of work, as the main criterion for determining the competent state, with exceptions and special rules). See to that effect Regulation 883/2004 (n 2) art 11-16; On long-term care, see Case C-160/96 *Manfred Molenaar, Barbara Fath-Molenaar v Allgemeine Ortskrankenkasse Baden Württemberg* [1998] ECR I-843.

opted for the possibility and is listed in Annex IV of the co-ordination Regulation 883/2004. Insured persons (also their family members) who are not pensioners and reside outside the competent state, generally, have a right to health care in the competent state while staying there.\textsuperscript{12}

The third relevant situation concerns cases in which a person travels outside the competent state for a specific purpose of obtaining health care in the other Member State (planned health care). In order to do the latter, and be covered by the competent state, the patient must obtain authorisation from the competent state (these rules also apply to covered person’s family members). The authorisation must be given when the treatment in question is covered by the state of residence’s legislation, and health care cannot be provided in that state within a medically justifiable time-limit, taking into account the person’s current state of health and probable course of his/her illness.\textsuperscript{13} If a pensioner (applicable also to family members) has residence in a state which is not the competent state, and the state of residence receives reimbursement for that person’s health care on basis of fixed amounts from the competent state, the state of residence covers planned health care obtained outside its territory. In case a person’s state of residence and the competent state are different states, the state of residence’s rules are relevant to define the range of covered health care.\textsuperscript{14}

Health care is provided on basis of tariffs of the state of treatment and the patient can only access those providers who are attached (employed or contracted by) to the social security system on the state of treatment. The patient only pays directly to the health care provider if the state of treatment’s legislation demands that, while the rest of the coverage is settled between the state of treatment’s and the competent state’s social security institutions. Travel and costs of stay which are inseparable from the treatment itself must be paid for by the competent state if they are covered for treatments obtained within the competent state (for the patient and, if necessary, for the accompanying person).\textsuperscript{15} How the notion of ‘inseparable’ stay is to be interpreted and whether it includes accommodation other than in the hospital itself, remains dubious.

With respect to planned health care, the Court of Justice has had an important role in strengthening patients’ social security entitlements related to cross-border health care within the context of social security co-ordination. First, it developed a rule whereby a patient is entitled to more effective health care outside the competent state.\textsuperscript{16} This jurisprudence resulted in amendments to the co-ordination regulations, whereby the rule that only benefits generally covered by the state of residence are part of the patient’s entitlement when accessing health care abroad was inserted. This means that, if the state of residence’s rules exclude aesthetic surgery from the cover, the patient cannot obtain aesthetic surgery in another Member State, unless he/she goes to a foreign provider via a private arrangement, and pays the whole cost by him/herself.\textsuperscript{17}

\textsuperscript{12} Regulation 883/2004 (n 2) art 18(1), 19, 27(1-2).
\textsuperscript{13} Regulation 883/2004 (n 2) art 20, 27(3).
\textsuperscript{14} Regulation 883/2004 (n 2) art 20, 27(3-5) and Regulation 987/2009 (n 2) art 26(2).
\textsuperscript{15} Regulation 883/2004 (n 2) art 20, 27; See, also, Regulation 987/2009 (n 2) art 26(8).
\textsuperscript{17} See Council Regulation (EEC) 2793/81 of 17 September 1981 amending Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community,
What happens if national legislation does not use explicit rules to include (‘white lists’) or exclude (‘black lists’) or exclude certain concrete treatments from the range of health care it socially covers, but uses wider notions to define the coverage, like ‘treatments for cancer’? In those cases, the competent state is under a duty to cover the most effective treatment available anywhere in the EU which falls into the definition, even if the treatment in question is not provided by the competent state’s health care providers.

Another important evolution of patients’ entitlements under social security co-ordination concerns the question of applicable tariffs and the level of reimbursement. According to the Court of Justice, when the competent state unlawfully refuses to give prior authorisation, and the level of social security coverage is lower in the state of treatment than in the competent state, the competent state must reimburse the difference to the patient, but not above the level of the actual treatment cost (on basis of TFEU provision on free movement of services). This case-law has been codified, in the meantime, by the EU legislator, within the co-ordination setting (entitling the patient to request the higher coverage). However, it remains unclear whether the right to additional reimbursement applies only in cases where prior authorisation was unlawfully refused, or every time when a patient paid some of the costs of health care treatment abroad.

Finally, according to the Court’s case-law, there are instances where prior authorisation cannot be required by the competent state. These are situations where, due to the urgency of a treatment, patient cannot wait for the decision on his/her authorisation application.

2. Application of free movement Treaty provisions

Second element of EU legal framework, concerning patients accessing socially covered health care in a Member State which is not the state of social protection, has been developed by the Court of Justice, since 1998, by directly applying the Treaty free movement provisions (mostly free provision of services). The mentioned case-law has been analysed in the


21 See Regulation 987/2009 (n 2) art 26(7).

22 See Elchinov (n 20) paras 43-51; See, also, Commission v France C-512/08 (n 20) para 27.

Applicability of Treaty rules concerning free provision of services (these also cover recipients’ freedom to travel abroad to receive services) to health care is not a novelty in the Court’s jurisprudence. A real breakthrough the relatively recent case-law brought is the fact that, according to the Court, free movement provisions are applicable to social security cover of treatments obtained outside the Member State of patient’s social protection, when a person goes abroad with an aim of obtaining treatment there (planned health care). The Treaty rules concerning free provision of services are applicable in these situations because of the patient paying upfront to the health care provider who provided the treatment abroad. When a patient pays directly to the health care provider outside the state of protection (competent state) the actual treatment cost, that payment represents remuneration for the health treatment received. Since existence of remuneration is a prerequisite for the applicability of free provision of


services Treaty rules, the latter rules are applicable to cases of planned cross-border health care.26

Therefore, organisation of social security health care system of the competent state is not crucial for the applicability of internal market rules, and Treaty provisions are applicable even if health care is provided free of charge in the competent state, as is generally the case, for instance, with the English National Health Service.27 It is strange that rules on free provision of services also apply to unplanned hospital health care which is obtained when a person is temporarily abroad, even though this health care is received by way of presenting one’s EHIC. EHIC entitles the patient to treatment under the same conditions as persons socially insured in the state of treatment and, if state of treatment’s rules provide for a symbolic co-payment or no payment at all, there is no transaction that would represent the real value of the treatment.28 Free provision of services Treaty rules are, however, not applicable to long-term care obtained while having residence in a Member State which is not the competent state, due to the permanent nature of residence on one side, and temporary nature of service provision on the other. There is no reason why the described reasoning concerning residence should not be applicable to health care other than long-term care.29

Under the internal market rules, Member States still retain the right to define the package of health care they cover, by themselves. This means that the competent state must only cover foreign health care treatments (the ‘depth’ of coverage30) which are provided by its national legislation. However, when defining the social security health care package, there must be no discrimination of foreign treatments/providers. When notions like ‘normal health care’ are used to define domestic coverage, those notions must be interpreted in a non-discriminatory manner, and be based on international medical standards and international medical science.31

Within the free movement setting, prior authorisation requirement is considered to be an obstacle to free movement, but it can be justified in certain situations. These situations include non-urgent hospital treatments and treatments involving major medical equipment, where prior authorisation is justified on grounds of preserving social security system’s financial balance, maintaining balanced medical and hospital service open to all, and maintaining a treatment facility or a medical service on national territory essential for public health or

