EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

Brussels, 21 February 2011
(OR. en)

2008/0142 (COD) **PE-CONS 6/11**

SAN 11
SOC 57
MI 36
CODEC 113

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare

In accordance with Article 294(8) of the Treaty on the Functioning of the European Union,

this document will not be the subject of approval by the Council;

it is intended solely for the information of delegates

DIRECTIVE 2011/.../EU
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

on the application of patients' rights in cross-border healthcare

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure[3],

---

1 OJ C 175, 28.7.2009, p. 116.
2 OJ C 120, 28.5.2009, p. 65.
3 Position of the European Parliament of 23 April 2009 (OJ C 184 E, 8.7.2010, p. 368), position of the Council at first reading of 3 September 2010 (OJ C 275 E, 12,10.2010, p. 1), position of the European Parliament of 19 January 2011.

Whereas:

(1) According to Article 168(1) of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. This implies that a high level of human health protection is to be ensured also when the Union adopts acts under other Treaty provisions.

(2) Article 114 TFEU is the appropriate legal basis since the majority of the provisions of this Directive aim to improve the functioning of the internal market and the free movement of goods, persons and services. Given that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, Union legislation has to rely on this legal basis even when public health protection is a decisive factor in the choices made. In this respect, Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health is to be guaranteed taking account in particular of any new development based on scientific facts.

(3) The health systems in the Union are a central component of the Union's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.

(4) Notwithstanding the possibility for patients to receive cross-border healthcare under this Directive, Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. Furthermore, the transposition of this Directive into national legislation and its application should not result in patients being encouraged to receive treatment outside their Member State of affiliation.

(5) As recognised by the Council in its Conclusions of 1-2 June 2006 on Common values and principles in European Union Health Systems[1] (hereinafter the "Council Conclusions") there is a set of operating principles that are shared by health systems throughout the Union. Those operating principles are necessary to ensure patients' trust in cross-border healthcare, which is necessary for achieving patient mobility as well as a high level of health protection. In the same statement, the Council recognised that the practical ways in which these values and principles become a reality vary significantly between Member States. In particular, decisions about the basket of healthcare to which citizens are entitled and the mechanisms used to finance and deliver that healthcare, such as the extent to which it is appropriate to rely on market mechanisms and competitive pressures to manage health systems, must be taken in the national context.

[1] OJ C 146, 22.6.2006, p. 1.

(6) As confirmed by the Court of Justice of the European Union (hereinafter the "Court of Justice") on several occasions, while recognising their specific nature, all types of medical care fall within the scope of the TFEU.

(7) This Directive respects and is without prejudice to the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States.

(8) Some issues relating to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have already been addressed by the Court of Justice. This Directive is intended to achieve a more general, and also effective, application of principles developed by the Court of Justice on a case-by-case basis.

(9) In the Council Conclusions, the Council recognised the particular value of an initiative on cross-border healthcare ensuring clarity for Union citizens about their rights and entitlements when they move from one Member State to another, in order to ensure legal certainty.

(10) This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.

(11) This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.

(12) The concept of "overriding reasons of general interest" to which reference is made in certain provisions of this Directive has been developed by the Court of Justice in its case law in relation to Articles 49 and 56 TFEU and may continue to evolve. The Court of Justice has held on a number of occasions that overriding reasons of general interest are capable of justifying an obstacle to the freedom to provide services 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. The Court of Justice has likewise acknowledged that the objective of maintaining, a balanced medical and hospital service open to all may also fall within one of the derogations, on grounds of public health, provided for in Article 52 TFEU in so far as it contributes to the attainment of a high level of health protection. The Court of Justice has also held that such provision of the TFEU permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health.

(13) It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation.

(14) This Directive should not apply to services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks. More specifically, this Directive should not apply to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined a life as possible. Thus, this Directive should not apply, for example, to long-term care services provided by home care services, in assisted living facilities and in residential homes or housing ("nursing homes").

(15) Given their specificity, access to and the allocation of organs for the purpose of organ transplants should fall outside the scope of this Directive.

