►B DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2011

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

(OJ L 88, 4.4.2011, p. 45)

Amended by:

		Official Journal		
		No	page	date
►M1	Council Directive 2013/64/EU of 17 December 2013	L 353	8	28.12.2013
►M2	Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021	L 458	1	22.12.2021
►M3	Directive (EU) 2024/2839 of the European Parliament and of the Council of 23 October 2024	L 2839	1	7.11.2024

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DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2011

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

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.

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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]);

(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 ([2]), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([3]) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ([4]);

(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 ([5]);

(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 ([6]);

(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 ([7]);

(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 ([8]);

(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 ([9]);

(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 ([10]);

(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 ([11]);

([1]) OJ L 40, 11.2.1989, p. 8.
([2]) OJ L 189, 20.7.1990, p. 17.
([3]) OJ L 169, 12.7.1993, p. 1.
([4]) OJ L 331, 7.12.1998, p. 1.
([5]) OJ L 201, 31.7.2002, p. 37.
([6]) OJ L 18, 21.1.1997, p. 1.
([7]) OJ L 180, 19.7.2000, p. 22.
([8]) OJ L 121, 1.5.2001, p. 34.
([9]) OJ L 311, 28.11.2001, p. 67.
([10]) OJ L 33, 8.2.2003, p. 30.
([11]) OJ L 102, 7.4.2004, p. 48.

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(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 ([1]);

(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 ([2]);

(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) ([3]);

(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 ([4]);

(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) ([5]), 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) ([6]) 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 ([7]);

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

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

([1]) OJ L 136, 30.4.2004, p. 1.
([2]) OJ L 284, 30.10.2009, p. 1.
([3]) OJ L 210, 31.7.2006, p. 19.
([4]) OJ L 354, 31.12.2008, p. 70.
([5]) OJ L 177, 4.7.2008, p. 6.
([6]) OJ L 199, 31.7.2007, p. 40.
([7]) OJ L 207, 6.8.2010, p. 14.

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(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 Regulations (EC) No 883/2004 and (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 those Regulations, 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;

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(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 paragraph 1(b) 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;

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(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;

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(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

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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

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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

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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:

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(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.

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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]).

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

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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

(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;

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(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 25 December 2012 and measures in points (c) and (d) shall be adopted by the Commission no later than 25 October 2012.

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 25 October 2012 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.

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:

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(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;

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(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 paragraph 4(a) 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:

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(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.

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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 3 months.

Article 17

Exercise of the delegation

1. The powers to adopt delegated acts referred to in Articles 11(5) and 12(5) shall be conferred on the Commission for a period of 5 years from 24 April 2011. The Commission shall make a report in respect of the delegated powers not later than 6 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.

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Article 18

Revocation of the delegation

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

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 2 months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by 2 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

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1. The Commission shall, by 25 October 2027 and subsequently every 5 years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.

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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.

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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 pursuant to 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 25 October 2013. 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 25 October 2013. They shall forthwith inform the Commission thereof.

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.

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3. By way of derogation from the first sentence of paragraph 1, France shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive in respect of Mayotte as an outermost region within the meaning of Article 349 TFEU by 30 June 2016.

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Article 22

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 23

Addressees

This Directive is addressed to the Member States.