\footnotesize{26 Watts (n 23) para 90. Although, as a possible basis for a wider interpretation of free provision of services rules and their applicability, see Geraets-Smits (n 23) para 58 and Commission v Portugal (n 23) para 50.
27 See National Health Service Act 2006, last amended by the Charities Act 2011 (hereinafter: NHS Act 2006); Social health care systems are usually divided into two main types. National health services cover all the inhabitants, are, generally, funded via taxation, with provider and the payer being a single entity. Social health insurance, generally, covers persons who are economically active, is mainly financed via contributions, with the provider and the insurer being separate entities. Insurance systems can be divided into reimbursement systems, in which the patient pays directly to the provider, subsequently being reimbursed by the insurer, and the benefits-in-kind systems, in which the insurer, not the patient, pays directly to the provider. The latter system is, also, named ‘third party payment system’. See to that effect Danny Pieters, Social Security: An Introduction to the Basic Principles (2nd edn Kluwer Law International, Alphen aan den Rijn 2006) 21-22, 89.
28 See Commission v Spain (n 23) para 50; See, also, on supply and demand-side subsidies and their relevance for the applicability of internal market rules, Gareth Davies, ‘Competition, Free Movement, and Consumers of Public Services’ (2006) 17 European Business Law Review 95, 98-100.
31 Geraets-Smits (n 23) paras 92-94.}
survival of the population. These justifications are based both on explicit justifications provided by the Treaty (public health), and the rule of reason.\textsuperscript{32}

In cases where prior authorisation requirement is allowed, the competent state does not have a free hand to refuse coverage. Prior authorisation can only be refused if the same or equally effective health treatment can be provided by domestic providers without undue delay. When deciding, individual patient's circumstances, like ‘clinical needs of the person concerned in the light of his medical condition and the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability’ must be taken into account by the competent state, as well as whether the degree of pain and the nature of the disability might make it impossible or extremely difficult for the person to carry out a professional activity. The prior authorisation provisions of co-ordination rules should be interpreted in the same way.\textsuperscript{33} Furthermore, the prior authorisation procedure must be organised along the following lines:

Thus, in order for a prior administrative authorisation scheme to be justified even though it derogates from a fundamental freedom of that kind, it must be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily ... Such a prior administrative authorisation scheme must likewise be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings.\textsuperscript{34}

On basis of free provision of services, health care must be paid for by the competent state on basis of the tariffs it applies for equivalent domestic treatments, unlike under the co-ordination rules where the tariffs defined by the state of treatment are applicable. In this way, financial stability of national social security systems is protected, according to the Court. In case the competent state provides for higher coverage than the state of treatment (for example, the state of treatment provides for a patient co-payment in the amount of 20% of the treatment cost, while the treatment is free of charge in the competent state), the patient is covered for the difference between those two amounts, to the level of the effective treatment cost. The entitlement to more favourable competent state coverage in cases when the patient paid for all or part of the treatment costs by him/herself has, also, become part of the EU co-ordination framework.\textsuperscript{35}

Coverage is conducted by way of patient paying upfront for the treatment, and subsequently claiming reimbursement from the competent state, unlike under the co-ordination rules where patient has to pay only in cases in which the state of treatment’s legislation demands that and the rest is settled between the national social security

\textsuperscript{32} Kohl (n 23) paras 41, 50-51 and EC Treaty art 56 (after amendment EC Treaty art 46 and today’s TFEU art 52) and EC Treaty art 66 (after amendment EC Treaty art 55 and today’s TFEU art 62) for services; See, also, for instance, Geraets-Smits (n Error! Bookmark not defined.) paras 72-74; See, on the rule of reason, Koen Lenaerts and Piet Van Nuffel, European Union Law (3rd edn Sweet and Maxwell, London 2011) 280-284.

\textsuperscript{33} Watts (n 23) paras 62-71.

\textsuperscript{34} Müller-Fauré (n 23) para 85.

\textsuperscript{35} Watts (n 23) para 131; See, also, Regulation 987/2009 (n 2) art 26(7).
institutions. Since this cross-border health care route is not based on co-ordination between national social security institutions, and all providers who are legally providing health care are service providers, the patient can access providers not affiliated with the state of treatment's social security system.

According to the Treaty free movement provisions, interpreted by the Court of Justice, patients are not, generally, entitled to coverage of travel and accommodation (outside the treating hospital) costs for cross-border health care. However, when the competent state covers travel and accommodation costs for health care provided by its own hospitals, that state must also cover the same costs related to health care obtained abroad.

Summing up the free movement of patients in cases of planned health care, some conclusions may be reached. First, the internal market rules offer a possibility for the patients to obtain health care without prior authorisation in certain circumstances, which go wider than is the case with social security co-ordination. Second, free provision of services offers patients possibilities to access providers not affiliated with any social security system. Third, under the internal market, patients obtain the coverage on basis of most favourable tariffs, which rule has, to some extent, been taken over by the co-ordination.

Apart from these additional possibilities of free movement, there are several problems which hamper that free movement. First, Member States are free to limit their general national coverage of health care by providing detailed and restrictive rules, in order to prevent covering more effective foreign treatments. Second, delimitation between situations in which Member States may impose prior authorisation, and those in which they may not, is not clear. It is hard to determine when major medical equipment is involved and in which it is not and whether different criteria should apply to different Member States, taking into account their financial situation. Third, the reimbursement system favours those patients who have enough resources to pay directly to the provider and risk subsequent reimbursement procedures and potential litigation in the competent state. Therefore, although the Court does put individual’s medical needs at the forefront of its reasoning, inequalities stemming from patients belonging to different national security systems and having different financial capabilities are acknowledged, and in some cases even exacerbated by the case-law. Fourth, the creation of two parallel systems of coverage of cross-border health care, with some overlaps, does not contribute to the clarity of patients’ entitlements.

Finally, it must be mentioned that, although Treaty provisions concerning free movement of services are applicable to cases of obtaining unplanned hospital health care in a state other than the state of social protection, those provisions do not give the patient the entitlement to the coverage on basis of (more favourable) competent state rules. The basis for this approach is the stance that the lack of the more favourable coverage does not deter persons from travelling abroad to receive non-medical services (like tourist or educational services). Regarding medical services, the Court's reasoning is that patients will, in any case, receive health care from the closest provider capable of providing it, because of urgency. However, situations where the patient has a possibility to return earlier than planned to the competent state, to obtain health care there, remain ambiguous.

36 Kohll (n 23) para 42; Decker (n 23) para 40; See, also, Regulation 883/2004 (n 2) art 20, 27.
37 See Stamatelaki (n 23) paras 24-38.
38 Watts (n 23) paras 139-140; confirmed by the Court in Acereda Herrera (n 23) para 38.
39 See Commission v Spain (n 23) paras 45-81.
In addition to that, potential financial consequences for national social security systems of increasing mobility of persons travelling for various reasons between EU Member State have also provided the basis for the Court's reasoning. However, these arguments do not seem convincing, since only a decrease in profit of covering cheaper foreign treatments under foreign tariffs may occur for Member States with more costly health systems, while real balancing problems may only strike systems with average cost level.\(^{40}\)

III. Patient Mobility Directive

1. General remarks

The described case-law has created a necessity for its codification into a coherent and transparent legal framework. This endeavour has had to balance patients’ rights to cross-border health care with historical competences of Member States, different health care models and protection of national social security systems’ financial stability.\(^{41}\) Within that balancing exercise, the solutions to the described problems emanating from the case-law needed to be found.