(16) For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service. The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued.

(17) This Directive should not affect Member States' rules concerning the sale of medicinal products and medical devices over the internet.

(18) This Directive should not give any person an entitlement to enter, stay or reside in a Member State in order to receive healthcare in that State. Where the stay of a person on the territory of a Member State is not in accordance with the legislation of that Member State concerning the right to enter or stay on its territory, such person should not be regarded as an insured person according to the definition in this Directive. Member States should continue to be able to specify in their national legislation who is considered as an insured person for the purposes of their public healthcare scheme and social security legislation as long as the patients' rights set out in this Directive are secured.

(19) When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. The rules applicable to cross-border healthcare should be those set out in the legislation of the Member State of treatment, given that, in accordance with Article 168(7) TFEU, the organisation and delivery of health services and medical care is the responsibility of the Member States. This should help the patient in making an informed choice, and should avoid misapprehension and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider.

(20) In order to help patients to make an informed choice when they seek to receive healthcare in another Member State, Member States of treatment should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which healthcare providers are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on specific aspects of the healthcare services they offer and on the treatment options. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.

(21) In its Conclusions the Council recognised that there is a set of common values and principles that are shared across the Union about how health systems respond to the needs of the population and patients that they serve. The overarching values of universality, access to good quality care, equity, and solidarity have been widely acknowledged in the work of various Union institutions. Therefore, Members States should also ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare needs rather than on the basis of their Member State of affiliation. In doing so, Member States should respect the principles of free movement of persons within the internal market, non-discrimination, inter alia with regard to nationality and necessity and proportionality of any restrictions on free movement. However, nothing in this Directive should oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients, for instance by increasing the waiting time for treatment of other patients. Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health, in accordance with Articles 52 and 62 TFEU. However, this limitation should be without prejudice to Member States' obligations under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems[1].

[1] OJ L 166, 30.4.2004, p. 1.

(22) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technologies.

(23) Ensuring clear common obligations in respect of the provision of mechanisms for responding to harm arising from healthcare is essential to prevent lack of confidence in those mechanisms being an obstacle to taking up cross-border healthcare. Systems for addressing harm in the Member State of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate for the patient.

(24) Member States should ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it should be for the Member State to determine the nature and modalities of such a mechanism.

(25) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patients' health. These personal data should be able to flow from one Member State to another, but at the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[1] establishes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.

(26) The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through eHealth services.

---

[1] OJ L 281, 23.11.1995, p. 31.

(27) In accordance with the principles established by the Court of Justice, and without endangering the financial balance of Member States' healthcare and social security systems, greater legal certainty as regards the reimbursement of healthcare costs should be provided for patients and for health professionals, healthcare providers and social security institutions.

(28) This Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004. In addition, this Directive should not affect an insured person's right to be granted an authorisation for treatment in another Member State where the conditions provided for by Union regulations on the coordination of social security systems are met, in particular by Regulation (EC) No 883/2004 or Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community[1], which are applicable by virtue of Regulation (EU) No 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[2] and Council Regulation (EC) No 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[3].

---

1 OJ L 149, 5.7.1971, p. 2.
2 OJ L 344, 29.12.2010, p. 1.
3 OJ L 124, 20.5.2003, p. 1.

(29) It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free movement of patients, services and goods in accordance with the TFEU and with this Directive. Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.

(30) For patients, therefore, the two systems should be coherent; either this Directive applies or the Union regulations on the coordination of social security systems apply.

(31) Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive. Where the patient is entitled to cross-border healthcare under both this Directive and Regulation (EC) No 883/2004, and the application of that Regulation is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation.

(32) Patients should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to the actual costs of healthcare received.

(33) This Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person. Equally, this Directive should not prevent the Member States from extending their benefits-in-kind scheme to healthcare provided in another Member State. This Directive should recognise that Member States are free to organise their healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.

