

# CUATRECASAS, GONÇALVES PEREIRA



## NEWSLETTER | HEALTH LAW

NEWSLETTER HEALTH LAW September – October, 2014

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## NEWSLETTER HEALTH LAW

### I. NATIONAL REFERENCE CENTERS

Following publication of Law no. 52/2014, of 25 August, on cross-border healthcare, the Ministry of Health will identify, approve and officially recognized national reference centers, particularly for diagnosis and treatment of rare diseases. To that extent, was published in September 30, 2014, the Order no. 194/2014, of 30 September, establishing the concept, the identification process, approval and recognition from the National Reference Centres for the care of health, particularly for diagnosis and treatment of rare diseases.

The reference centers are defined in this legal framework as any type of service, department or health facility, recognized as the highest exponent of expertise in providing quality health care in clinical situations that require a concentration of highly differentiated technical and technological resources, knowledge and experience, due to the low prevalence of the disease, the complexity in diagnosis or treatment and / or the high cost of it, being able to conduct postgraduate education and scientific research in their respective medical fields.

The process for recognition of the National Reference Centers is also established in this Order, being the Regulation on the Application for the Recognition of Reference Centers an attachment to this Order.

This recognition process is a responsibility of the Ministry of Health and is formalized by decision of the member of the Government responsible for the health sector, and valid for a 4 year period, without prejudice of the Centers being subjected to periodic evaluation by external audit, in order to verify the compliance of the general and specific requirements that were the basis of their recognition.

By this Order it is also incorporated the National Commission for the Reference Centers, which, among others, has an essential role in the recognition of Reference Centers, with the aim to propose to the responsible member of the Government the recognition decision, or the termination of such recognition as a Reference Center.

Members of the National Commission for the Reference Centers were appointed by Order No. 13163-C / 2014 and must submitted before December 15, 2014 a report on priority areas for the establishment of reference centers.

### II. UNCONVENTIONAL THERAPIES

The activity relating to non-conventional therapies has recently been subject to extensive regulation.

The Order No. 182/2014 of 12 September came to establish the minimum requirements of organization and operation, human resources and technical facilities related to the activity of non-conventional therapies. Accordingly, the organization and functioning of unconventional therapies are now subject to compliance with the rules of safety and

quality issued by the Directorate-General for Health and, mutatis mutandis, to the legal regime of private health care units.

In addition, it was established that the private clinics and practitioners of unconventional therapies should follow certain rules on public information, namely: should be visible to the public the opening hours, identification of the clinical director, the procedures to be adopted in emergencies, the rights and obligations of users and the price list. It is also determined that the clinics shall keep the therapeutic records of their users.

As for human resources, the Order stipulated a period of one year after its entry into force of the issuance of the regulation for obtaining of the professional certificate for those responsible for carrying out the clinical direction, that is, until October 2016.

In what respects technical requirements, it was established that the clinics or practitioners shall observe general standards on construction, safety and privacy. Additionally, the waste management should directly assured by the clinic or using third-party in accordance with the applicable legal provisions. Finally, it was established that whenever clinic of unconventional therapeutic also provides medical services, they must meet the demands and requirements listed on their diplomas.

Also, in what respects the legal requirements to access the professional practice of unconventional therapies, Order no. 182-A/2014 of 12 September came to fix the amount of fees payable for professional registration and issuance of professional licenses in € 60. We also note Order no. 200/2014 of 3 October, which clarifies that the professionals of unconventional therapies should conclude a liability insurance with a minimum value of € 150,000 annuity and accident, including claims for direct damages , indirect, moral as well as legal defense, appeal and court costs..

Finally, the seven legal categories of non conventional therapeutic activities which have been regulated are: ((i) naturopathic (ii) osteopathy, (iii) homeopathy (iv) chiropractic (v) herbal medicine (vi) acupuncture and (vii) traditional Chinese medicine. This new regulation was passed through a set of ordinances that came to characterize and establish the professional content of each category.

### III. NATIONAL LEGISLATION

#### **Tackling irregularities in the fields of Medicine and Complementary Methods of Diagnosis and Therapy**

**Order No. 11111/2014. D. R. No. 168, Series II, 2014-09-02**

**Ministry of Health – Minister’s Office**

Renewal of the Working Group “Tackling irregularities in the fields of Medicine and Complementary Methods of Diagnosis and Therapy” mandate.

**Order No. 12984/2014. D. R. No. 206/2014, Series II of 2014-10-24**

**Ministry of Health – Minister’s Office**

Establishment of the Working Group "Tackling irregularities in the fields of Medicine and Complementary Methods of Diagnosis and Therapy".

**Emergency Services**

**Order No. 11226/2014. D. R. No. 171, Series II of 2014-09-05**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Determines the implementation of the processes that promote clinical computerization of Emergency Services.