The Patient Mobility Directive has been adopted on basis of TFEU art 114(former EC Treaty art 95), on the harmonisation of the internal market, through ordinary legislative procedure, and the TFEU art 168 (former EC Treaty art 152), according to which ‘a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.’ The adoption took place almost three years after the initial proposal by the Commission, which shows complexity and political sensitivity of the subject matter.\(^{42}\)

The use of the mentioned Treaty provisions is logical, since the Directive is based on applicability of the internal market Treaty provisions to social security cover of cross-border health care. The use of the legal basis also demonstrates that cross-border health care does not fall under the complementary EU competences, as one might conclude after reading TFEU art 153 and TFEU art 168 in conjunction with TFEU art 4 and TFEU art 6, but under the internal market competence which is shared between the Union and the Member States according to the TFEU art 6, instead (the same holds true for the aspects of cross-border health care covered by co-ordination regulations, which are also based on internal market Treaty provisions).

The Directive’s personal scope of application includes those persons who are subject to EU social security co-ordination, including persons who are not Union nationals. It, also,

\(^{40}\) See Commission v Spain (n 23) paras 76-81; See, also, Van der Mei (n 20) 437-438.
applies to third-country nationals who fulfil the state of affiliation’s (competent state) conditions for entitlement to health care.\textsuperscript{43}

The Directive covers cross-border health care, which is defined in a broad way, without making any distinction on basis of its private or public (social) nature. EHealth, whereby the service is provided without the patient actually crossing the border to access the provider established in another Member State, is also covered.\textsuperscript{44} However, long-term care for the purpose of assisting people with daily tasks, access to and allocation of organs for transplant purposes, and public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures, are not covered by the Directive.\textsuperscript{45}

It must be emphasised that co-ordination rules include long-term care within their scope of application, while there has been no case-law that would determine whether this type of care falls under the internal market rules, except in cases of residence abroad. However, since remuneration in the state of treatment is the crucial criterion for applicability of free movement of services, there is no reason why long-term care would generally be excluded from the application of the Treaty rules, when the remuneration exists.\textsuperscript{46}

It seems that Patient Mobility Directive does not apply to cases where a person obtains (health) care while residing (without a foreseeable limit to the duration of that residence) outside the state of affiliation. This conclusion is based on the fact that free movement of services rules are not applicable to the described residence situations, according to the Court of Justice to whose jurisprudence the Directive refers.\textsuperscript{47} Since TFEU art 114 can only be used to harmonise internal market, and is not applicable to free movement of persons according to TFEU art 114(2), it can be argued that this legal basis could not have been used to adopt measures relating to health care obtained in the state of residency outside the state of affiliation, mentioned above. It seems that Patient Mobility Directive is applicable to cases where a person obtains health care while staying temporarily outside the state of affiliation, outside his/her state of affiliation, while he/she exercises right of establishment in the state of affiliation.

\textsuperscript{43} Patient Mobility Directive (n 1) art 3, 7; The co-ordination rules apply to Member State nationals; third-country nationals residing and moving within the EU (except regarding Denmark, while the old rules apply to the UK); stateless persons and refugees residing and moving within the EU; their family members and survivors. The co-ordination, also, applies to survivors (of persons who have been subject to a Member States legislation) who are Member States nationals, stateless persons or refugees residing in a Member State. See to that effect Council Regulation (EC) 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality [2003] OJ L124/1, Regulation (EU) 1231/2010 of the European Parliament and of the Council of 24 November 2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality [2010] OJ L344/1 and Regulation 883/2004 (n 2) art 2.

\textsuperscript{44} See Patient Mobility Directive (n 1) art 3, 7 and Preamble to the Patient Mobility Directive (n 1) para 26. Health care is defined as ‘health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices’.

\textsuperscript{45} Patient Mobility Directive (n 1) art 1(3); Patient Mobility Directive (n 1) Chapter IV (art 10-15).

\textsuperscript{46} Regulation 883/2004 (n 2) art i(va); See, also, Pennings (n 24) 438 and von Chamier-Gliszczinski (n 29) paras 75- 77.

\textsuperscript{47} von Chamier-Gliszczinski (n 29) paras 75- 77; See, also, for example, Preamble to the Patient Mobility Directive (n 1) para 8; It remains questionable whether the Directive could apply to cases where a person resides outside his/her state of affiliation, while he/she exercises right of establishment in the state of affiliation.
since no explicit distinction is made by the provision of the Patient Mobility Directive between planned and unplanned health care.

Member State of affiliation is defined as state which is competent to give prior authorisation under co-ordination rules. In case no Member State is competent for third-country nationals on basis of co-ordination rules, the Member State of insurance or the Member State granting the right to sickness benefits will be the state of affiliation.\(^{48}\) Since, according to the Regulation 883/2004, planned health care which is obtained by the pensioner in a Member State which is not his/her state of residence is covered by the state of residence if that state has opted for reimbursement based on fixed amounts,\(^ {49}\) the Member State of residence provides authorisation in the described situation.\(^ {50}\) Concerning this issue, the Patient Mobility Directive provides that:

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\text{...if a Member State is listed in Annex IV to Regulation (EC) No 883/2004 and in compliance with that Regulation has recognised the rights to sickness benefits for pensioners and the members of their families, being resident in a different Member State, it shall provide them healthcare under this Directive at its own expense when they stay on its territory, in accordance with its legislation, as though the persons concerned were residents in the Member State listed in that Annex.}^{51}\]

Therefore, a Belgian pensioner living in Spain who obtains a health treatment in Belgium (which is listed in Annex IV), will be covered by Belgium.

In addition to that:

\[
\text{… if the healthcare provided in accordance with this Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation (EC) No 883/2004, and is provided in the territory of the Member State that according to that Regulation and Regulation (EC) No 987/2009 is, in the end, responsible for reimbursement of the costs, the costs shall be assumed by that Member State. This Member State may assume the costs of the healthcare in accordance with the terms, conditions, criteria of eligibility and regulatory and administrative formalities that it has established, provided that these are compatible with the TFEU.}^{52}\]

This provision could be interpreted that costs of health care for a person receiving UK pension in Spain, and travels to get non-hospital treatment in the UK, will be covered by the UK, since the latter state, in the end, pays for the costs of mentioned treatment within the co-ordination framework (fixed amounts for reimbursing Spain include those costs).

2. Reimbursement of costs

\[^{48}\text{Patient Mobility Directive (n 1) art 3.}\]
\[^{49}\text{Regulation 883/2004 (n 2) art 27(5).}\]
\[^{50}\text{Regulation 883/2004 (n 2) art 27(5).}\]
\[^{51}\text{Patient Mobility Directive (n 1) art 7(2).}\]
\[^{52}\text{Patient Mobility Directive (n 1) art 7(2) and Regulation 883/2004 (n 2) art 17-35.}\]
Central part of the Directive deals with reimbursement rules, which determine in which situations the state of affiliation is required to cover health treatments obtained outside its territory. The first important issue one must turn to is defining the range of covered treatments. In that sense, the Directive has incorporated important parts of recent case-law in its Preamble (para 34), whereby broad national definitions of general health care coverage mean that most effective foreign treatment, which may be caught by wording of those definitions, must be paid for by the state of affiliation, even if not available on its territory.