(34) Member States of affiliation should give patients the right to receive at least the same benefits in another Member State as those provided for by the legislation of the Member State of affiliation. If the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation. The fact that the obligation to reimburse cross-border healthcare under this Directive is limited to such healthcare that is among the benefits to which the patient is entitled within its Member State of affiliation does not preclude Member States from reimbursing the cost of cross-border healthcare beyond those limits. Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory.

(35) This Directive should not provide either for the transfer of social security entitlements between Member States or other coordination of social security systems. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State should be to enable freedom to provide healthcare for patients and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently this Directive should fully respect the differences in national healthcare systems and the Member States' responsibilities for the organisation and delivery of health services and medical care.

(36) This Directive should provide for the right for a patient to receive any medicinal product authorised for marketing in the Member State of treatment, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State. Nothing should oblige a Member State of affiliation to reimburse an insured person for a medicinal product prescribed in the Member State of treatment, where that medicinal product is not among the benefits provided to that insured person by the statutory social security system or national health system in the Member State of affiliation.

(37) Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State, provided that such conditions are necessary, proportionate to the aim, not discretionary or discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions should be made as quickly as possible. This should be without prejudice to the rights of the Member States to lay down criteria or conditions for prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.

(38) In the light of the case law of the Court of Justice, making the assumption by the statutory social security system or national health system of costs of healthcare provided in another Member State subject to prior authorisation is a restriction to the free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the assumption of the costs of healthcare provided in another Member State subject to prior authorisation, where the costs of that care, if it had been provided in its territory, would have been borne by its statutory social security system or national health system.

(39) Patient flows between Member States are limited and expected to remain so, as the vast majority of patients in the Union receive healthcare in their own country and prefer to do so. However, in certain circumstances patients may seek some forms of healthcare in another Member State. Examples include highly specialised care or healthcare provided in frontier areas where the nearest appropriate facility is on the other side of the border. Furthermore, some patients wish to be treated abroad in order to be close to their family members who are residing in another Member State, or in order to have access to a different method of treatment than that provided in the Member State of affiliation or because they believe that they will receive better quality healthcare in another Member State.

(40) According to the constant case law of the Court of Justice, Member States may make the assumption of costs by the national system of hospital care provided in another Member State subject to prior authorisation. The Court of Justice has judged that this requirement is both necessary and reasonable, since the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are equipped, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. The Court of Justice has found that such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. In addition, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. According to the Court of Justice, such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources made available for healthcare are not unlimited, whatever mode of funding is applied.

(41) The same reasoning applies to healthcare not provided in a hospital but subjected to similar planning needs in the Member State of treatment. This may be healthcare which requires planning because it involves use of highly specialised and cost-intensive medical infrastructure or medical equipment. In light of technological progress, the development of new methods of treatment and the different policies of the Member States regarding the roles of hospitals in their healthcare systems, the question of whether this kind of healthcare is delivered within hospital or ambulatory care facilities is not the decisive factor for deciding whether it requires planning or not.

(42) Given that the Member States are responsible for laying down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be for the Member States to decide whether there is a need to introduce a system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system in accordance with the criteria defined by this Directive and in the light of the case law of the Court of Justice. The information concerning this healthcare should be made publicly available in advance.

(43) The criteria attached to the grant of prior authorisation should be justified in the light of the overriding reasons of general interest capable of justifying obstacles to the free movement of healthcare, 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. The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all and the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. It is also important to take into consideration the general principle of ensuring the safety of the patient, in a sector well known for information asymmetry, when managing a prior authorisation system. Conversely, the refusal to grant prior authorisation may not be based on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment.

(44) According to the constant case law of the Court of Justice, the criteria for granting or refusing prior authorisation should be limited to what is necessary and proportionate in the light of these overriding reasons in the general interest. It should be noted that the impact on national health systems caused by patient mobility might vary between Member States or between regions within a Member State, depending on factors such as geographical location, language barriers, location of hospitals in border regions or the size of the population and healthcare budget. It should therefore be for Member States to set such criteria for refusing prior authorisation that are necessary and proportionate in that specific context, also taking into account which healthcare falls within the scope of the prior authorisation system, since certain treatments of a highly specialised nature will be more easily affected even by a limited patient outflow than others. Consequently, Member States should be able to set up different criteria for different regions or other relevant administrative levels for the organisation of healthcare, or indeed for different treatments, as long as the system is transparent and easily accessible and the criteria are made public in advance.

