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 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.