However, the autonomy of Member States in determining by themselves the general national basket of covered health care, including the right to do it not only via national statutes or statutory instruments but, also, on regional or local level, has been prescribed by the normative part of the Directive, as well as that patients are only entitled to foreign health treatments which are part of the state of affiliation’s package. Read together, these provisions may be interpreted as giving more leeway for Member States than the Court of Justice’s jurisprudence. According to the Directive, national legislation, which contains an explicit or implicit entitlement to local bodies who purchase health care (like the English Primary Care Trusts, or PCTs) to define significant parts of the health care coverage by themselves, can be interpreted as lawfully limiting health care to those treatments which are approved by those local bodies. This possibility for Member States to limit their coverage is definitely a setback for patients’ rights to access cross-border health care, and reflects the wish of the Member States to protect, via EU secondary legislation, their social policy choices (such as local commissioning of health care).

The next important consideration must be given to the prior authorisation. Member States may impose prior authorisation for health care which:

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:
(i) involves overnight hospital accommodation of the patient in question for at least one night; or
(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;
(b) involves treatments presenting a particular risk for the patient or the population; or
(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

53 Patient Mobility Directive (n 1) art 7.
54 See NHS Act 2006 (n 27); There is an argument that national social policy cannot be equated with national constitutional identity, since policy is a variable of national government. This implies a stricter scrutiny by the Court of Justice over policy choices than over Member States’ fundamental constitutional choices. See to that effect Siniša Rodin, ‘National Identity and Market freedoms after The Treaty of Lisbon’ (2011) Available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2005691> accessed 10 January 2012.
55 Patient Mobility Directive (n 1) art 8(2).
Member States must notify the categories under a) to the Commission. In this way, Member States have a wider set of options to impose prior authorisation under the Directive than under the case-law applying the Treaty. Seemingly, the only improvement for the individual patient’s position when compared to the case-law is that, according to the Directive, a treatment which is a hospital treatment, but does not involve overnight accommodation, does not warrant prior authorisation. However, according to the case-law, ‘services provided in a hospital environment but that could also be provided by a practitioner in his surgery or in a health centre could, for that reason, be placed on the same footing as non-hospital services.’ Therefore, the possibility of patients accessing hospital out-patient treatment without prior authorisation existed even before the Directive was adopted.

What is striking is that there is no explicit entitlement to access health care without waiting for prior authorisation, in cases of urgency, while that entitlement exists under the Treaty and the co-ordination rules. There is only a statement in the Preamble (para 47) that the patient should receive decisions regarding cross-border health care within a reasonable amount of time, and that time can be shortened due to urgency, and a provision that, when deciding on requests for cross-border health care, urgency must be taken into account. These provisions can be interpreted in various ways. So, the provisions of the Directive can be seen as significantly limiting patients’ entitlements to obtain health care without prior authorisation.

If we look at the grounds for refusing the authorisation, some interesting things can be observed. There is a closed list of grounds for refusal, some of which have been mentioned by the Court (medically justifiable time-limit for provision of health care), but some have not (public health risks, provider related concerns and patient safety risks). Furthermore, wording of the provision stating the cases in which prior authorisation may not be refused, differs from the wording of the provision stating the cases in which authorisation may be refused. The former provision is based on the case-law, while the latter reiterated the wording of the co-ordination rules. Since the Court’s interpretations of the Treaty and of the co-ordination rules have been aligned in this respect, there should be no major legal problem stemming from the Directive (although, the case-law based provision omitted one’s disability to carry out a professional activity as a relevant criterion, which may cause problems).

A question remains on whether the prior authorisation can be applied in cases of unplanned health care. Although, a logical answer would be in a negative, there is a

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56 See Commission v France C-512/08 (n 20) para 35; See, also, Pennings (n 24) 440.
57 See Elchinov (n 20) paras 43-51; See, also, Commission v France C-512/08 (n 20) para 27 and Patient Mobility Directive (n 1) art 9.
58 A Member State may refuse authorisation when ‘healthcare can be provided on its territory within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned’, according to the Patient Mobility Directive (n 1) art 8(6).
59 A Member State may refuse authorisation when ‘a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare; (b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question; (c) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment;’, according to the Patient Mobility Directive (n 1) art 8(6).
60 See Müller-Fauré (n 23) para 90, Watts (n 23) paras 62-71 and Pennings (n 24) 442.
possibility that it could become necessary for a person to obtain health care, which does not have to be provided right away, while temporarily staying abroad, in order to finish a semester of studying abroad, for example. Could prior authorisation be imposed in these cases? Under the case-law applying the Treaty, the answer is no, as well as under the co-ordination regulations, but the Directive is not clear on this issue. As co-ordination regulations remain applicable, the Directive’s limitations may be avoided by the patients by simply not opting for the procedure prescribed by the Directive, since the Directive applies without prejudice to co-ordination regulations and does not affect patients’ entitlements stemming from co-ordination, concerning unplanned health care.62

Apart from the authorisation, concerning which the Directive limits patients’ rights to cross-border health care, there is an additional limitation imposed, regarding reimbursement. Member State may limit the application of the rules on reimbursement:

... based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.63

How and when Member States may have recourse to the cited provision remains unclear, The rule in question, due to its vague wording, opens up a scenario whereby different Member States may apply a wide range of different criteria for limiting the application of the reimbursement rules (whatever the phrase ‘limit the application’ might mean). The limitation imposed by the Directive upon the Member States’ autonomy to apply this provision, which might be used as a starting point for the judicial control of the Member States’ transposing legislation by the Court of Justice, is that the rules in question ‘shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services’.64

In terms of payment methods and applicable tariffs, the Directive does not depart from the case-law, concerning planned health care. Thus, the patient pays to the provider directly and is reimbursed afterwards by the state of affiliation (which may, also, pay directly). The tariffs prescribed by the legislation in the state of affiliation are applicable, and the reimbursement does not have to exceed the real price of the treatment the patient paid (unless the state of affiliation voluntarily decides to pay more).65 On the other hand, the entitlement to cover on basis of the legislation of the state of affiliation, concerning unplanned health care, is a gain for patients, when compared to the case-law.66 Member States (those that do not have them already, which may be the case for national health services) must set up transparent, non-discriminatory and objective systems for calculating reimbursement.67

Travel and costs of other than hospital accommodation may be reimbursed by the state of affiliation, but the Directive’s normative part does not lay down an explicit duty for that state

61 See Commission v Spain (n 23) paras 75-76 and Regulation 883/2004 (n 2) art 19.
62 Patient Mobility Directive (n 1) art 2 and Preamble to the Patient Mobility Directive (n 1) para 28.
63 Patient Mobility Directive (n 1) art 7(9).
64 Patient Mobility Directive (n 1) art 7(11).
65 Patient Mobility Directive (n 1) art 7(4); See, also, Watts (n 23) para 131.
66 See Commission v Spain (n 23) paras 45-81.
67 Patient Mobility Directive (n 1) art 7(6); See, also, Watts (n 23) paras 74, 133.
to do so, even when it covers the costs in question on its own territory. In this way, the legislator refrained from expressly reaffirming the case-law on the issue.\(^\text{68}\)