**National Network for Integrated Continuous Care**

**Resolution No. 174/2014. D. R. No. 174, Series I of 2014-09-10**

**Ministries of Finance, Health and Solidarity, Employment and Social Security**

Defines the conditions of establishment and operation to be followed by inpatient units and outpatient and operating conditions of the management teams and the teams highest integrated continuous care of the National Network for Integrated Continuous Care.

**Advertising**

**Order No. 11344/2014. D. R. No. 174, Series II of 2014-09-10**

**Ministries of Economy and Health - Offices of the Deputy Secretaries of State and the Economy and the Deputy Minister of Health**

Determines the establishment of a working group with the aim of analyzing the legal regime applicable to acts of advertising practiced by health care providers.

**Order No. 12284/2014 - Gazette No. 192/2014, Series II of 2014-10-06**

**Ministry of Health - Office of the Secretary of State for Health**

Determines and updates the amount of the benefit from which a communication to Infarmed must be made. Repeals Order No. 4138/2013 of 20 March.

**Integrated Management System for Enrolled Subscribers of Surgery**

**Resolution No. 179/2014. D. R. No. 175, Series I of 2014-09-11**

**Ministry of Health**

Amending the Annex to Resolution No. 45/2008, of 15 January, which approves the Regulation of Integrated Management System for Enrolled Subscribers of Surgery.

**Pediatrics**

**Order No. 11420/2014. D. R. No. 175, Series II of 2014-09-11**

**Ministries of Health and Solidarity, Employment and Social Security - Offices of the Secretaries of State to the Minister of Health and Solidarity and Social Security**

Mandates the establishment of a working group for the development of legislation on the conditions of establishment and operation of inpatient units and outpatient within pediatric age.

**Unconventional therapies**

**Resolution No. 181/2014. D. R. No. 176, Series I of 2014-09-12**

**Ministry of Health**

Establishes, within the Central Administration of the Health System, a Working Group for the Assessment of the Curriculum of Professionals of Non-conventional therapies.

**Resolution No. 182/2014 - Official Gazette No. 176/2014, Series I of 2014-09-12**

**Ministry of Health**

Establishes minimum requirements regarding the organization, operation, technical and human resources of non-conventional therapeutic activities.

**Resolution No. 182-A / 2014 - Gazette No. 176/2014, Supplement 1, Series I of 2014-09-12**

**Ministries of Finance and Health**

Establishing the amount of fees payable by the professional registration and issuance of professional licenses for the exercise of professions within unconventional therapeutics.

**Resolution No. 207-A / 2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the naturopathic profession.

**Resolution No. 207-B / 2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the osteopathic profession.

**Resolution No. 207-C/2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the homeopathic profession

**Resolution No. 207-D/2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the chiropractic profession.

**Resolution No. 207-E/2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the herbalist profession.

**Resolution No. 207-F/2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the acupuntor profession.

**Resolution No. 207-G/2014 - Gazette No. 194/2014, Supplement 1, Series I of 2014-10-08**

**Ministries of Health and Education and Science**

Fixing the characterization and the functional content of the chinese traditional medicine specialist profession.

**Transportation of Patients**

**Resolution No. 184/2014 - Gazette No. 177/2014, Series I of 2014-09-15**

**Ministry of Health**

Second Amendment to Resolution No. 142-B/2012 of May 15, which defines the conditions under which the National Health Service provides the expenses of the transport of non-emergency patient that is instrumental to the provision of healthcare.

**Health Technologies**

**Order No. 11712/2014 - Gazette No. 181/2014, Series II of 2014-09-19**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Designates INFARMED - National Authority of Medicines and Health Products, I.P., as the national authority responsible for the evaluation of health technologies.

**Cross-border healthcare**

**Order No. 11713/2014 - Gazette No. 181/2014, Series II of 2014-09-19**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Designates the Central Administration of the Health System, I.P. as a national reference contact for cross-border healthcare.

**Order No. 11778/2014 - Gazette No. 182/2014, Series II of 2014-09-22**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Determines that the prescriptions of medical devices prescribed in other member states of the European Union are recognized in Portugal, subject to meeting the stipulated requirements.

**Resolution No. 191/2014 - Gazette No. 185/2014, Series I of 2014-09-25**

**Ministry of Health**

Determines which cross-border healthcare is subject to prior authorization.

**Healthcare online**

**Order No. 11779/2014 - Gazette No. 182/2014, Series II of 2014-09-22**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Designates the Shared Services of the Ministry of Health, E.P.E. as the national authority responsible for cooperation regarding healthcare online.

**Loures Hospital**

**Order No. 11960/2014 - Gazette No. 186/2014, Series II of 2014-09-26**

**Ministry of Health - Office of the Minister**

Delegates to the Secretary of State for Health, with sub-delegation powers, the necessary powers for all acts and procedures that are necessary to authorize the sale of the share capital of SGHL - Management Company of Loures Hospital, S.A. and the HL - Management Company of the Building, S.A., including the transfer or encumbrance of shares.