(45) Where the patient is entitled to healthcare and that healthcare cannot be provided within a time-limit which is medically justifiable, the Member State of affiliation should in principle be obliged to grant prior authorisation. However, in certain circumstances, cross-border healthcare may expose the patient or the general public to a risk which overrides the interest of the patient to receive the cross-border healthcare sought. In such instances, the Member State of affiliation should be able to refuse the request for prior authorisation, in which case the Member State of affiliation should direct the patient towards alternative solutions.

(46) In any event, if a Member State decides to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member State in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Regulation (EEC) No 1408/71 or Regulation (EC) No 883/2004 are fulfilled, the authorisation should be granted and the benefits provided in accordance with Regulation (EC) No 883/2004 unless otherwise requested by the patient. This should apply in particular in instances where the authorisation is granted after an administrative or judicial review of the request and the person concerned has received the treatment in another Member State. In that event, Articles 7 and 8 of this Directive should not apply. This is in line with the case law of the Court of Justice which has specified that patients who were refused prior authorisation on grounds that were subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

(47) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non-discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This should also apply to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment. It is appropriate that , under normal circumstances, patients be entitled to receive decisions regarding cross-border healthcare within a reasonable period of time. However, that period should be shortened where warranted by the urgency of the treatment in question.

(48) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for providing such information is to establish national contact points within each Member State. Information that has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may be provided in any other language.

(49) The Member States should decide on the form and number of their national contact points. Such national contact points may also be incorporated in, or build on, activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. National contact points should be established in an efficient and transparent way and they should be able to consult with patient organisations, healthcare insurers and healthcare providers. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare. The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Union level. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.

(50) Member States should facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient cross-border healthcare. This could be of particular importance in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local population, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology (hereinafter "ICT") systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis.
Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications[1] stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State is not, subject to specific provisions of Union law, to be restricted for any reason relating to professional qualifications. This Directive should be without prejudice to Directive 2005/36/EC.

[1] OJ L 255, 30.9.2005, p. 22.

(51) The Commission should encourage cooperation between Member States in the areas set out in Chapter IV of this Directive and may, in accordance with Article 168(2) TFEU, take, in close contact with the Member States, any useful initiative to facilitate and promote such cooperation. In that context, the Commission should encourage cooperation in cross-border healthcare provision at regional and local level, particularly by identifying major obstacles to collaboration between healthcare providers in border regions, and by making recommendations and disseminating information and best practices on how to overcome such obstacles.

(52) The Member State of affiliation may need to receive confirmation that the cross-border healthcare will or has been delivered by a legally practising health professional. It is therefore appropriate to ensure that information on the right to practise contained in the national or local registers of health professionals, if established in the Member State of treatment, are, upon request, made available to the authorities of the Member State of affiliation.

(53) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. The removal of regulatory and administrative barriers to such recognition should be without prejudice to the need for appropriate agreement of the patient's treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. The recognition of prescriptions from other Member States should not affect any professional or ethical duty that would require pharmacists to refuse to dispense the prescription. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products among the benefits covered by the social security system of affiliation. It should further be noted that the reimbursement of medicinal products is not affected by the rules on mutual recognition of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in Chapter III of this Directive. The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing should prevent Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States that contain the common list of elements from being recognised. The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

(54) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases. This Directive should therefore give incentives to Member States to reinforce the continued development of European reference networks. European reference networks are based on the voluntary participation of their members, but the Commission should develop criteria and conditions that the networks should be required to fulfil in order to receive support from the Commission.

(55) Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and they are all serious, chronic and often life threatening. Some patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy, difficulties which were also recognised by the Council Recommendation of 8 June 2009 on an action in the field of rare diseases[2].