The Directive, also, prescribes the requirements that authorisation and reimbursement procedures must satisfy. These do not provide concrete gains for the patients. What is especially important is that the legislator did not use the possibility of setting explicit deadlines for reaching the decisions on coverage of cross-border health care.\(^\text{69}\)

Taken all this together, it can be assumed that the Patient Mobility Directive will be mostly relevant as a legal instrument for accessing health care which does not require prior authorisation, depending on how the Court of Justice will interpret obvious differences between the Directive and its case-law applying the Treaty on when the authorisation may be imposed. In cases in which prior authorisation is required, using co-ordination regulations provides the patients with an opportunity to obtain health care on basis of the tariffs set by the state of treatment, while maintaining the entitlement to the higher coverage by the competent state (although, it is not clear if this additional right applies only in cases in which authorisation has been refused without merits). Furthermore, the co-ordination provides for lesser number of grounds on which authorisation may be refused than the Patient Mobility Directive.\(^\text{70}\)

3. Prescriptions

Patient Mobility Directive contains rules on recognition of medical prescriptions by Member States. If there is an authorisation for a medicinal product to be marketed on their territory, Member States must make it possible that prescriptions, issued for that item in a different Member State, are dispensed on their territory according to their legislation. No restrictions concerning recognition of individual prescriptions are allowed, except in enumerated cases. The rules on prescription recognition do not affect Directive’s reimbursement rules.\(^\text{71}\)

4. Access to health care in the state of treatment

State of treatment is not allowed to discriminate between domestic and foreign patients.\(^\text{72}\) However, it may limit access to health care on its territory, on basis of overriding reasons of general interest, to prevent increase of domestic waiting lists, because of inflow of foreign patients. The measures in question must be necessary, proportionate, must not constitute arbitrary discrimination and must be publicised in advance.\(^\text{73}\) In terms of tariffs:

Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable medical situation, or that they charge a price

\(^{68}\) Patient Mobility Directive (n 1) art 7(4); See, also, Watts (n 23) paras 139-140.

\(^{69}\) Patient Mobility Directive (n 1) art 9.

\(^{70}\) See Regulation 883/2004 (n 2) art 20 and Regulation 987/2009 (n 2) art 26(7).

\(^{71}\) Patient Mobility Directive (n 1) art 11(1).

\(^{72}\) Patient Mobility Directive (n 1) art 4(3).

\(^{73}\) Patient Mobility Directive (n 1) art 4(3) and Preamble to the Patient Mobility Directive (n 1) para 21.
calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients. This paragraph shall be without prejudice to national legislation which allows healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.\textsuperscript{74}

It is unclear whether this provision enables Member States to calculate tariffs for foreign incoming patients by using different formulas than domestic patients, which may be to the detriment of foreign patients in some cases, but also to their advantage in other. In any case, the Patient Mobility Directive leaves a lot of space for the state of treatment to limit access of foreign patients to their health care providers.

5. Right to information

Significant gains for the patients’ access to cross-border health care concern right to information. Both the state of affiliation and the state of treatment must establish contact points which will, upon request, provide the patients with the relevant data on cross-border health care.\textsuperscript{75}

In the Member State of treatment, the data includes:

“...information concerning healthcare providers, including, on request, information on a specific provider’s right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients’ rights, complaints 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.”\textsuperscript{76}

Article 4(2)(a) deals with information concerning standards of quality and safety.

Member State of affiliation must provide the patient, upon request, with all the information concerning reimbursement conditions and procedures for coverage of health care abroad.\textsuperscript{77}

Finally, there are provisions concerning Member States’ co-operation and European reference networks, which will be analysed separately from the clear legislative commands of the Directive.

IV. Croatian legal framework

1. System of bilateral agreements

\textsuperscript{74} Patient Mobility Directive (n 1) art 4(4); See, also, Case C-411/98 Angelo Ferlini v Centre Hospitalier de Luxembourg [2000] ECR I-8081.
\textsuperscript{75} Patient Mobility Directive (n 1) art 6.
\textsuperscript{76} Patient Mobility Directive (n 1) art 6(3).
\textsuperscript{77} Patient Mobility Directive (n 1) art 6(4), 5(b).
The system of social coverage of health care obtained abroad is currently regulated in Croatia through several legal instruments. The first one to be analysed consists of bilateral agreements on social security co-ordination, concluded between Croatia and individual EU Member States. Bilateral agreements are analysed first because they are, in terms of legal force, above national statutes, once ratified. Those aspects of the agreements which deal with the same issues (planned and unplanned health care obtained while temporarily abroad) as the Patient Mobility Directive, will represent the focal point of the analysis.

Croatia has concluded bilateral agreements, including those taken over from former Yugoslavia, with 17 Member States of the European Union. These are: Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Italy, Luxembourg, the Netherlands, Poland, Romania, Slovakia, Slovenia, Sweden and the United Kingdom.

In general terms, it must be emphasised that the agreements significantly vary among themselves. The first differentiation one should mention deals with their personal scope of application. Thus, the agreements can be divided into those which cover only nationals of the countries which are parties to the agreements in question, their family members and, in some cases, refugees and stateless persons; and those which cover all persons socially insured by those countries and their family members. The main criterion for determining the competent state is law of the place of work or *lex loci laboris*.

In terms of unplanned health care, minority of the agreements provide for the coverage of health care by Health Insurance Institute of Croatia, or HIIC, taking into account the person’s length of stay. Some of the agreements do not contain specific provisions on coverage of unplanned health care abroad at all, while the other agreements provide for coverage of emergency (urgent) health care, to prevent danger for one’s life and health. The coverage is, generally, provided by competent state on basis of the state of treatment’s rules and tariffs (settled between the two states) and patients can only access providers attached to the social security of the latter state. These are all differences when compared to the Patient Mobility

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80 The first group consists of agreements with Bulgaria, Denmark, France, Germany, Italy, Poland, Slovenia, Sweden and the United Kingdom. The second group consists of agreements with Austria, Belgium, Czech Republic, Hungary, Luxembourg, the Netherlands, Poland and Romania. See Rismondo (n 79) 14.
81 These include agreements with Austria and Germany. See, for example, Agreement on Social Insurance between Republic of Croatia and Republic of Austria (Official Gazette – International Agreements 15/97 and 13/98) (Ugovor o socijalnom osiguranju između Republike Hrvatske i Republike Austrije NN-MU, 15/97 i 13/98) (hereinafter: Croatia - Austria Agreement 1997) art 11.
82 These include agreements with Bulgaria, Denmark, France and Sweden. There are some special rules on posted workers. See, for example, Agreement on Social Insurance between Republic of Croatia and Republic of Bulgaria (Official Gazette – International Agreements 4/04 and 7/04) (Ugovor između Republike Hrvatske i Republike Bugarske o socijalnom osiguranju NN-MU, 4/04 i 7/04) (hereinafter: Croatia - Bulgaria Agreement 2004) art 8.
83 These include agreements with Belgium, Czech Republic, Hungary, Italy, Luxembourg, the Netherlands, Poland, Romania, Slovakia, Slovenia and the United Kingdom. See, for example, Agreement on Social Insurance between Republic of Croatia and Republic of Hungary (Official Gazette – International Agreements 11/05 and 3/06) (Ugovor o socijalnom osiguranju između Republike Hrvatske i Republike Mađarske NN-MU, 11/05 i 3/06) (hereinafter: Croatia – Hungary Agreement 2006) art 11.
Directive, which provides wider possibilities for patients to access health care abroad (on basis of the state of affiliation’s tariffs).84

