SUBSIDIARY LEGISLATION 528.03

CROSS-BORDER HEALTHCARE REGULATIONS

25th October, 2013*

LEGAL NOTICE 389 of 2013, as amended by Legal Notice 473 of 2014 and 173 of 2019.

General Provisions

Citation and scope.

1. (1) The title of these regulations is the Cross-Border Healthcare Regulations.

(2) These regulations implement the provisions of 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.

Interpretation.
Amended by: L.N. 473 of 2014; L.N. 173 of 2019.

2. In these regulations, unless the context otherwise requires -

"Commission" means the European Commission;

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

"Government Formulary List" shall have the same meaning as is assigned to it in regulation 5 of the Availability of Medicinal Products within the Government Health Services Regulations; S.L. 458.31

"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;

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

"insured person" means an insured person under the Social Security Act, as well as their dependent member of the family as defined under the Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, residing with the insured person, as well as, any person entitled to a pension under the Social Security Act, and where applicable, survivors as provided for under the Social Security Act, residing with the insured person immediately preceding the death of the insured person; Cap. 318.

"local private healthcare provider" means any healthcare provider established under whatsoever form on the Maltese territory;

"medical device" means a medical device as defined in the Medical Devices Regulations; S.L. 427.44

*see regulation 1(3) of these Regulations, as originally promulgated.

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"medicinal product" means a medicinal product as defined in the Medicines Act;

"Member State of affiliation" means the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State;

"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;

"Minister" means the Minister responsible for health;

"national contact point" means the national contact point for cross-border healthcare established by regulation 4;

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

"prescription" means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession;

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"Register" means the register established by article 25 of the Health Act.

The competent authority.

3. The Department for Policy in Health shall be the competent authority responsible for all matters pertaining to cross-border healthcare.

The National Contact Point for Cross-Border Healthcare

Establishment of national contact point.

4. There shall be a national contact point for the purposes of cross-border healthcare, hereinafter called the national contact point, having such powers and functions as set out in these regulations.

Seat of the national contact point.

5. The national contact point shall have its office at such address as the Minister for Health may, from time to time, determine.

Mission of the national contact point.

6. It shall be the mission of the national contact point to be the main point of reference for all matters related to information on cross-border healthcare, including the provision of information to patients, patients' organisations, healthcare providers, healthcare insurers and other contact points of other Member States.

Functions of the national contact point.
Amended by: L.N. 473 of 2014.

7. (1) The national contact point shall have those functions, in general, as may be prescribed by the Minister from time to time, but in particular these shall include:

(*a*) the cooperation with the Commission and with the other contact points of other Member States on matters relating to cross-border healthcare;

(*b*) the consultation with patient organisations, healthcare providers and healthcare insurers;

(*c*) the facilitation of the exchange of information referred to in paragraph (*d*) and the cooperation with other contact points;

(*d*) the provision to patients and health professionals, on

their request and in accordance with established practices, of information related to:

(i) the contact details of national contact points in other Member States;

(ii) their rights and entitlements related to receiving cross-border healthcare including the terms and conditions for prior authorisation and the reimbursement of costs;

(iii) procedures for accessing and determining those entitlements;

(iv) healthcare providers, including information on a specific provider's right to provide services and any restrictions on its practice;

(v) patients' rights in relation to cross-border care in accordance with these regulations;

(vi) complaints procedures and mechanisms for seeking remedies in relation to cross-border healthcare in accordance with these regulations;

(vii) the legal and administrative options available for settling disputes, including those related to harm arising from cross-border healthcare;

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

(ix) the elements to be included in prescriptions issued in a Member State other than the Member State where they are dispensed, as provided for in the Prescription and Dispensing Requirement Rules. S.L.458.49

(2) The national contact point shall ensure that all relevant information requested under the Act and under these regulations, including all contact details, shall be readily available to the public, including by electronic means and in formats accessible to persons with a disability, as appropriate.

(3) The national contact point shall act as the Technical Secretariat for the Cross-Border Prior Authorisations Committee established under these regulations. It shall also be the function of the national contact point to communicate to the patient whether authorisation has been granted or not in accordance with regulation 11(5).

(4) The national contact point shall be responsible to receive claims for reimbursement and for determining whether such claims fulfil conditions for reimbursement under these regulations.