---

1 OJ L 18, 22.1.2000, p. 1.
2 OJ C 151, 3.7.2009, p. 7.

(56) Technological developments in cross-border provision of healthcare through the use of ICTs may result in the exercise of supervisory responsibilities by Member States being unclear, and can thus hinder the free movement of healthcare and give rise to possible additional risks to health protection. Widely different and incompatible formats and standards are used for provision of healthcare using ICTs throughout the Union, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary for Member States to aim at interoperability of ICT systems. The deployment of health ICT systems, however, is entirely a national competence. This Directive therefore should recognise the importance of the work on interoperability and respect the division of competences by providing for the Commission and Member States to work together on developing measures which are not legally binding but provide additional tools that are available to Member States to facilitate greater interoperability of ICT systems in the healthcare field and to support patient access to eHealth applications, whenever Member States decide to introduce them.

(57) The interoperability of eHealth solutions should be achieved whilst respecting national regulations on the provision of healthcare services adopted in order to protect the patient, including legislation on internet pharmacies, in particular national bans on mail order of prescription-only medicinal products to the extent that they are compatible with the case law of the Court of Justice and Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts[1] and Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market[2].

(58) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoid duplication of effort, and provide a better evidence base for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. Such cooperation requires sustained structures involving all the relevant authorities of the Member States, building on existing pilot projects and consultation of a wide range of stakeholders. This Directive should therefore provide a basis for continued Union support for such cooperation.

---

1 OJ L 144, 4.6.1997, p. 19.
2 OJ L 178, 17.7.2000, p. 1.

(59) According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new Regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[1] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(60) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of measures that would exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, as provided for in this Directive. In order to identify the reference networks which should benefit from support by the Commission, the Commission should also be empowered to adopt delegated acts in respect of the criteria and conditions that European reference networks have to fulfil.

(61) It is of particular importance that, when empowered to adopt delegated acts in accordance with Article 290 TFEU, the Commission carry out appropriate consultations during its preparatory work, including at expert level.

---

[1] OJ L 184, 17.7.1999, p. 23.

(62) In accordance with point 34 of the Interinstitutional Agreement on better law-making[1], Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(63) The European Data Protection Supervisor has also delivered his opinion on the proposal for this Directive[2].

(64) Since the objective of this Directive, namely providing rules for facilitating the access to safe and high quality cross-border healthcare in the Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

---

1 OJ C 321, 31.12.2003, p. 1.
2 OJ C 128, 6.6.2009, p. 20.

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare. This Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.

2. This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

3. This Directive shall not apply to:

   (a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;

(b) allocation of and access to organs for the purpose of organ transplants;

(c) with the exception of Chapter IV, 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.

4. This Directive shall not affect laws and regulations in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. In particular, nothing in this Directive obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.

Article 2

Relationship with other Union provisions

This Directive shall apply without prejudice to:

(a) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems[1];

[1] OJ L 40, 11.2.1989, p. 8.

(b) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[1], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[2] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[3];

(c) Directive 95/46/EC and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector[4];

(d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services[5];

(e) Directive 2000/31/EC;

(f) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin[6];

(g) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[7];

---

1 OJ L 189, 20.7.1990, p. 17.
2 OJ L 169, 12.7.1993, p. 1.
3 OJ L 331, 7.12.1998, p. 1.
4 OJ L 201, 31.7.2002, p. 37.
5 OJ L 18, 21.1.1997, p. 1.
6 OJ L 180, 19.7.2000, p. 22.
7 OJ L 121, 1.5.2001, p. 34.

(h) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[1];

(i) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[2];

(j) Regulation (EC) No 859/2003;

(k) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[3];

(l) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4];

(m) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems[5];

---

1 OJ L 311, 28.11.2001, p. 67.
2 OJ L 33, 8.2.2003, p. 30.
3 OJ L 102, 7.4.2004, p. 48.
4 OJ L 136, 30.4.2004, p. 1.
5 OJ L 284, 30.10.2009, p. 1.