When we look at planned health care, the situation is even worse. Only a small number of agreements contain provisions concerning planned health care. In those cases, coverage is, generally, provided by the competent state) on basis of the state of treatment’s rules and tariffs (settled between the two states) and patients can only access providers attached to the social security of the latter state. Prior authorisation is required, but can be granted afterwards if it had not been requested in time for objective reasons, in case of Germany, Hungary and Slovenia.85 When compared to the Patient Mobility directive, whereby there is an entitlement to access health care abroad with no prior authorisation in several situations, and patients can access providers not attached to any social security system, the agreements appear to significantly limit access to cross-border health care.86

2. Statutory framework

Central legal source regulating social security coverage of health care in Croatia is Compulsory Health Insurance Act from 2008 (hereinafter: Health Insurance Act 2008). This act, adopted by Croatian Parliament, determines personal scope of application of Croatian social security health care system, range of covered health care in general and cover of health treatments obtained outside Croatia.87

Every resident of Croatia (but also foreigners granted permanent stay, except in cases in which international agreements determine otherwise; an exception also exists concerning children under 18 years of age which are considered to be insured) is under a duty to obtain social insurance with the HII on one of the grounds enumerated by the Health Insurance Act 2008. These grounds include conducting of a professional activity, putting Croatia somewhere in between professional and occupational systems of social security. Health care is covered mainly through direct payments by HIIC to the providers, making the system a benefits-in-kind system. Range of covered health care is prescribed using wide notions and different

84 See, for example, Croatia - Austria Agreement 1997 (n 81) art 11; There are, also, some agreements which provide for reciprocity, meaning that each country covers treatments provided on its own territory, without a refund from the competent state. See, for example, Convention on Social Insurance between Federal People’s Republic of Yugoslavia and United Kingdom of Great Britain and Northern Ireland (Official Gazette – International Agreements 7/58, taken over by Croatia on basis of the Decision on Publication of Bilateral International Agreements the Republic of Croatia is a Party to on Basis of Succession, Official Gazette – International Agreements 11/97) (Konvencija o socijalnom osiguranju između Federativne Narodne Republike Jugoslavije i Ujedinjenog Kraljevstva Velike Britanije i Sjeverne Irske SL-MUIDS, 7/58, preuzeta temeljem Odluke o objavljivanju dvostranih međunarodnih ugovora kojih je Republika Hrvatska stranka na temelju sucesije NN-MU, 11/97) (hereinafter: Yugoslavia – UK Convention 1958); Some of the agreements contain provisions whereby an authorisation by the competent state is required for health treatments and appliances with a higher cost, with exceptions. See, for example, Croatia - Austria Agreement 1997 (n 81) art 11; See, also, Patient Mobility Directive (n 1) art 3, 7.
85 These include agreements with Austria, Germany, Hungary, Italy, Luxembourg and Slovenia. See, for example, Croatia - Austria Agreement 1997 (n 81) art 11 and Agreement on Social Insurance between Republic of Croatia and Republic of Slovenia (Official Gazette – International Agreements 16/97 and 3/98) (Sporazum o socijalnom osiguranju između Republike Hrvatske i Republike Slovenije NN-MU, 16/97 i 3/98) (hereinafter: Croatia – Slovenia Agreement 1998) art 12.
86 See Patient Mobility Directive (n 1) art 3, 7.
87 Compulsory Health Insurance Act (Official Gazette 150/08 to 22/12) (Zakon o obveznom zdravstvenom osiguranju NN 150/08 do 22/12) (hereinafter: Health Insurance Act 2008).
criteria, which include the types of medical conditions (diseases), types of patients (for instance, free of charge provision for persons who have not turned 18) and types of medical procedures (health treatments). This technique opens up possibilities for patients to access best possible health care anywhere in the EU (once Croatia accedes to the latter) which fit into those wide notions.

One of the patients’ statutory entitlements concerns health care abroad. Apart from the general entitlement, it is prescribed that a co-payment in the amount of 20% of the treatment cost, with an upper limit, must be paid in case of accessing health care abroad, according to a general act adopted by HIIC. Co-payments are covered by voluntary insurance provided by HIIC. Therefore, it is imperative to turn to the statutory instrument which regulates health care abroad in more detail.

3. Statutory instrument

The statutory instrument regulating health care abroad has been adopted by HIIC (after the consent given by the minister of health care). The instrument must be applied in line with the higher law, meaning the relevant statutes and international agreements.

According to this general framework, patients have possibilities of accessing health care outside Croatia. The first possibility concerns cases of unplanned health care obtained while temporarily abroad. Persons who are abroad for business, studying or personal reasons, and their family members, are entitled to HIIC covered health care under certain conditions. Persons privately staying abroad and students and pupils studying abroad on their own account have an entitlement to emergency health care (also family members of persons sent abroad for work or education). The latter includes diagnostic and therapeutic procedures necessary to eliminate a direct peril for a person’s life and health. Other persons are entitled to health care that cannot be postponed until the patient’s return to Croatia care (also family members of persons sent abroad for education or work). For some treatments (namely, dialysis), prior HIIC authorisation is required.

Persons who, despite being entitled to covered health care abroad, ended up paying the costs in the state of treatment, are entitled to reimbursement, in accordance with the relevant international agreement. When there is no agreement, or the existing social security agreement does not regulate the issue, reimbursement is conducted in the following amount: real cost of health care is reimbursed, less the co-payment requirement. Only in the latter situation can the patient access health care providers who are not affiliated with the social security health care system in the state of treatment. It must be added that the only possibility
of accessing unplanned health care outside Croatia, covered by HIIC, exists if a special contribution has been paid by the patient, his/her employer or a third person in some cases. The patient must get HIIC certificate before travelling abroad, otherwise there will be no coverage (an exception concerns business trips). The person who had to apply for the certificate pays the costs.\(^{95}\)

Compared to the Patient Mobility Directive, provisions on special contribution, and coverage only of emergency health care in some cases, represent an additional restriction on patients’ cross-border health care entitlements. Duty to pay the special contribution only for health care abroad can be seen as a discrimination against foreign providers of health care, and will be hard to reconcile with the Directive. However, reference to real treatment cost may prove advantageous, in case health care is obtained in a country with higher costs.\(^{96}\)

In terms of planned health care abroad, there are several restrictions to patients’ entitlements. An authorisation can be given for entitlement to health care abroad for treating congenital defects, for carrying out organ transplants, and for treating malignant diseases. The authorisation can be given if treatments which are necessary cannot be provided by HIIC affiliated health care providers in Croatia, while they can be provided abroad. This includes treatments which are recognised by medical science, but not provided in Croatia. Exceptionally, authorisation may be granted for treatments abroad not related to the mentioned diseases. Treatments can be provided by providers not affiliated with the state of treatment’s social security system (these will not be covered under bilateral agreements). Whether a treatment is recognised (not still in an experimental or trial stage) is determined by medical experts who take part in the decision-making process. There was a case regarding a previous version of the relevant statutory instrument, whereby the authorisation was not granted, due to an alternative non-standard treatment being performed successfully in Croatia.\(^{97}\) According to the rules on the applicable tariffs real cost of health care is reimbursed, less the co-payment requirement if there is any (in case of no relevant provisions of bilateral agreements).\(^{98}\)