**National Vaccination Programme**

**Order No. 11961/2014 - Gazette No. 186/2014, Series II of 2014-09-26**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Approves the recommended vaccination schedule for the National Immunization Program. Repeals order no. 17067/2011 published in the Official Gazette, 2nd Series, No. 243, of 21 December.

**National Reference Centers**

**Resolution No. 194/2014 - Gazette No. 188/2014, Series I of 2014-09-30**

**Ministry of Health**

Establishes the concept, the identification process, the approval and recognition of the National Reference Centers for the provision of health care, particularly for the diagnosis and treatment of rare diseases.

**Order No. 13163-C/2014 - Gazette No. 209/2014, Supplement 2, Series II of 2014-09-29**

**Ministry of Health - Office of the Minister**

Appointment of members of the National Commission for Reference Centers.

**National Council of Ethics for the Life Sciences**

**Resolution No. 27/2014 - Gazette No. 192/2014, Series II of 2014-10-06**

**Presidency of the Council of Ministers - Council of Ministers**

Appoints members of the National Council of Ethics for the Life Sciences.

**Nurses**

**Order No. 12425-A / 2014 - Gazette No. 194/2014, Supplement 1, Series II of 2014-10-08**

**Ministry of Health - Office of the Secretary of State to the Minister of Health**

Creates a Monitoring Group to implement the activities of the family nurse.

**Regulation No 448/2014 - Gazette No. 199/2014, Series II of 2014-10-15**

**Nurses Bar**

First amendment and republishing of the Disciplinary Rules of the Nurses Bar.

**Public Procurement Contracts**

**Order No. 12528/2014 - Gazette No. 197/2014, Series II of 2014-10-13**

**Ministry of Health - Office of the Secretary of State for Health**

Establishes provisions regarding the Shared Services of the Ministry of Health, EPE (SPMS, EPE), referring to public procurement contracts that determine the conditions of the supply of Cardiovascular Drugs.

**Order No. 12529/2014 - Gazette No. 197/2014, Series II of 2014-10-13**

**Ministry of Health - Office of the Secretary of State for Health**

Establishes provisions within the SPMS, EPE, referring to public procurement contracts that determine the conditions of supply of medicines regarding the cerebrospinal nervous system, except: anesthetics, muscle relaxants, analgesics, antipyretics, antidepressants and antipsychotics.

**Order No. 12530/2014 - Gazette No. 197/2014, Series II of 2014-10-13**

**Ministry of Health - Office of the Secretary of State for Health**

Establishes provisions within the SPMS, EPE, referring to public procurement contracts that determine the conditions of supply of medicines regarding the digestive tract.

**Order No. 12573/2014 - Gazette No. 198/2014, Series II of 2014-10-14**

**Ministry of Health - Office of the Secretary of State for Health**

Establishes provisions within the SPMS, EPE, referring to public procurement contracts that determine the conditions of supply of oncological drugs.

**Primary Health Care**

**Resolution of the National Assembly No. 85/2014 - Gazette No. 199/2014, Series I of 2014-10-15**

**National Assembly**

Recommends to the Government concrete steps in defense of Primary Health Care in the Algarve, of its users and health professionals.

**Misericórdias Hospitals**

**Order No. 13001-A/2014 - Gazette No. 206/2014, Supplement I, Series II of 2014-10-24**

**Ministry of Health - Office of the Secretary of State for Health**

Determines the establishment of the Committee for Monitoring the process of return of the Misericórdias Hospitals provided for in Decree-Law No. 138/2013 of 9 October.

**Public Contribution**

**Order No. 12976/2014 - Gazette No. 206/2014, Series II of 2014-10-24**

**Ministries of Internal Administration and Health - Offices of the Secretaries of State to the Minister of the Internal Administration and Health**

Determines that the public contribution to pharmacies provided by the sickness assistance programs of the Republican National Guard and Public Security Police is assumed by the National Health Service.



**Ebola**

**Resolution of the Council of Ministers No. 60/2014 - Gazette No. 211/2014, Series I of 2014-10-31**

**Presidency of the Council of Ministers**

Creates the Interministerial Committee for the Coordination regarding the Response to Ebola.

IV. EU LEGISLATION

**Cosmetics**

**Regulation (EU) No, 1003/2014 of the Commission, September 18, 2014**

Amending Annex V of the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products.

**Regulation (EU) No. 1004/2014 of the Commission, September 18, 2014**

Amending Annex V of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products.

**Insurance**

**2014/C 364/04**

Request for operators of medical and paramedical services (hospitals, clinics, laboratories, medical centers and individuals which are active in the medical/paramedic sector), as well as pharmacies, to place their services at the disposal of members/beneficiaries of the common system of health insurance at a lower price.

IV. INFARMED

**European procedure for single assessment of Periodic Safety Update Reports from national medicines**

**Information Note No. 199/CD/8.1.6 of 201-09-09**

Information and clarification on the single European procedure for assessment of Periodic Safety Update Reports from national medicines that will begin in October 2014.

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