(n) Directive 2005/36/EC;

(o) Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC)[1];

(p) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work[2];

(q) Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)[3], Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)[4] and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law;

(r) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation[5];

(s) Regulation (EU) No 1231/2010.

---

1 OJ L 210, 31.7.2006, p. 19.
2 OJ L 354, 31.12.2008, p. 70.
3 OJ L 177, 4.7.2008, p. 6.
4 OJ L 199, 31.7.2007, p. 40.
5 OJ L 207, 6.8.2010, p. 14.

Article 3

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) "healthcare" means 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;

(b) "insured person" means:

(i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation, and

(ii) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits;

(c) "Member State of affiliation" means:

(i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009,

(ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to that Regulation, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State;

(d) "Member State of treatment" means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established;

(e) "cross-border healthcare" means healthcare provided or prescribed in a Member State other than the Member State of affiliation;

(f) "health professional" means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment;

(g) "healthcare provider" means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State;

(h) "patient" means any natural person who seeks to receive or receives healthcare in a Member State;

(i) "medicinal product" means a medicinal product as defined by Directive 2001/83/EC;

(j) "medical device" means a medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;

(k) "prescription" means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued;

(l) "health technology" means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare;

(m) "medical records" means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process.

CHAPTER II
RESPONSIBILITIES OF MEMBER STATES WITH REGARD TO CROSS-BORDER HEALTH CARE

Article 4

Responsibilities of the Member State of treatment

1. Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with:

(a) the legislation of the Member State of treatment;

(b) standards and guidelines on quality and safety laid down by the Member State of treatment; and

(c) Union legislation on safety standards.

2. The Member State of treatment shall ensure that:

(a) patients receive from the national contact point referred to in Article 6, upon request, relevant information on the standards and guidelines referred to in point (b) of paragraph 1 of this Article, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities;

(b) healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and that they also provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;

(c) there are transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

(d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;

(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

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

3. The principle of non-discrimination with regard to nationality shall be applied to patients from other Member States.

This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by 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, to adopt measures regarding access to treatment aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare within its territory. Such measures shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination and shall be made publicly available in advance.

4. 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 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.

5. This Directive shall not affect laws and regulations in Member States on the use of languages. Member States may choose to deliver information in other languages than those which are official languages in the Member State concerned.

Article 5

Responsibilities of the Member State of affiliation

The Member State of affiliation shall ensure that:

(a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;

(b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with Article 7(6) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with Article 9. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004;

(c) where a patient has received cross-border healthcare and where medical follow-up proves necessary, the same medical follow-up is available as would have been if that healthcare had been provided on its territory;

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

Article 6

National contact points for cross-border healthcare

1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission. The Commission and the Member States shall make this information publicly available. Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers.

2. National contact points shall facilitate the exchange of information referred to in paragraph 3 and shall cooperate closely with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.

3. In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with 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.

4. National contact points in the Member State of affiliation shall provide patients and health professionals with the information referred to in Article 5(b).

5. The information referred to in this Article shall be easily accessible and shall be made available by electronic means and in formats accessible to people with disabilities, as appropriate.

CHAPTER III
REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTHCARE

Article 7

General principles for reimbursement of costs

1. Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

2. By way of derogation from paragraph 1:

(a) 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;

(b) 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. That Member State may assume the costs of the healthcare in accordance with the terms, conditions, criteria for eligibility and regulatory and administrative formalities that it has established, provided that these are compatible with the TFEU.

3. It is for the Member State of affiliation to determine, whether at a local, regional or national level, the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided.

4. The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.

Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.

The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs.

5. Member States may adopt provisions in accordance with the TFEU aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

6. For the purposes of paragraph 4, Member States shall have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level.

7. The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods**,** unless it is objectively justified by 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.

8. The Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorisation except in the cases set out in Article 8.

9. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare 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.

10. Notwithstanding paragraph 9, Member States shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed in accordance with the authorisation.