In addition to treatments and appliances (in case they are covered within a planned treatment abroad), persons who get authorisation have a right to reimbursement of medical transportation as well as of public transportation costs, according to the other Croatian rules which regulate those rights, and of hospital accommodation which is part of the hospital treatment. A companion may be authorised by HIIC to get the coverage of travel costs.\(^{99}\) Exceptionally, if a child has been authorised to obtain a treatment abroad, coverage of

\(^{95}\) See Health Care Abroad Ordinance 2009 (n 91) art 5-14; See, also, Contributions Act (Official Gazette 84/08 to 22/11) (Zakon o doprinosima NN 84/08 do 22/11); According to some bilateral agreements, the state of treatment can request certificate afterwards. See, for example, Administrative Agreement on the Implementation of the Agreement on Social Insurance between Republic of Croatia and Republic of Slovenia (Official Gazette – International Agreements 5/98) (Administrativni sporazum o provedbi Sporazuma o socijalnom osiguranju izmedu Republike Hrvatske i Republike Slovenije NN-MU, 5/98) (hereinafter: Croatia - Slovenia Administrative Agreement 1998) art 6.

\(^{96}\) See, Patient Mobility Directive (n 1) art 3, 7.

\(^{97}\) Health Care Abroad Ordinance 2009 (n 91) art 21; See also Health Insurance Act 2008 (n 87) art 20 and Us-2107/2008 Administrative Court of the Republic of Croatia 12 January 2011.; On experimental treatments, see Us-4587/2009 Administrative Court of the Republic of Croatia 20 January 2011.

\(^{98}\) Can be derived from Health Care Abroad Ordinance 2009 (n 91) art 30.

accommodation costs (by referring to public servants’ entitlements during a foreign official trip) may be authorised to child’s mother in case of need for breastfeeding and when the child has not reached five years of age and there is a medical necessity.\footnote{Health Care Abroad Ordinance 2009 (n 91) art 25a.}

When compared to the Patient Mobility Directive, the Croatian framework is more restrictive for patients, in terms of lack of possibilities to obtain planned health care abroad without prior authorisation. Furthermore, authorisation procedure is pretty cumbersome, with at least two specialists having to give a green light (at least three for other diseases than those which are expressly mentioned by the statutory instrument).\footnote{Health Care Abroad Ordinance 2009 (n 91) art 22.}

V. Overall assessment

In some cases, Patient Mobility Directive can be considered a step back for patients’ social security rights in cross-border health care. Possibilities for Member States to impose prior authorisation and refuse reimbursement have been enhanced, when compared to the co-ordination regulations and the case-law on freedom to provide services, concerning planned health care. On the other hand, it seems that the Directive departs from the case-law in that it gives patients’ entitlement to more favourable reimbursement according to the state of affiliation’s tariffs in cases of unplanned health care. Since case-law is based on EU primary law, it remains to be seen how the Court of Justice will resolve the described differences. It is possible that the Court interprets some of the dubious provisions in the light of the Treaty free movement rules,\footnote{See, for example, Case C-47/90 Établissements Delhaize Frères et Compagnie Le Lion SA v Promalvin SA and AGE Bodegas Unidas SA [1992] ECR I-3669 para 26.} and it is, also, possible that the provisions which cannot be interpreted in that way are set aside as invalid.\footnote{See, especially, TFEU art 263, 267, 277.}

In those instances where the Treaty offers more leeway for the Member States (namely, where there is no entitlement to additional coverage in cases of unplanned health care), the legal nature of the Directive is crucial. In case the Directive is a ‘field occupying’ Directive, one that provides for total harmonisation of a certain area, Member States are not permitted to use the Treaty based grounds for imposing restrictions. In case the Directive is a ‘minimum harmonisation’ Directive, those grounds are available to the states.\footnote{On these notions, see Tamara K. Hervey, ‘If Only It Were So Simple - Public Health Services and EU Law’, in Marise Cremona, (ed), Market Integration and Public Services in the European Union (OUP, Oxford 2011); See, also, Case C-205/07 Criminal proceedings against Gysbrechts and Santurel Inter BVBA [2008] ECR I-9947 para 33.} Since the Directive states that it respects national competences in organising health care, and taking into account the legal basis (TFE art 168) which supports the same conclusion, it seems that Member States may use the Treaty to restrict reimbursement for unplanned health care.\footnote{See Patient Mobility Directive (n 1) art 1.}

However, the issue of substantial differences between the Directive and the judgements applying primary law remains ambiguous, especially in those areas in which the Directive gives more leeway to the states than does the case-law. If we remember that, apart from the case-law applying the Treaty and the Directive, there are also EU co-ordination rules which
regulate the same area, it is not hard to conclude that clarity of patients’ cross-border entitlements and legal certainty suffer from the existing complex EU legal framework. When it comes to rules on reimbursement and social cover, there are now, in effect, three parallel legal instruments which apply to the same area: co-ordination regulations, Treaty free movement provisions and the Patient Mobility Directive. A logical question arises: Was it possible to incorporate the changes brought about by the case-law into the co-ordination regulations? Some of them, actually, have been incorporated (considering the right to additional reimbursement according to the competent state’s rules and travel and accommodation costs in planned health care). On the other hand, it is much easier to adopt a directive on basis of TFEU art 114 than to amend the coordination rules, where unanimity, essentially, still applies. In terms of substance, however, spelling all the rules on social security cover of cross-border health care in a single legal instrument would have benefited the patients due to increased clarity and transparency of the framework. In any case, the Court should use its future jurisprudence to clarify the remaining questions.

A bonus for the patients has been provided by the part of the Patient Mobility Directive which deals with state of treatment’s obligations and the patients’ right to information. One can find provisions which prescribe a duty for the state of treatment to provide for professional liability insurance (or similar) and remedies for patients who suffer harm as a result of health care obtained. In addition to that, principles of universality, good quality care, equity and solidarity have found their place within the framework of the Directive. Taking all this together, it has been observed that some degree of substantive harmonisation of national health care systems (not just for incoming cross-border patients) can be derived from the Directive, which is a step forward from the EU co-ordination system. Finally, the mere fact that a codification exists, in addition to casuistic jurisprudence, makes it harder for a Member State to claim that individual judgements by the Court are not applicable to it, because of some unique characteristic of its system.

While the Directive’s effect in improving patients’ entitlements, when compared to the existing EU legal framework, is of ambivalent character, its consequences are clearer within the Croatian setting. First, Croatian framework is a mix of bilateral agreements and statutory provisions, as well as of statutory instruments. The latter two elements apply for those EU Member States with which Croatian has no bilateral arrangements, but they also apply, to some extent, in cases where bilateral agreements do apply (particularly their procedural provisions, since the agreements do not regulate procedure in a detailed manner). This makes the whole system even more complicated for individual patients than the European one.