Reimbursement of Cross-Border Healthcare

Conditions for reimbursement. *Amended by: L.N. 473 of 2014.*

8. (1) The costs related to cross-border healthcare shall only be reimbursed to an insured person after all the conditions laid down in these regulations have been satisfied and if the healthcare for which reimbursement is being requested forms part of the Register provided for in the Act:

Provided that notwithstanding the above, for the purpose of cross-border care, organ transplants, vaccination programmes against infectious diseases, long-term and community care services are excluded.

In respect of medicines, medicinal products and medical devices, reimbursement of cross-border health care shall refer only to those instances where these are provided in the context of a health service and where such products form part of the Government Formulary List.

(2) An insured person who is resident in a Member State other than in Malta, and for whom Malta is the competent Member State under Regulation (EC) No. 883/2004, shall be entitled to the services offered by the Maltese public healthcare system at the same conditions of other insured persons residing in Malta, if such a service:

(*a*) is not a service requiring prior authorisation in the Member State where the insured person resides; and

(*b*) is not provided in accordance with Chapter 1 of Title III of Regulation (EC) No 883/2004.

(3) No costs shall be reimbursed in relation to healthcare provided by local private healthcare providers.

Maximum reimbursement. *Amended by: L.N. 473 of 2014.*

9. (1) The maximum amount of costs to be reimbursed shall be either the amount of the relative healthcare service or services costs according to the Register provided for in the Act, or the actual costs of the healthcare service or services received, whichever is the lowest. No ancillary or related costs shall be reimbursed.

(2) Reimbursement of the costs of cross-border healthcare shall be subject to the same conditions, criteria of eligibility and regulatory and administrative formalities, as applicable if this healthcare was provided under the Maltese public healthcare system:

Provided that notwithstanding the above, the Directorate for Policy in Health shall retain the right to 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 Malta or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources:

Provided further that the same conditions, criteria of eligibility, tariffs and regulatory and administrative formalities shall apply in the case of a person insured in a Member State, other than Malta, seeking cross-border healthcare under the Maltese public healthcare system.

(3) Notwithstanding anything contained in these regulations, any cross-border healthcare for which a prior authorisation has already been granted, even before the entry into force of these regulations, shall be reimbursed in accordance with that same authorisation.

(4) Notwithstanding the provisions of this regulation, the Minister shall retain the right to adopt measures regarding access to treatment aimed at fulfilling the fundamental responsibility to ensure sufficient and permanent access to healthcare within Malta and that are justified by overriding reasons of general interest.

Healthcare subject to Prior Authorisation

Healthcare subject to prior authorisation.

10. (1) No insured person seeking to exercise his rights under these regulations shall be required to seek prior authorisation for the treatment sought save under the following circumstances:

(*a*) if it involves hospital accommodation of the patient in question for at least one night; or

(*b*) if it requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or

(*c*) if it involves treatments presenting a particular risk for the patient or the population, or

(*d*) if it is provided by a healthcare provider that 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 European Union legislation ensuring a minimum level of safety and quality throughout the European Union.

(2) For the purpose of this regulation, the Directorate for Policy in Health shall publish a list of procedures which shall be known as the List of Procedures Requiring Prior Authorisation for Cross-Border Healthcare, and which may be updated from time to time, that require prior authorisation under sub-regulation (1).

Refusal of prior authorisation.

11. (1) Prior authorisation may be refused 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 in Malta 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.

(2) Without prejudice to the provisions of paragraphs (*a*) to (*c*) of sub-regulation (1), prior authorisation may not be refused when this healthcare cannot be provided in Malta 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.

(3) There shall be established a Committee, to be appointed by the Minister and to be known as the Cross-Border Prior Authorisations Committee, whose function shall be to ascertain whether all the conditions laid down under the Act and under these regulations have been met and to decide whether such prior authorisations shall be granted.

(4) Any request for cross-border healthcare shall be dealt with within a period of six weeks from the date such request is received, unless the urgency of the case or the particular medical condition requires a shorter period.

(5) Any decision taken regarding the use of cross-border healthcare and, or reimbursement, shall be properly reasoned and forwarded to the patient, and subject to appeal under the provisions of the Act.

Information to patients. *Added by: L.N. 473 of 2014.*

12. Healthcare providers shall 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 Malta. They shall 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.

Medical follow-ups. *Added by: L.N. 473 of 2014.*

13. A person receiving cross-border healthcare shall be entitled to the medical follow-up in Malta, as prescribed, but only insofar as such a follow-up is provided for in the Register and insofar as it forms part of the Government Formulary List. Such a medical follow-up shall also be subject to the same access criteria required for similar follow-ups for healthcare provided in Malta.