11. The decision to limit the application of this Article pursuant to paragraph 9 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. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9.

Article 8

Healthcare that may be subject to prior authorisation

1. The Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare, in accordance with this Article and Article 9. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

2. Healthcare that may be subject to prior authorisation shall be limited to healthcare 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.

Member States shall notify the categories of healthcare referred to in point (a) to the Commission.

3. With regard to requests for prior authorisation made by an insured person with a view to receiving cross-border healthcare, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation unless the patient requests otherwise.

4. When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice.

5. Without prejudice to points (a) to (c) of paragraph 6, the Member State of affiliation may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with Article 7**,** and when this healthcare cannot be provided on its territory within a time-limit which is medically justifiable**,** based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed.

6. The Member State of affiliation may refuse to grant prior authorisation for the following reasons:

   (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;

(d) this 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.

7. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.

Article 9

Administrative procedures regarding cross-border healthcare

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved.

2. Any administrative procedure of the kind referred to in paragraph 1 shall be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. Such a procedure shall be capable of ensuring that requests are dealt with objectively and impartially.

3. Member States shall set out reasonable periods of time within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member states shall take into account:

   (a) the specific medical condition,

   (b) the urgency and individual circumstances.

4. Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

5. This Directive is without prejudice to Member States' right to offer patients a voluntary system of prior notification whereby, in return for such notification, the patient receives a written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply.

Member States may choose to apply the mechanisms of financial compensation between the competent institutions as provided for by Regulation (EC) No 883/2004. Where a Member State of affiliation does not apply such mechanisms, it shall ensure that patients receive reimbursement without undue delay.

CHAPTER IV
COOPERATION IN HEALTHCARE

Article 10

Mutual assistance and cooperation

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their national contact points in accordance with Article 6**,** including on provisions on supervision and mutual assistance to clarify the content of invoices.

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through ICT and other forms of cross-border cooperation.

3. The Commission shall encourage Member States, particularly neighbouring countries, to conclude agreements among themselves. The Commission shall also encourage the Member States to cooperate in cross-border healthcare provision in border regions.

4. Member States of treatment shall ensure that information on the right to practise of health professionals listed in national or local registers established on their territory is, upon request, made available to the authorities of other Member States, for the purpose of cross-border healthcare, in accordance with Chapters II and III and with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, and the principle of presumption of innocence. The exchange of information shall take place via the Internal Market Information system established pursuant to Commission Decision 2008/49/EC of 12 December 2007 concerning the implementation of the Internal Market Information System (IMI) as regards the protection of personal data[1].

Article 11

Recognition of prescriptions issued in another Member State

1. If a medicinal product is authorised to be marketed on their territory, in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:

   (a) limited to what is necessary and proportionate to safeguard human health, and non-discriminatory, or

[1] OJ L 13, 16.1.2008, p. 18.

(b) based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of medicinal products is covered by Chapter III of this Directive.

In particular, the recognition of prescriptions shall not affect a pharmacist's right, by virtue of national rules, to refuse, for ethical reasons, to dispense a product that was prescribed in another Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

The Member State of affiliation shall take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation.

This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.

2. In order to facilitate implementation of paragraph 1, the Commission shall adopt:

(a) measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;

(b) guidelines supporting the Member States in developing the interoperability of ePrescriptions;

(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;

(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.

Measures referred in point (a) shall be adopted by the Commission no later than ...* and measures in points (c) and (d) shall be adopted by the Commission no later than ...**.

3. The measures and guidelines referred to in points (a) to (d) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

4. In adopting measures or guidelines under paragraph 2, the Commission shall have regard to the proportionality of any costs of compliance with, as well as the likely benefits of, the measures or guidelines.

5. For the purpose of paragraph 1, the Commission shall also adopt, by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19 and no later than …** measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions provided for under this Article, where necessary in order to safeguard public health.

6. Paragraph 1 shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

---

* OJ: Please insert the date - 20 months after the date of entry into force of this Directive.