Furthermore, the additional limitations prescribed by national rules, when compared to the Directive, make it clear that the possibilities of persons insured with HIIC to access health care abroad will enhance with the transposition of the Directive, and national rules will have

106 See Regulation 987/2009 (n 2) art 26(7-8).
107 See Patient Mobility Directive (n 1) art 4.
109 See, as a particularly good example, Watts (n 23).
110 Health Care Abroad Ordinance 2009 (n 91) art 22.
to be adapted. Those national rules which will not conform with the Directive will have to be set aside by Croatian courts when applying the EU law.\textsuperscript{111} Therefore, the Croatian approach to cross-border health care and social security entitlements concerning other countries will have to be reevaluated.

VI. Does it matter in the end?

Having gone through the relevant legal framework, what is the future of cross-border health care the Directive deals with, that is, concerning temporary stay outside the competent state (the state of affiliation)? It is still a rare phenomenon, with estimates that cross-border care relates to around 1% of total health care spending.\textsuperscript{112} Furthermore, the EU framework does not harmonise national health care packages, and the Member States are not all in the same position as regards the possibilities to cover most effective treatments for the entire population.\textsuperscript{113} So, for which categories of patients or areas does the EU action in cross-border health care really matter?

Definitely, cross-border health care has an important role in border areas with a lot of cross-border movement. Furthermore, EU can play a significant part where there are imbalances concerning the health care provision on the national level. These problems can be relieved, for example, by cross-border contracting of health care, whereby social security institutions from one Member State enter into contracts with health care providers from another Member State. Public debate on the Union level has helped to bring these possibilities to notice of national social security institutions.\textsuperscript{114}

European Union’s role in steering the processes involving several Member States, and setting them within a coherent European wide framework, can be envisaged. In practical terms, the EU is best placed, with capabilities of obtaining enough information on different national systems and co-ordinating them, to be the driving force behind the new developments. In legal terms, the EU has a competence in health care, as demonstrated by TFEU art 6 and TFEU art 168, to support and complement Member States’ action, which is precisely the case here. The guidelines on block purchasing from 2005 represent one of the steps in that direction.\textsuperscript{115}

The Patient Mobility Directive is another important milestone, not in developing a coherent Union level health policy and regulation, but in providing a framework for co-ordinating and guiding national policies to a set of desirable outcomes. Thus, in addition to the right to information enabling patient choice, it contains important provisions on co-

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\textsuperscript{111} See Elchinov (n 20) para 31.
\textsuperscript{113} See Elchinov (n 20).
\textsuperscript{114} See Matthias Wismar, Willy Palm, Josep Figueras, Kelly Ernst and Ewout van Ginneken, (eds.), Cross-border Health Care in the European Union – Mapping and analysing practices and policies (WHO, Copenhagen 2011) and Andreas Obermaier, The End of Territoriality? The Impact of ECJ Rulings on Bristih German and French Social Policy (Ashgate, Farnham 2009).
operation and mutual assistance between national authorities, including co-operation on standards and guidelines on quality and safety.\textsuperscript{116} Furthermore, it explicitly mentions European reference networks, based on voluntary participation of European health care providers and centres of expertise, and defines their objectives, \textit{inter alia}:

\begin{quote}
\textit{“...a) to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies; }

\textit{...(d) to maximise the cost-effective use of resources by concentrating them where appropriate; }

\textit{... (h) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality;”}\textsuperscript{117}
\end{quote}

The Commission has a role in determining a list of criteria and conditions the networks and providers must fulfil.\textsuperscript{118}

Therefore, the emphasis is placed precisely on the structural imbalances of health care provision on national level. These imbalances are especially arduous for smaller Member States where maintenance of capacity for treating certain medical conditions is not feasible, and for those Member States which, due to economic reasons, cannot invest comparable resources into health care as some other Member States can. Croatia is a particularly good example of both of the described problems, which is precisely the reason why Croatian patients have an entitlement to access health care abroad if necessary treatments cannot be provided by HIIC affiliated health care providers in Croatia, while they can be provided abroad (meaning, access treatments not provided on Croatian territory).\textsuperscript{119}

We can see the Patient Mobility Directive as a legal instrument showing the limits of the positivist approach towards the EU role in the field of health (illustrated by the limitations on patients’ health care cover). Once this has been accepted, we can start to look at the Directive, with its provisions on the right to information, contact points, quality requirements, co-operation and European reference networks, as one of the stepping stones for the development of alternative or new forms of health care governance in the EU, the forms which are not, primarily, based on top-down legislative command.\textsuperscript{120} Since financing and organising health

\textsuperscript{116} Patient Mobility Directive (n 1) art 10. See, also, Patient Mobility Directive (n 1) art 15, concerning health technology assessment, as a form of Open Method of Co-ordination.

\textsuperscript{117} Patient Mobility Directive (n 1) art 12; See, also, Patient Mobility Directive (n 1) art 13 concerning rare diseases and art 14 concerning eHealth.

\textsuperscript{118} Patient Mobility Directive (n 1) art 12(4).

\textsuperscript{119} Health Care Abroad Ordinance 2009 (n 91) art 21.

\textsuperscript{120} The new governance can be defined as ‘...the use of legal and political authority, wealth and information to exercise control in the management of relationships and resources in the pursuit of social and economic ends (or, very simply, forms of normative ordering), involving institutional actors at the EU level, that do not follow the ‘command and control’ model of the classic Community method.’ See Hervey (n 115) 304; See, also, Joanne Scott and David M. Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the European Union’ (2002) 8 European Law Journal 1 and Colin Scott, ‘The Governance of the European Union: The Potential for Multi-Level Control’ (2002) 8 European Law Journal 59; The combination of the two approaches within the same instrument has been labelled ‘hybrid governance’. See Tamara Hervey and Louise Trubek, ‘Freedom to
care is left to the Member States, with all the differences between the more and less developed this situation entails and no possibilities of significant redistribution and equalisation from the EU budget, helping the Member States relieving their internal imbalances through EU level co-operation is as far as the Union can go at this time.

VII. Conclusion

Patient Mobility Directive has evolved as a result of the jurisprudence by the Court of Justice which has applied the internal market rules of the TFEU on situations in which a person accesses health care in a Member State which is not his/her state of social protection. The result of the legislative procedure has not literally followed the approach by the Court of Justice. Although, in some instances, the Directive enhances patients’ rights to reimbursement of health care abroad (namely, concerning unplanned health care), the additional grounds for imposing prior authorisation and possibilities to refuse reimbursement significantly weaken patients’ legal position. Furthermore, the Directive has added to the complexity of legal regulation of cross-border health care, since several parallel legal routes are now in existence covering the same area. The Court of Justice should use its future case-law to clarify the relevant legal framework.

On the other hand, Croatia’s legal framework will strengthen patient’s entitlements, provided the Directive is correctly transposed into the national setting. Possibilities to access health care abroad without prior authorisation, abolishing special contribution for foreign obtained treatments and more coherent legal framework are gains from the Directive’s future implementation in Croatia.

Finally, although Directive’s effects in terms of patients’ entitlements to social cover remain ambivalent, there are some additional gains from its adoption. The latter concern forms of new types of governance, based on co-operation and bottoms-up approach to policy problems. In terms of these developments, the Directive provides a push into the direction of a more active EU role in the area of health care. This Union role will primarily be present within the realm of help and guidance in complementing national health care policies.