

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 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.

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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.