** OJ: Please insert the date - 18 months after the date of entry into force of this Directive.

Article 12

European reference networks

1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.

2. European reference networks shall have at least three of the following objectives:

   (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;

   (b) to contribute to the pooling of knowledge regarding sickness prevention;

(c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;

(d) to maximise the cost-effective use of resources by concentrating them where appropriate;

(e) to reinforce research, epidemiological surveillance like registries and provide training for health professionals;

(f) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;

(g) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;

(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.

3. Member States are encouraged to facilitate the development of the European reference networks:

(a) by connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory;

(b) by fostering the participation of healthcare providers and centres of expertise in the European reference networks.

4. For the purposes of paragraph 1, the Commission shall:

(a) adopt a list of specific criteria and conditions that the European reference networks must fulfil and the conditions and criteria required from healthcare providers wishing to join the European reference network. These criteria and conditions shall ensure, inter alia, that European reference networks:

(i) have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;

(ii) follow a multi-disciplinary approach;

(iii) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;

(iv) make a contribution to research;

(v) organise teaching and training activities; and

(vi) collaborate closely with other centres of expertise and networks at national and international level.

(b) develop and publish criteria for establishing and evaluating European reference networks;

(c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and their evaluation.

5. The Commission shall adopt the measures referred to in point (a) of paragraph 4 by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19. The measures referred to in points (b) and (c) of paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

6. Measures adopted pursuant to this Article shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

Article 13

Rare diseases

The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

(a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;

(b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

Article 14

eHealth

1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2. The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders, and

(ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

Article 15

Cooperation on health technology assessment

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

2. The objectives of the health technology assessment network shall be to:

   (a) support cooperation between national authorities or bodies;

(b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;

(c) support the analysis of the nature and type of information that can be exchanged;

(d) avoid duplication of assessments.

3. In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:

(a) contribute to the financing of administrative and technical support;

(b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;

(c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;

(d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;

(e) facilitate the consultation of stakeholders on the work of the network.

4. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

5. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.

6. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.

7. Measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

CHAPTER V
IMPLEMENTING AND FINAL PROVISIONS

Article 16

Committee

1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

   The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

Article 17

Exercise of the delegation

1. The powers to adopt delegated acts referred to in Article 11(5) and Article 12(5) shall be conferred on the Commission for a period of five years from ...*. The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 18.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 18 and 19.

Article 18

Revocation of the delegation

1. The delegation of power referred to in Article 11(5) and 12(5) may be revoked at any time by the European Parliament or by the Council.

---

* OJ: please insert the date of entry into force of this Directive.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 19

Objections to delegated acts

1. The European Parliament or the Council may object to the delegated act within a period of two months from the date of notification.

   At the initiative of the European Parliament or the Council this period shall be extended by two months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 20

Reports

1. The Commission shall by …* and subsequently every three years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.

2. The report shall in particular include information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and Article 8, and on the functioning of the European reference networks and national contact points. To this end, the Commission shall conduct an assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Union legislation relating to patient mobility.

---

* OJ: Please insert the date - 54 months from the date of entry into force of this Directive.

The Member States shall provide the Commission with assistance and all available information for carrying out the assessment and preparing the reports.

3. Member States and the Commission shall have recourse to the Administrative Commission established under Article 71 of Regulation (EC) No 883/2004, in order to address the financial consequences of the application of this Directive on the Member States which have opted for reimbursement on the basis of fixed amounts, in cases covered by Articles 20(4) and 27(5) of that Regulation.

The Commission shall monitor and regularly report on the effect of Article 3(c)(i) and Article 8 of this Directive. A first report shall be presented by …*. On the basis of these reports, the Commission shall, where appropriate, make proposals to alleviate any disproportionalities.

Article 21

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by …*. They shall forthwith inform the Commission thereof.

* OJ: Please insert the date - 30 months from the date of entry into force of this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 22

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 23

Addressees

This Directive is addressed to the Member States.

Done at

For the European Parliament	*For the Council*
The President	*The President*